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CODE OF FEDERAL REGULATIONS

Title 40
Protection of Environment

Parts 723 to 789

Revised as of July 1, 2019

Containing a codification of documents
of general applicability and future effect

As of July 1, 2019

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Cite this Code: CFR

To cite the regulations in this volume use title, part and section number. Thus, 40 CFR 723.50 *refers to title 40, part 723, section 50.*

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The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16.....as of January 1
Title 17 through Title 27.....as of April 1
Title 28 through Title 41.....as of July 1
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The term ''[Reserved]'' is used as a place holder within the Code of Federal Regulations. An agency may add regulatory information at a ''[Reserved]'' location at any time. Occasionally ''[Reserved]'' is used editorially to indicate that a portion of the CFR was left vacant and not accidentally dropped due to a printing or computer error.

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The Federal Register Index is issued monthly in cumulative form. This index is based on a consolidation of the ''Contents'' entries in the daily Federal Register.

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OLIVER A. POTTS,
Director,
Office of the Federal Register.
July 1, 2019.

THIS TITLE

Title 40—PROTECTION OF ENVIRONMENT is composed of thirty-seven volumes. The parts in these volumes are arranged in the following order: Parts 1–49, parts 50–51, part 52 (52.01–52.1018), part 52 (52.1019–52.2019), part 52 (52.2020–end of part 52), parts 53–59, part 60 (60.1–60.499), part 60 (60.500–end of part 60, sections), part 60 (Appendices), parts 61–62, part 63 (63.1–63.599), part 63 (63.600–63.1199), part 63 (63.1200–63.1439), part 63 (63.1440–63.6175), part 63 (63.6580–63.8830), part 63 (63.8980–end of part 63), parts 64–71, parts 72–79, part 80, part 81, parts 82–86, parts 87–95, parts 96–99, parts 100–135, parts 136–149, parts 150–189, parts 190–259, parts 260–265, parts 266–299, parts 300–399, parts 400–424, parts 425–699, parts 700–722, parts 723–789, parts 790–999, parts 1000–1059, and part 1060 to end. The contents of these volumes represent all current regulations codified under this title of the CFR as of July 1, 2019.

Chapter I—Environmental Protection Agency appears in all thirty-seven volumes. OMB control numbers for title 40 appear in §9.1 of this chapter.

Chapters IV–VIII—Regulations issued by the Environmental Protection Agency and Department of Justice, Council on Environmental Quality, Chemical Safety and Hazard Investigation Board, Environmental Protection Agency and Department of Defense; Uniform National Discharge Standards for Vessels of the Armed Forces, and the Gulf Coast Ecosystem Restoration Council appear in volume thirty seven.

For this volume, Ann Worley was Chief Editor. The Code of Federal Regulations publication program is under the direction of John Hyrum Martinez, assisted by Stephen J. Frattini.

Title 40—Protection of Environment

(This book contains parts 723 to 789)

Part

CHAPTER I—Environmental Protection Agency (Continued) 723

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)

EDITORIAL NOTE: Nomenclature changes to chapter I appear at 65 FR 47324, 47325, Aug. 2, 2000; 66 FR 34375, 34376, June 28, 2001.

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SUBCHAPTER R—TOXIC SUBSTANCES CONTROL ACT

PART 723—PREMANUFACTURE NOTIFICATION EXEMPTIONS

Subpart A [Reserved]

Subpart B—Specific Exemptions

Sec.

723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

723.175 Chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.

723.250 Polymers.

AUTHORITY: 15 U.S.C. 2604.

Subpart A [Reserved]

Subpart B—Specific Exemptions

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

(i) Chemical substances manufactured in quantities of 10,000 kilograms or less per year.

(ii) Chemical substances with low environmental releases and human exposures.

(2) To manufacture a new chemical substance under the terms of this exemption a manufacturer must:

(i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under paragraph (e) of this section.

(ii) Comply with all other provisions of this section.

(3) This section does not apply to microorganisms subject to part 725 of this chapter.

(b) *Definitions.* The following definitions apply to this subpart.

(1) *Act* means the Toxic Substances Control Act (15 U.S.C. 2601 et seq).

(2) *Consumer* means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

(3) *Environment* has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(4) *Environmental transformation product* means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(5) *Metabolite* means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(6) *Serious acute effects* means human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(7) *Serious chronic effects* means human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(8) *Significant environmental effects* means:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society;

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the

damage persists beyond a single generation of the damaged resource or beyond a single year; or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. Endangered or threatened species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(9) *Site* means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

(10) The terms *byproduct*, *EPA*, *importer*, *impurity*, *known to or reasonably ascertainable*, *manufacture*, *manufacturer*, *new chemical substance*, *person*, *possession or control*, *and test data* have the same meanings as in §720.3 of this chapter.

(c) *Exemption categories.* Except as provided in paragraph (d) of this section, this exemption applies to:

(1) Any manufacturer of a new chemical substance manufactured in quantities of 10,000 kilograms or less per year under the terms of this exemption.

(2) Any manufacturer of a new chemical substance satisfying all of the following low environmental release and low human exposure eligibility criteria:

(i) *Consumers and the general population.* For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance:

(A) No dermal exposure.

(B) No inhalation exposure (except as described in paragraph (c)(2)(iv) of this section.

(C) Exposure in drinking water no greater than a 1 milligram per year (estimated average dosage resulting from drinking water exposure in streams from the maximum allowable concentration level from ambient surface water releases established under paragraph (c)(2)(iii) of this section or a higher concentration authorized by EPA under paragraph (c)(2)(iii) of this section).

(ii) *Workers.* For exposure of workers to the new chemical substance during all manufacturing, processing, distribution in commerce, use and disposal of the substance:

(A) No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable EPA guidance).

(B) No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable EPA guidance).

(iii) *Ambient surface water.* For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion, calculated using the methods prescribed in §§721.90 and 721.91, unless EPA has approved a higher surface water concentration supported by relevant and scientifically valid data submitted to EPA in a notice under paragraph (e) of this section on the substance or a close structural analogue of the substance which demonstrates that the new substance will not present an unreasonable risk of injury to aquatic species or human health at the higher concentration.

(iv) *Incineration.* For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration, calculated using the formula:

(kg/day of release after treatment) multiplied by (number of release days per year) multiplied by (9.68×10^{-6}) micrograms per cubic meter.

(v) *Land or groundwater.* For releases to land or groundwater, no releases to groundwater, to land, or to a landfill unless the manufacturer has demonstrated to EPA's satisfaction in a notice under paragraph (e) of this section that the new substance has negligible groundwater migration potential.

(d) *Chemical substances that cannot be manufactured under this exemption.* A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraphs (c)(1) or (c)(2) of

this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance, any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance:

(1) Serious acute (lethal or sublethal) effects.

(2) Serious chronic (including carcinogenic and teratogenic) effects.

(3) Significant environmental effects.

(e) *Exemption notice.* (1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to EPA at least 30 days before manufacture of the new chemical substance begins. Exemption notices and modifications must be submitted to EPA on EPA Form No. 7710–25 via CDX using e-PMN software in the manner set forth in this paragraph. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Notices and any related support documents, must be generated and completed (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(2) The notice shall contain the information described below, pursuant to the referenced provisions of § 720.45.

(i) Manufacturer identity.

(ii) Chemical identity (§ 720.45(a)).

(iii) Impurities (§ 720.45(b)).

(iv) Known synonyms or trade names (§ 720.45(c)).

(v) Byproducts (§ 720.45(d)).

(vi) Production volume (§ 720.45(e)). (A) Manufacturers submitting an exemption application under paragraph (c)(1) of this section will be assumed to be manufacturing at an annual production volume of 10,000 kilograms. Manufacturers who intend to manufacture an exempted substance at annual volumes of less than 10,000 kilograms and wish EPA to conduct its risk assessment based upon such lesser annual production level rather than a 10,000–kilograms level, may so specify by writing the lesser annual production volume in the appropriate box on the PMN form and marking the adjacent binding option box. Manufacturers who opt to specify annual production levels below 10,000 kilograms and who mark the production volume binding option box shall not manufacture more than the specific annual amount of the exempted substance unless a new exemption notice for a higher (up to 10,000 kgs) manufacturing volume is submitted and approved pursuant to this section.

(B) Manufacturers submitting an exemption under paragraph (c)(2) of this section shall list the estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12–month period during the first 3 years of production.

(vii) Description of intended categories of use (§ 720.45(f)).

(viii) For manufacturer-controlled sites, the manufacturer shall supply identity of manufacturing sites, process descriptions, and worker exposure and environmental release information (§ 720.45(g)); for sites not controlled by the manufacturer, processing and use operation descriptions, estimated number of processing and use sites, and worker exposure/environmental release information (§ 720.45(h)). A manufacturer applying for an exemption under paragraph (c)(1) of this section need not provide information on worker exposure and environmental release referenced in paragraphs (e)(2)(viii) of this section if such information is not known or not readily available to the manufacturer. To assist in reporting this information, manufacturers may obtain a copy of EPA's Guidance for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50, available from the Environmental Assistance Division at the address listed in paragraph (e)(1) of this section. Where worker exposure and environmental release information is not supplied by the manufacturer, EPA will generally apply ''bounding estimates'' (i.e., exposure estimates higher than those incurred by persons in the population with the highest exposure) to account for uncertainties in actual exposure and release scenarios.

(ix) Type and category of notice. The manufacturer must clearly indicate on the first page of the PMN form that the submission is a ''TSCA section 5(h)(4) exemption notice,'' and must indicate whether the notice is being submitted under paragraph (c)(1) or (c)(2) of this section. Manufacturers of chemical substances that qualify for an exemption under both paragraph (c)(1) and (c)(2) of this section may apply for either exemption, but not both.

(x) Test data (§ 720.50).

(xi) Certification. In addition to the certifications required in EPA form 7710–25, the following certifications shall be included in notices under this section. The manufacturer must certify that:

(A) The manufacturer intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(D) For substances manufactured under paragraph (c)(1) of this section, the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30–day review period.

(xii) Sanitized copy of notice. (A) The manufacturer must make all claims of confidentiality in accordance with paragraph (l) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (l)(3) of this section.

(B) If the manufacturer does not provide the second copy, the submission will be considered incomplete.

(3) *Incomplete notices.* If EPA receives a submission which does not include all of the information required under this paragraph (e) of this section, the submission will be determined to be incomplete by EPA. When a submission for a new chemical substance has been determined to be incomplete, a manufacturer reapplying for an exemption for the new chemical substance must submit a new exemption notice containing all the information required under this paragraph (e) of this section including a certification page containing an original dated signature; partial submissions sent to EPA to supplement notices declared incomplete will not be accepted. Photocopied pages from previously submitted exemption forms will be accepted provided that the certifications page contains an original dated signature.

(f) *Multiple exemption holders.* (1) A manufacturer who intends to manufacture a substance for which an exemption under this section was previously approved may apply for an exemption under paragraph (c)(1) or (c)(2) of this section; however, EPA will not approve any subsequent exemption application under paragraph (c)(1) of this section unless it can determine that the potential human exposure to, and environmental release of, the new chemical substance at the higher aggregate production volume will not present an unreasonable risk of injury to human health or the environment.

(2)(i) If EPA proposes to deny an exemption application for a substance for which another manufacturer currently holds an exemption, and that proposed denial is based exclusively on the cumulative human exposure or environmental release of the substance which precludes the EPA from determining that the subsequent applicant's activities will not present an unreasonable risk of injury to human health or the environment, the EPA will notify the first exemption holder that it must, within 21 days of its receipt of EPA's notice, either:

(A) Provide a new certification that it has commenced, or that it will commence, manufacture of the new chemical substance under this section within 1 year of the expiration of its exemption review period; or

(B) Withdraw its exemption for the new chemical substance.

(ii) If the first exemption holder does not respond to the EPA's notice under paragraph (f)(2)(i) of this section within the prescribed time period, EPA shall issue a notice of ineligibility to the first exemption holder under the

provisions of paragraph (h)(2) of this section.

(g) *Review period.* (1) EPA will review the notice submitted under paragraph (e) of this section to determine whether manufacture of the new chemical substance is eligible for the exemption. The review period will end 30 days after receipt of the notice by the TSCA Document Control Officer. To provide additional time to address any unresolved issues concerning an exemption application, the exemption applicant may, at any time during the review period, request a suspension of the review period pursuant to the provisions of § 720.75(b) of this chapter.

(2) Upon expiration of the 30–day review period, if EPA has taken no action, the manufacturer may consider its exemption approved and begin to manufacture the new chemical substance under the terms described in its notice and in this section.

(h) *Notice of ineligibility*—(1) *During the review period.* If the EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of this section or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30–day review period, EPA will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the reasons for the ineligibility determination. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act or submitting a new notice under paragraph (e) of this section that satisfies EPA's concerns.

(2) *After the review period.* (i)(A) If at any time after the review period specified in paragraph (g) of this section the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (''the Assistant Administrator'') makes a preliminary determination that manufacture of the new chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms of the section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (h)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (h)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (h)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (h)(2)(i)(A) of this section may submit, within 15 days of receipt of written notification, detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (h)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that manufacture of the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 7 days of the written notification under paragraph (h)(2)(iii) of this section. The manufacturer may not resume manufacture, processing, distribution in commerce, and use of

the new chemical substance until it submits a notice under section 5(a)(1) of the Act and part 720 of this chapter and the notice review period has ended.

(vi) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (h)(2)(i)(A) of this section.

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and part 720 of this chapter within 15 days of receipt of the written notification under paragraph (h)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, or 17 of the Act.

(i) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify under terms of this section, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information. If, during the notice review period specified in paragraph (g) of this section, the submitter obtains possession, control, or knowledge of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must send that information to the address listed on the notice form within 10 days of receiving the new information, but no later than 5 days before the end of the notice review period. The new submission must clearly identify the submitter and the exemption notice to which the new information is related. If the new information becomes available during the last 5 days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(j) *Changes in manufacturing site, use, human exposure and environmental release controls, and certain manufacturing volumes.* (1) Except as provided in paragraph (j)(6) of this section, chemical substances manufactured under this section must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice under paragraph (e) of this section.

(2) Where the manufacturer lists a specific physical form in which the new chemical substance will be manufactured, processed, and/or used, the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in either the same physical form described in the notice under paragraph (e), or in a physical form which will not increase the human exposure to or environmental release of the new chemical substance over those exposures or releases resulting from the specified physical form (e.g., a manufacturer which specifies that the new chemical substance will be produced in a nonvolatile liquid form generally may not change to a respirable powder form).

(3) The annual production volume of chemical substances manufactured under paragraph (c)(1) of this section for which the manufacturer designated a binding annual production volume pursuant to paragraph (e)(2)(vi) of this section must not exceed that designated volume.

(4) Any person who manufactures a new chemical substance under paragraph (c)(1) or (c)(2) of this section must comply with the provisions of this section, including submission of a new notice under paragraph (e) of this section, before:

(i) Manufacturing the new chemical substance at a site that was not approved in a previous exemption notice for the substance, except as provided in paragraph (j)(6) of this section.

(ii) Manufacturing the new chemical substance for a use that was not approved in a previous exemption notice for the substance.

(iii) Manufacturing the new chemical substance without employing the human exposure and environmental release controls approved in a previous exemption notice for the substance.

(iv) Manufacturing the new chemical substance in a physical form different than that physical form approved in a previous exemption notice for the substance and which form may increase the human exposure to, or environmental release of, the new chemical substance over those exposures or releases resulting from the physical form approved in the previous notice.

(v) Manufacturing the chemical substance in annual production volumes above any volume designated by the manufacturer as binding under paragraph (e)(2)(vi) of this section in a previous exemption notice for the substance.

(5) In an exemption notice informing EPA of a change in site, use, or worker protection, or environmental release controls, the manufacturer is not required to provide all of the same information submitted to EPA in a previous exemption notice for that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and location of the new site, new worker protection or environmental release controls, and new use information. The notice must also include the EPA-designated exemption number assigned to the previous notice and a new certification by the manufacturer, as described in paragraph (e)(2)(xi) of this section.

(6)(i) A manufacturer may, without submitting a new notice, manufacture the new chemical substance at a site not listed in its exemption application under the following conditions:

(A) the magnitude, frequency, and duration of exposure of individual workers to the new chemical substance at the new manufacturing site is equal to, or less than, the magnitude, frequency, and duration of exposure of the individual workers to the new chemical substance at the manufacturing site for which the EPA performed its original risk-assessment pursuant to the original exemption notice; and

(B) Either (*1*) at the new manufacturing site, the manufacturer does not release to surface waters any of the new chemical substance, or any waste streams containing the new chemical substance; or (*2*) at the new manufacturing site, the manufacturer maintains surface water concentrations of the chemical substance, resulting from direct or indirect discharges from the manufacturing site, at or below 1 part per billion, or at or below an alternative concentration level approved by the Agency in writing or under the procedures described in paragraph (c)(2)(iii) of this section, using the water concentration calculation method described at §§ 721.90 and 721.91.

(ii) The manufacturer shall notify EPA of any new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance under the exemption at the new manufacturing site as follows:

(A) The notification must contain the EPA-designated exemption number to which the notification applies, manufacturer identity, the street address of the new manufacturing site, the date on which manufacture commenced at the new site, the name and telephone number of a technical contact at the new site, any claim of confidentiality, and a statement that the notification is an amendment to the original exemption application under the terms of this section.

(B) The notification must be submitted electronically to EPA via CDX as a support document to the original notification. Prior to submission to EPA via CDX, such notices must be generated and completed using the e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software.

(k) *Customer notification.* (1) Manufacturers of new chemical substances described in paragraphs (c)(1) and (c)(2) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice at paragraph (e) of this section. The manufacturer must also inform processors and industrial

users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) A manufacturer of a new chemical substance described in paragraph (c)(2) of this section may distribute the chemical substance only to other persons who agree in writing to not further distribute the substance until it has been reacted, incorporated into an article, or otherwise rendered into a physical form or state in which environmental releases and human exposures above the eligibility criteria in paragraph (c)(2) of this section are not likely to occur.

(3) If the manufacturer learns that a direct or indirect customer is processing or using the new substance in violation of use restrictions or without imposing prescribed worker protection or environmental release controls, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately unless the manufacturer is able to document each of the following:

(i) That the manufacturer has, within 5 working days, notified the customer in writing that the customer has failed to comply with the conditions specified in this section and the exemption notice under paragraph (e) of this section.

(ii) That, within 15 working days of notifying the customer of the noncompliance, the manufacturer received from the customer, in writing, a statement of assurance that the customer is aware of the terms of this section and the exemption notice and will comply with those terms.

(4) If, after receiving a statement of assurance from a customer under paragraph (k)(3)(ii) of this section, the manufacturer obtains knowledge that the customer has again failed to comply with any of the conditions specified in this section or the exemption notice, the manufacturer shall cease supplying the new chemical substance to that customer and shall report the failure to comply to EPA within 15 days of obtaining this knowledge. Within 30 days of its receipt of the report, EPA will notify the manufacturer whether, and under what conditions, distribution of the chemical substance to the customer may resume.

(l) *Confidentiality.* (1) If the manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with ''CONFIDENTIAL'' or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph (l) must provide a generic chemical name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible.

(ii) The generic name provided by the manufacturer will be subject to EPA review and approval in accordance with the procedures specified in §720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice with all information claimed as confidential deleted. EPA will place the second copy in the public file.

(m) *Exemptions granted under superseded regulations.* Manufacturers holding exemptions granted under the superseded requirements of this section (as in effect on May 26, 1995) shall either continue to comply with those requirements (including the production volume limit) or apply for a new exemption pursuant to this section. EPA will not accept requests to amend exemptions granted under the superseded requirements; manufacturers wishing

to amend such exemptions must submit a new exemption under paragraph (e) of this section. If a new exemption for a new chemical substance is granted under this exemption to the manufacturer holding an exemption under the superseded requirements, the exemption under the superseded requirements for such substance shall be void.

(n) *Recordkeeping.* (1) A manufacturer of a new chemical substance under paragraph (c) of this section must maintain the records described in this paragraph at the manufacturing site or site of importation for a period of 5 years after their preparation.

(2) The records must include the following to demonstrate compliance with this section:

(i) Records of annual production volume and import volume.

(ii) Records documenting compliance with the applicable requirements and restrictions of paragraphs (c), (e), (f), (h), (i), (j), and (k) of this section.

(3) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA, permit such person at all reasonable times to have access to and to copy records kept under paragraph (n)(2) of this section.

(4) The manufacturer must submit the records listed in paragraph (n)(2) of this section to EPA upon request. Manufacturers must provide these records within 15 working days of receipt of such request.

(o) *Compliance.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other action under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 1616).

[60 FR 16346, Mar. 29, 1995, as amended at 60 FR 34465, July 3, 1995; 62 FR 17932, Apr. 11, 1997; 64 FR 31989, June 15, 1999; 71 FR 33642, June 12, 2006; 75 FR 787, Jan. 6, 2010; 77 FR 46292, Aug. 3, 2012; 78 FR 72828, Dec. 4, 2013; 80 FR 42746, July 20, 2015]

§ 723.175 Chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture and processing of new chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles. This section does not apply to microorganisms subject to part 725 of this chapter.

(2) To manufacture a new chemical substance under the terms of this exemption, a manufacturer of instant photographic or peel-apart film articles must:

(i) Submit an exemption notice when manufacture begins under paragraph (i) of this section.

(ii) Comply with certain requirements to limit exposure to the new chemical substance under paragraphs (e) through (h) of this section.

(iii) Comply with all recordkeeping requirements under paragraph (j) of this section.

(iv) Remit the applicable fee specified in § 700.45(c) of this chapter.

(b) *Definitions*—(1) *Act* means the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*).

(2) An *article* is a manufactured item—

(i) Which is formed to a specific shape or design during manufacture;

(ii) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and

(iii) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 710.2 of

this chapter except that fluids and particles are not considered articles regardless of shape or design.

(3) The terms *byproduct*, *EPA*, *impurities*, *person*, and *site* have the same meanings as in § 710.3 of this chapter.

(4) The term *category of chemical substances* has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

(5) The terms *chemical substance*, *distribute in commerce*, *distribution in commerce*, *environment*, *manufacture*, *new chemical substance*, and *process* have the same meanings as in section 3 of the Act (15 U.S.C. 2602).

(6) *Director of the Office of Pollution Prevention and Toxics* means the Director of the EPA Office of Pollution Prevention and Toxics or any EPA employee designated by the Office Director to carry out the Office Director's functions under this section.

(7) The term *exemption category* means a category of chemical substances for which a person(s) has applied for or been granted an exemption under section 5(h)(4) of the Act (15 U.S.C. 2604).

(8) The term *instant photographic film article* means a self-developing photographic film article designed so that all the chemical substances contained in the article, including the chemical substances required to process the film, remain sealed during distribution and use.

(9) *Intermediate* means any chemical substance which is consumed in whole or in part in a chemical reaction(s) used for the intentional manufacture of another chemical substance.

(10) *Known to or reasonably ascertainable* means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden or cost.

(11) The term *peel-apart film article* means a self-developing photographic film article consisting of a positive image receiving sheet, a light sensitive negative sheet, and a sealed reagent pod containing a developer reagent and designed so that all the chemical substances required to develop or process the film will not remain sealed within the article during and after the development of the film.

(12) *Photographic article* means any article which will become a component of an instant photographic or peel-apart film article.

(13) *Special production area* means a demarcated area within which all manufacturing, processing, and use of a new chemical substance takes place, except as provided in paragraph (f) of this section, in accordance with the requirements of paragraph (e) of this section.

(14) *Test data* means:

(i) Data from a formal or informal study, test, experiment, recorded observation, monitoring, or measurement.

(ii) Information concerning the objectives, experimental methods and materials, protocols, results, data analyses (including risk assessments), and conclusions from a study, test, experiment, recorded observation, monitoring, or measurement.

(15) *Used in or for the manufacturing or processing of an instant photographic or peel-apart film article*, when used to describe activities involving a new chemical substance, means the new chemical substance—

(i) Is included in the article; or

(ii) Is an intermediate to a chemical substance included in the article or is one of a series of intermediates used to manufacture a chemical substance included in the article.

(16) *Wet mixture* means a water or organic solvent-based suspension, solution, dispersion, or emulsion used in the manufacture of an instant photographic or peel-apart film article.

(c) *Exemption category*. The exemption category includes new chemical substances used in or for the manufacture or processing of instant photographic or peel-apart film articles which are manufactured and processed under the terms of this section.

(d) *Applicability*. This exemption applies only to manufacturers of instant photographic or peel-apart film articles who:

(1) Manufacture the new chemical substances used in or for the manufacture or processing of the instant photographic or peel-apart film articles.

(2) Limit manufacture and processing of a new chemical substance to the site(s) listed in the exemption notice for that new chemical substance submitted under paragraph (i) of this section.

(3) Comply with the requirements of paragraphs (e), (f), (g), (h), and (j) of this section.

(4) Do not distribute in commerce or use a peel-apart film article containing a new chemical substance until submission of a premanufacture notice under section 5(a)(1)(A) of the Act (15 U.S.C. 2604) and until the review period for the notice has ended without EPA action to prevent distribution or use.

(e) *Conditions of manufacture and processing in the special production area.* All manufacturing, processing, and use operations involving the new chemical substance must be performed in a special production area under the conditions set forth in this paragraph until the new chemical substance has been incorporated into a wet mixture, photographic article, or instant photographic or peel-apart film article.

(1) *Exposure limits.* In the special production area, the ambient air concentration of the new chemical substance during manufacture, processing, and use cannot exceed an 8-hour time weighted average (TWA) of 10 ppm for gases and vapors and 50 μg/m^3 for particulates, with an allowable TWA excursion of 50 percent above those concentrations for a duration of 30 minutes or less.

(2) *Respiratory protection*—(i) *Respirator requirement.* Except as specified in paragraph (e)(2)(ii) of this section, each person in the special production area must wear an appropriate respiratory protection device to protect against dusts, fumes, vapors, and other airborne contaminants, as described in 29 CFR 1910.134. Selection of an appropriate respirator must be made according to the guidance of American National Standard Practices for Respiratory Protection Z88.2–1969 and the NIOSH Certified Equipment List, U.S. Department of Health and Human Services, NIOSH publication No. 80–144.

(ii) *Waiver of respirator requirement.* Employees are not required to wear respirators if monitoring information collected and analyzed in accordance with paragraph (e)(3) of this section demonstrates that the ambient 8-hour TWA concentration of the new chemical substance in the area is less than 1 ppm for gases and vapors and 5 μg/m^3 for particulates with an allowable TWA excursion of 50 percent above these concentrations for a duration of 30 minutes or less.

(iii) *Quantitative fit test.* Each respirator must be issued to a specific individual for personal use. A quantitative fit test must be performed for each respirator before its first use by that person in a special production area.

(3) *Monitoring*—(i) *When to monitor.* (A) When suitable sampling and analytic methods exist, periodic monitoring in accordance with this paragraph must be done to ensure compliance with the exposure limits of paragraphs (e)(1) and (e)(2)(ii) of this section.

(B) When suitable sampling and analytic methods do not exist, compliance with the exposure limits of paragraph (e)(1) and the requirements of paragraph (e)(10) of this section must be determined by an evaluation of monitoring data developed for a surrogate chemical substance possessing comparable physical-chemical properties under similar manufacturing and processing conditions.

(ii) *Monitoring methods.* A suitable air sampling method must permit personal or fixed location sampling by conventional collection methods. A suitable analytic method must have adequate sensitivity for the volume of sample available and be specific for the new chemical substance being monitored. If chemical-specific monitoring methods are not available, nonspecific methods may be used if the concentration of the new chemical substance is assumed to be the total concentration of chemical substances monitored.

(iii) *Monitoring frequency.* (A) When suitable air sampling and analytical procedures are available, monitoring must be done in each special production area during the first three 8-hour work shifts involving the manufacture or processing of each new chemical substance. Thereafter, monitoring must be done in each special production area for at least one 8-hour period

per month, during a production run in which the new chemical substance is manufactured or processed. Samples must be of such frequency and pattern as to represent with reasonable accuracy the mean level and maximum 30-minute level of employee exposure during an 8-hour work shift. In monitoring for an 8-hour work shift or the equivalent, samples must be collected periodically or continuously for the duration of the 8-hour work shift. Samples must be taken during a period which is likely to represent the maximum employee exposure.

(B) If the manufacturer demonstrates compliance with the exposure limits for 3 consecutive months, further monitoring of the identical process must be performed only every 6 months thereafter, unless there is a significant change in the process, process design, or equipment. If there is such a change, the manufacturer must begin monitoring again according to the schedule in paragraph (e)(3)(iii)(A) of this section.

(iv) *Location of monitoring.* Air samples must be taken so as to ensure that the samples adequately represent the ambient air concentration of a new chemical substance present in each worker's breathing zone.

(4) *Engineering controls and exposure safeguards.* Engineering controls such as, but not limited to, isolation, enclosure, local exhaust ventilation, and dust collection must be used to ensure compliance with the exposure limits prescribed in paragraph (e)(1) or (e)(2)(ii) of this section.

(5) *Training, hygiene, and work practices*—(i) *Training.* No employee may enter a special production area before the completion of a training program. The training program must be adapted to the individual circumstances of the manufacturer and must address: The known physical-chemical and toxicological properties of the chemical substances handled in the area; procedures for using and maintaining respirators and other personal safeguards; applicable principles of hygiene; special handling procedures designed to limit personal exposure to, and inadvertent release of, chemical substances; and procedures for responding to emergencies or spills.

(ii) *Hygiene.* Appropriate standards of hygiene must be observed by all employees handling a new chemical substance in manufacturing, processing, or transfer operations. The manufacturer must provide appropriate facilities for employee changing and wash-up. Food, beverages, tobacco products, and cosmetics must not be allowed in special production areas.

(iii) *Work practices.* Operating procedures such as those related to chemical weighing and filtering, or the charging, discharging and clean-up of process equipment, must be designed and conducted to ensure compliance with the exposure limits prescribed in paragraph (e)(1) or (e)(2)(ii) of this section. Written procedures and all materials necessary for responding to emergency situations must be immediately accessible to all employees in a special production area. Any spill or unanticipated emission must be controlled by specially trained personnel using the equipment and protective clothing described in paragraph (e)(6) of this section.

(6) *Personal protection devices.* All workers engaged in the manufacture and processing of a new chemical substance in the special production area must wear suitable protective clothing or equipment, such as chemical-resistant coveralls, protective eyewear, and gloves.

(7) *Caution signs.* Each special production area must be clearly posted with signs identifying the area as a special production area where new chemical substances are manufactured and processed under controlled conditions. Each sign must clearly restrict entry into the special production area to qualified personnel who are properly trained and equipped with appropriate personal exposure safeguards.

(8) *Removal for storage or transportation.* A new chemical substance that is not incorporated into a wet mixture, photographic article, or instant photographic or peel-apart film article may be removed from the special production area for purposes of storage between operational steps or for purposes of transportation to another special production area. Such storage or transportation must be conducted in a manner that limits worker and environmental

exposure through the use of engineering controls, training, hygiene, work practices, and personal protective devices appropriate to the chemical substance in question.

(9) *Labeling.* (i) Any new chemical substance removed from a special production area or stored or transported between operational steps must be clearly labeled. The label must show the identity of the new chemical substance or an appropriate identification code, a statement of any known hazards associated with it, a list of special handling instructions, first aid information, spill control directions, and where applicable, the appropriate U.S. Department of Transportation notations.

(ii) No label is required if the new chemical substance has been incorporated into a photographic article, or if it is contained in a sealed reaction vessel or pipeline, or if it has been incorporated into an instant photographic or peel-apart film article.

(10) *Areas immediately adjacent to the special production area.* The ambient air concentration of the new chemical substance in areas immediately adjacent to the special production area must not exceed the exposure limit established in paragraph (e)(2)(ii) of this section for waiver of respirator protection within the special production area. Periodic monitoring in accordance with paragraph (e)(3) of this section must be performed in immediately adjacent areas where it is reasonable to expect a risk of inhalation exposure.

(f) *Conditions of processing outside the special production area.* A wet mixture may be incorporated into a photographic article or an instant photographic or peel-apart film article outside the special production area under the conditions listed in this paragraph:

(1) *Engineering controls and exposure safeguards.* Engineering controls must limit the exposure to a new chemical substance contained in a wet mixture.

(2) *Training, hygiene and work practices*—(i) *Training.* Training of employees involved in the handling of wet mixtures containing a new chemical substance must be adapted to the individual circumstances of the employees' activities and must address: Procedures for using personal exposure safeguards, applicable principles of hygiene, handling procedures designed to limit personal exposure, and procedures for responding to emergencies and spills.

(ii) *Hygiene.* Appropriate standards of hygiene that limit exposure must be observed by all employees handling wet mixtures that contain new chemical substances.

(iii) *Work practices.* Work practices and operating procedures must be designed to limit exposure to any new chemical substance contained in wet mixtures. Any spills or unanticipated releases of a wet mixture must be controlled by trained personnel wearing appropriate protective clothing or equipment such as gloves, eye protection, and, where necessary, respirators or chemically impervious clothing.

(3) *Personal protection devices.* All workers engaged in the processing of a wet mixture containing a new chemical substance must wear suitable protective clothing or equipment such as coveralls, protective eyewear, respirators, and gloves.

(g) *Incorporation of photographic articles into instant photographic and peel-apart film articles.* A photographic article may be incorporated into the instant photographic or peel-apart film article outside the special production area. The manufacturer must take measures to limit worker and environmental exposure to new chemical substances during these operations using engineering controls, training, hygiene, work practices, and personal protective devices.

(h) *Environmental release and waste treatment*—(1) *Release to land.* Process waste from manufacturing and processing operations in the special production area that contain a new chemical substance are considered to be hazardous waste and must be handled in accordance with the requirements of parts 262 through 267 and parts 122 and 124 of this chapter.

(2) *Release to water.* All wastewater or discharge which contain the new chemical substance must be appropriately pretreated before release to a Publicly Owned Treatment Works (POTW) or other receiving body of water. In the case of release to a POTW, the pretreatment must prevent structural

damage to, obstruction of, or interference with the operation of the POTW. The treatment of direct release to a receiving body of water must be appropriate for the new chemical substance's physical-chemical properties and potential toxicity.

(3) *Release to air.* All process emissions released to the air which contain the new chemical substance must be vented through control devices appropriate for the new chemical substance's physical-chemical properties and potential toxicity.

(i) *Exemption notice.* An exemption notices must be submitted to EPA when manufacture of the new chemical substance begins.

(1) *Contents of exemption notice.* The exemption notice must include the following information:

(i) *Manufacturer and sites.* The notice must identify the manufacturer and the sites and locations where the new chemical substance and the instant photographic or peel-apart film articles will be manufactured and processed.

(ii) *Chemical identification.* The notice must identify the new chemical substance as follows:

(A) *Class 1 substances.* For chemical substances whose composition can be represented by a definite structural diagram (Class 1 substances), the notice must provide the chemical name (preferably CAS or IUPAC nomenclature), the molecular formula, CAS Registry Number (if available), known synonyms (including trade names), and a structural diagram.

(B) *Class 2 substances.* For chemical substances that cannot be fully represented by a structural diagram, (Class 2 substances), the notice must provide the chemical name, the molecular formula, the CAS Registry Number (if available), and known synonyms (including trade names). The notice must identify the immediate precursors and reactants by name and CAS Registry Number (if available). The notice must include a partial or incomplete structural diagram, if available.

(C) *Polymers.* For a polymer, the notice must identify monomers and other reactants used in the manufacture of the polymer by chemical name and CAS Registry Number. The notice must indicate the amount of each monomer used (by weight percent of total monomer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram, if available. The notice must indicate the number average molecular weight of the polymer and characterize the anticipated low molecular weight species. The notice must include this information for each typical average molecular weight composition of the polymer to be manufactured.

(iii) *Impurities.* The notice must identify the impurities that can be reasonably anticipated to be present in the new chemical substance when manufactured under the exemption by name and CAS Registry Number, by class of substances, or by process or source. The notice also must estimate the maximum percent (by weight) of each impurity in the new chemical substance and the percent of unknown impurities present.

(iv) *Physical-chemical properties.* The notice must describe the physical-chemical properties of the new chemical substance. Where specific physical-chemical data are not available, reasonable estimates and the techniques used to develop these estimates must be provided.

(v) *Byproducts.* The notice must identify the name, CAS Registry number (if available), and the volume of each byproduct that would be manufactured during manufacture of the new chemical substance.

(vi) *Production volume.* The notice must include an estimate of the anticipated maximum annual production volume.

(vii) *Test data.* The notice must include all information and test data on the new chemical substance's health and environmental effects that are known to or reasonably ascertainable by the manufacturer.

(viii) *Identity of the article.* The notice must identify and describe the instant photographic film article(s) or peel-apart film article(s) that will contain the new chemical substance.

(ix) *Release to water.* The notice must include a description of the methods used to control and treat wastewater or discharge released to a POTW or

other receiving body of water. The notice must also identify the POTW or receiving body of water.

(x) *Certification.* The manufacturer must certify in the notice that it is familiar with the terms of the exemption and that the manufacture, processing, distribution, use, and disposal of the new chemical substance will comply with those terms.

(xi) *Fee payment ID number.* The manufacturer or processor must include a payment identity number on the front page of the notice.

(2) *Duplication of information in premanufacture notice.* If a manufacturer who submits an exemption notice under this paragraph has already submitted, or simultaneously submits, a premanufacture notice under section 5(a)(1)(A) of the Act for the new chemical substance, it may, in lieu of submitting the information required by this paragraph, reference the required information to the extent it is included in the premanufacture notice. At a minimum, the exemption notice must identify the manufacturer and the new chemical substance, and contain the certification required by paragraph (i)(1)(x) of this section.

(3) *Address.* The exemption notice must be addressed to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

(j) *Recordkeeping.* (1) Manufacturers of a new chemical substance under this exemption must keep the following records for 30 years from the final date of manufacture.

(i) *Production records.* Each manufacturer must maintain records of the annual production volume of each new chemical substance manufactured under the terms of the exemption. This record must indicate when manufacture of the new chemical substance began.

(ii) *Exposure monitoring records.* Manufacturers must maintain an accurate record of all monitoring required by this section. Monitoring records may be adapted to the individual circumstances of the manufacturer but, at a minimum, must contain the following information: The chemical identity of the new chemical substance, date of the monitoring, the actual monitoring data for each monitoring location and sampling, and a reference to or description of the collection and analytic techniques. If the manufacturer does not monitor, the manufacturer must maintain a record of the reasons for not monitoring and the methods used to determine compliance with the exposure limits of paragraph (e)(1) of this section.

(iii) *Training and exposure records.* For each employee engaged in the manufacture or processing of a new chemical substance, the company must develop and maintain a record of the worker's participation in required training. This record must also demonstrate the regular use of personal exposure safeguards, including the results of any personal exposure monitoring, the results of the quantitative fit test for the worker's personal respirator, and any additional information related to the worker's occupational exposure.

(iv) *Treatment records.* Manufacturers who release treated wastewater or discharge containing a new chemical substance to a POTW or other receiving body of water must maintain records of the method of treatment.

(2) The manufacturer must make the records listed in paragraph (j)(1) of this section available to EPA upon written request by the Director of the Office of Pollution Prevention and Toxics. The manufacturer must provide these records within 15 working days of receipt of this request.

(k) *Confidentiality.* If the manufacturer submits information under paragraph (i) or (j) of this section which it claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to the Agency by bracketing, circling, or underlining it and stamping it with ''CONFIDENTIAL'' or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission will be made available to the public without further notice to the submitter.

(l) *Amendment and repeal.* (1) EPA may amend or repeal any term of this

exemption if it determines that the manufacture, processing, distribution, use, and disposal of new chemical substances under the terms of the exemption may present an unreasonable risk of injury to health or the environment. EPA also may amend this exemption to enlarge the exemption category or to reduce the restrictions or conditions of the exemption.

(2) As required by section 5(h)(4) of the Act, EPA will amend or repeal the substantive terms of an exemption granted under this part only by the formal rulemaking procedures described in section 6(c)(2) and (3) of the Act (15 U.S.C. 2605(c)).

(m) *Prohibition of use of the exemption.* The Director of the Office of Pollution Prevention and Toxics may prohibit the manufacture, processing, distribution, use, or disposal of any new chemical substance under the terms of this exemption if he or she determines that the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance may present an unreasonable risk of injury to health or the environment.

(n) *Enforcement.* (1) A failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this part is a violation of this regulation and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture of a new chemical substance in violation of this exemption or act to seize any chemical substances manufactured in violation of the exemption under the authority of section 17 of the Act (15 U.S.C. 2616).

[83 FR 52719, Oct. 17, 2018]

§ 723.250 Polymers.

(a) *Purpose and scope.* (1) This section grants an exemption from certain of the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of certain polymers. This section does not apply to microorganisms subject to part 725 of this chapter.

(2) To manufacture a new chemical substance under the terms of this section, a manufacturer must:

(i) Determine that the substance meets the definition of polymer in paragraph (b) of this section.

(ii) Determine that the substance is not specifically excluded by paragraph (d) of this section.

(iii) Ensure that the substance meets the exemption criteria of paragraph (e) of this section.

(iv) Submit a report as required under paragraph (f) of this section.

(v) Comply with the recordkeeping requirements of paragraph (j) of this section.

(b) *Definitions.* In addition to the definitions under section 3 of the Act, 15 U.S.C. 2602, the following definitions apply to this part.

Act means the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*).

Biopolymer means a polymer directly produced by living or once-living cells or cellular components.

Category of chemical substances has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

Cationic polymer means a polymer that contains a net positively charged atom(s) or associated groups of atoms covalently linked to its polymer molecule.

Chemical substance, *Director*, *EPA*, *importer*, *impurity*, *Inventory*, *known to or reasonably ascertainable*, *manufacture*, *manufacturer*, *mixture*, *new chemical*, *person*, *possession or control*, *process and test data* have the same meanings as in § 720.3 of this chapter.

Equivalent weight of a functional group means the ratio of the molecular weight to the number of occurrences of that functional group in the molecule. It is the weight of substance that contains one formula-weight of the functional group.

Fluorotelomers means the products of telomerization, which is the reaction of a telogen (such as pentafluoroethyl iodide) with an ethylenic compound (such as tetrafluoroethylene) to form low molecular weight polymeric compounds, which contain an array of saturated carbon atoms covalently bonded

to each other (C-C bonds) and to fluorine atoms (C-F bonds). This array is predominantly a straight chain, and depending on the telogen used produces a compound having an even number of carbon atoms. However, the carbon chain length of the fluorotelomer varies widely. The perfluoroalkyl groups formed by this process are usually, but do not have to be, connected to the polymer through a functionalized ethylene group as indicated by the following structural diagram: (Rf-CH_2CH_2-Anything).

Internal monomer unit means a monomer unit that is covalently bonded to at least two other molecules. Internal monomer units of polymer molecules are chemically derived from monomer molecules that have formed covalent bonds between two or more other monomer molecules or other reactants.

Monomer means a chemical substance that is capable of forming covalent bonds with two or more like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

Monomer Unit means the reacted form of the monomer in a polymer.

Number-average molecular weight means the arithmetic average (mean) of the molecular weight of all molecules in a polymer.

Oligomer means a polymer molecule consisting of only a few monomer units (dimer, trimer, tetramer)

Other reactant means a molecule linked to one or more sequences of monomer units but which, under the relevant reaction conditions used for the particular process, cannot become a repeating unit in the polymer structure.

Perfluoroalkyl carboxylate (PFAC) means a group of saturated carbon atoms covalently bonded to each other in a linear, branched, or cyclic array and covalently bonded to a carbonyl moiety and where all carbon-hydrogen (C-H) bonds have been replaced with carbon-fluorine (C-F) bonds. The carbonyl moiety is also covalently bonded to a hetero atom, typically, but not necessarily oxygen (O) or nitrogen (N).

Perfluoroalkyl sulfonate (PFAS) means a group of saturated carbon atoms covalently bonded to each other in a linear, branched, or cyclic array and covalently bonded to a sulfonyl moiety and where all carbon - hydrogen (C-H) bonds have been replaced with carbon - fluorine (C-F) bonds. The sulfonyl moiety is also covalently bonded to a hetero atom, typically, but not necessarily oxygen (O) or nitrogen (N).

Polyester means a chemical substance that meets the definition of polymer and whose polymer molecules contain at least two carboxylic acid ester linkages, at least one of which links internal monomer units together.

Polymer means a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition, sequence means that the monomer units under consideration are covalently bound to one another and form a continuous string within the molecule, uninterrupted by units other than monomer units.

Polymer molecule means a molecule which contains a sequence of at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant.

Reactant means a chemical substance that is used intentionally in the manufacture of a polymer to become chemically a part of the polymer composition.

Reactive functional group means an atom or associated group of atoms in a chemical substance that is intended or can reasonably be anticipated to undergo further chemical reaction.

Reasonably anticipated means that a knowledgeable person would expect a given physical or chemical composition or characteristic to occur based on such factors as the nature of the precursors used to manufacture the polymer, the type of reaction, the type of manufacturing process, the products

produced in polymerization, the intended uses of the substance, or associated use conditions.

(c) *Applicability*. This section applies to manufacturers of new chemical substances that otherwise must submit a premanufacture notice to EPA under §720.22 of this chapter. New substances are eligible for exemption under this section if they meet the definition of ''polymer'' in paragraph (b) of this section, and the criteria in paragraph (e) of this section, and if they are not excluded from the exemption under paragraph (d) of this section.

(d) *Polymers that cannot be manufactured under this section*—(1) *Cationic polymers*. A polymer cannot be manufactured under this section if the polymer is a cationic polymer as defined under paragraph (b) of this section or if the polymer is reasonably anticipated to become a cationic polymer in a natural aquatic environment (e.g., rivers, lakes) unless:

(i) The polymer is a solid material that is not soluble or dispersible in water and will be used only in the solid phase (e.g., polymers that will be used as ion exchange beads), or

(ii) The combined (total) functional group equivalent weight of cationic groups in the polymer is equal to or greater than 5,000.

(2) *Elemental limitations*. (i) A polymer manufactured under this section must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

(ii) A polymer cannot be manufactured under this section if it contains as an integral part of its composition, except as impurities, any elements other than the following:

(A) The elements listed in paragraph (d)(2)(i) of this section.

(B) Sodium, magnesium, aluminum, potassium, calcium, chlorine, bromine, and iodine as the monatomic counterions Na^{+}, Mg^{+2}, Al^{+3}, K^{+}, Ca^{+2}, Cl^{-}, Br^{-}, or I^{-}.

(C) Fluorine, chlorine, bromine, and iodine covalently bound to carbon.

(D) Less than 0.20 weight percent of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium.

(3) *Polymers which degrade, decompose, or depolymerize*. A polymer cannot be manufactured under this section if the polymer is designed or is reasonably anticipated to substantially degrade, decompose, or depolymerize, including those polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so. For the purposes of this section, degradation, decomposition, or depolymerization mean those types of chemical change that convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation, hydrolysis, attack by solvents, heat, light, or microbial action.

(4) *Polymers manufactured or imported from monomers and reactants not on the TSCA Chemical Substance Inventory*. A polymer cannot be manufactured under this section if the polymer being manufactured or imported is prepared from monomers and/or other reactants (that are either charged to the reaction vessel or incorporated in the polymer at levels of greater than 2 weight percent) that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

(5) *Water absorbing polymers with number average molecular weight (MW) 10,000 and greater*. A polymer cannot be manufactured under this section if the polymer being manufactured or imported is a water absorbing polymer and has a number average MW greater than or equal to 10,000 daltons. For purposes of this section, a water-absorbing polymer is a polymeric substance that is capable of absorbing its weight of water.

(6) *Polymers which contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length*. Except as provided in paragraph (d)(6)(i), after February 26, 2010, a polymer cannot be manufactured under this section if the polymer contains as an integral part of its composition, except as impurities, one or more of the following perfluoroalkyl moieties consisting of a CF3- or longer chain length: Perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to

either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.

(i) Any polymer that has been manufactured previously in full compliance with the requirements of this section prior to February 26, 2010 may no longer be manufactured under this section after January 27, 2012.

(ii) [Reserved]

(e) *Exemption criteria*. To be manufactured under this section, the polymer must meet one of the following criteria:

(1) *Polymers with number average MW greater than or equal to 1,000 and less than 10,000 daltons (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000)*. (i) The polymer must have a number average MW greater than or equal to 1,000 and less than 10,000 daltons and contain less than 10 percent oligomeric material below MW 500 and less than 25 percent oligomeric material below MW 1,000.

(ii) The polymer cannot contain reactive functional groups unless it meets one of the following criteria:

(A) The polymer contains only the following reactive functional groups: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered ''ordinary,''(i.e., not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, e.g., strongly electron-withdrawing sulfone group with which the olefinic groups interact), butenedioic acid groups, those conjugated olefinic groups contained in naturally-occurring fats, oils, and carboxylic acids, blocked isocyanates (including ketoxime-blocked isocyanates), thiols, unconjugated nitrile groups, and halogens (except that reactive halogen-containing groups such as benzylic or allylichalides cannot be included).

(B) The polymer has a combined (total) reactive group equivalent weight greater than or equal to 1,000 for the following reactive functional groups: acidhalides; acid anhydrides; aldehydes, hemiacetals; methylolamides,- amines or,- ureas; alkoxysilanes with alkoxy greater than C_2-alkoxysilanes; allyl ethers; conjugated olefins; cyanates; epoxides; imines; or unsubstituted positions *ortho* or *para* to phenolic hydroxyl; or

(C) If any reactive functional groups not included in paragraph (e)(1)(ii)(A) and (B) of this section are present, the combined (total) reactive group equivalent weight, including any groups listed in paragraph (e)(1)(ii)(B), is greater than or equal to 5,000.

(2) *Polymers with number average MW greater than or equal to 10,000 (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000)* . The polymer must have a number average MW greater than or equal to 10,000 daltons and contain less than 2 percent oligomeric material below MW 500 and less than 5 percent oligomeric material below MW 1000.

(3) *Polyester polymers*. The polymer is a polyester as defined in paragraph (b) of this section and is manufactured solely from one or more of the reactants in the following table 1:

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE

Reactant	CAS No.
Monobasic Acids and Natural Oils	
Benzoic acid	65–85–0
Canola oil	120962–03–0
Coconut oil	8001–31–8*
Corn oil	8001–30–7*
Cottonseed oil	8001–29–4*
Dodecanoic acid	143–07–7
Fats and glyceridic oils, anchovy	128952–11–4*
Fats and glyceridic oils, babassu	91078–92–1*
Fats and glyceridic oils, herring	68153–06–0*
Fats and glyceridic oils, menhaden	8002–50–4*
Fats and glyceridic oils, sardine	93334–41–9*
Fats and glyceridic oils, oiticica	8016–35–1*
Fatty acids,C_{16-18} and C_{18}-unsatd.	67701–08–0*
Fatty acids, castor-oil	61789–44–4*
Fatty acids, coco	61788–47–4*
Fatty acids, dehydrated castor-oil	61789–45–5*

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
Fatty acids, linseed oil	68424–45–3*
Fatty acids, safflower oil.	
Fatty acids, soya	68308–53–2*
Fatty acids, sunflower oil	84625–38–7*
Fatty acids, sunflower-oil, conjugated	68953–27–5*
Fatty acids, tall-oil	61790–12–3*
Fatty acids, tall-oil, conjugated*.	
Fatty acids, vegetable oil	61788–66–7*
Glycerides, C_{16-18} and C_{18}-unsatd.	67701–30–8*
Heptanoic acid	111–14–8
Hexanoic acid	142–62–1
Hexanoic acid, 3,3,5-trimethyl-	3302–10–1
Linseed oil	8001–26–1*
Linseed oil, oxidized	68649–95–6*
Nonanoic acid	112–05–0
Oils, Cannabis*.	
Oils, palm kernel	8023–79–8*
Oils, perilla	68132–21–8*
Oils, walnut	8024–09–7
Safflower oil	8001–23–8*
Soybean oil	8001–22–7*
Sunflower oil	8001–21–6*
Tung oil	8001–20–5*
Di and Tri Basic Acids:	
1,2-Benzenedicarboxylic acid	88–99–3
1,3-Benzenedicarboxylic acid	121–91–5
1,3-Benzenedicarboxylic acid, dimethyl ester	1459–93–4
1,4-Benzenedicarboxylic acid	100–21–0
1,4-Benzenedicarboxylic acid, diethyl ester	636–09–9
1,4-Benzenedicarboxylic acid, dimethyl ester	120–61–6
1,2,4-Benzenetricarboxylic acid	528–44–9
Butanedioic acid	110–15–6
Butanedioic acid, diethyl ester	123–25–1
Butanedioic acid, dimethyl ester	106–65–0
2-Butenedioic acid (E)–	110–17–8
Decanedioic acid	111–20–6
Decanedioic acid, diethyl ester	110–40–7
Decanedioic acid, dimethyl ester	106–79–6
Dodecanedioic acid	693–23–2
Fatty acids, C_{18}-unsatd., dimers	61788–89–4*
Heptanedioic acid	111–16–0
Heptanedioic acid, dimethyl ester	1732–08–7
Hexanedioic acid	124–04–9
Hexanedioic acid, dimethyl ester	627–93–0
Hexanedioic acid, diethyl ester	141–28–6
Nonanedioic acid	123–99–9
Nonanedioic acid, dimethyl ester	1732–10–1
Nonanedioic acid, diethyl ester	624–17–9
Octanedioic acid	(505–48–6)
Octanedioic acid, dimethyl ester	1732–09–8
Pentanedioic acid	(110–94–1)
Pentanedioic acid, dimethyl ester	1119–40–0
Pentanedioic acid, diethyl ester	818–38–2
Undecanedioic acid	1852–04–6
Polyols	
1,3-Butanediol	107–88–0
1,4-Butanediol	110–63–4
1,4-Cyclohexanedimethanol	105–08–8
1,2-Ethanediol	107–21–1
Ethanol, 2,2′-oxybis-	111–46–6
1,6-Hexanediol	629–11–8
1,3-Pentanediol, 2,2,4-trimethyl-	144–19–4
1,2-Propanediol,	57–55–6
1,3-Propanediol, 2,2-bis(hydroxymethyl)-	115–77–5
1,3-Propanediol, 2,2-dimethyl-	126–30–7
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-	77–99–6
1,3-Propanediol, 2-(hydroxymethyl)-2-methyl-	77–85–0
1,3-propanediol, 2-methyl	2163–42–0
1,2,3-Propanetriol	56–81–5
1,2,3-Propanetriol, homopolymer	25618–55–7
2-Propen-1-ol, polymer with ethenylbenzene	25119-62–4

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
Modifiers	
Acetic acid, 2,2′-oxybis-	110–99–6
1-Butanol	71–36–3**
Cyclohexanol	108–93–0
Cyclohexanol, 4,4′-(1-methylethylidene)bis-	80–04–6
Ethanol, 2-(2-butoxyethoxy)-	112–34–5
1-Hexanol	111–27–3
Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane	72318–84–4*
1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)-	13393–93–6
Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2,2′- [(1-methylethylidene)bis(4,1-phenyleneoxymethylene)] bis[oxirane].	25036-25–3
Siloxanes and Silicones, di-Me, di-Ph, polymers with Ph silsesquioxanes, methoxy-terminated	68440–65–3*
Siloxanes and Silicones, di-Me, methoxy Ph, polymers with Ph silsesquioxanes, methoxy-terminated	68957–04–0*
Siloxanes and Silicones, Me Ph, methoxy Ph, polymers with Ph silsesquioxanes, methoxy- and Ph-terminated.	[1]68957–06–2*
Silsesquioxanes, Ph Pr	[1]68037–90–1*

* Chemical substance of unknown or variable composition,complex reaction products, and biological materials (UVCB). The CAS Registry Numbers for UVCB substances are not used in CHEMICAL ABSTRACTS and its indexes.

** These substances may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters, which may be formed by reaction of these reactants.

(f) *Exemption report for polymers manufactured under the terms of this section.* For substances exempt under paragraphs (e)(1), (e)(2), and (e)(3) of this section a report of manufacture or import must be submitted (postmarked) by January 31 of the year subsequent to initial manufacture. The notice must include:

(1) *Manufacturer's name.* This includes the name and address of the manufacturer and the name and telephone number of a technical contact.

(2) *Number of substances manufactured.* Number of substances manufactured. The manufacturer must identify the number of polymers manufactured under terms of the exemption for the first time in the year preceding the notice.

(g) *Chemical identity information.* For substances exempt under paragraph (e) of this section the manufacturer must to the extent known to or reasonably ascertainable by the manufacturer identify the following and maintain the records in accordance with paragraph (j) of this section:

(1) A specific chemical name and CAS Registry Number (or EPA assigned Accession Number) for each ''reactant,'' as that term is defined in paragraph (b) of this section, used at any weight in the manufacture of the polymer. For purposes of determining chemical identity, the manufacturer may determine whether a reactant is used at greater than two weight percent according to either the weight of the reactant charged to the reaction vessel or the weight of the chemically combined (incorporated) reactant in the polymer. Manufacturers who choose the ''incorporated'' method must have analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate compliance with this paragraph. Reactants that introduce into the polymer elements, properties, or functional groups that would render the polymer ineligible for the exemption are not allowed at any level.

(2) A representative structural diagram, if possible.

(h) *Certification.* To manufacture a substance under the terms of this section, a manufacturer must as of the date of first manufacture, make the following certification statements and maintain them in accordance with paragraph (j) of this section:

(1) The substance is manufactured or imported for a commercial purpose other than for research and development.

(2) All information in the certification is truthful.

(3) The new chemical substance meets the definition of a polymer, is not specifically excluded from the exemption in paragraph (d) of this section, and meets the conditions of the exemption in paragraph (e) of this section.

(i) *Exemptions granted under superseded regulations.* Manufacturers granted exemptions under the superseded requirements of §723.250 (as in effect on May 26, 1995) shall either continue to comply with those requirements or follow all procedural and recordkeeping requirements pursuant to this section. If an exemption holder continues to follow the superseded regulations, the Notice of Commencement requirements apply and the exempt polymer will continue to be listed on the Inventory with exclusion criteria and exemption category restrictions on residual monomer/reactant and low molecular weight species content limitations.

(j) *Recordkeeping.* (1) A manufacturer of a new polymer under paragraphs (e) of this section, must retain the records described in this paragraph at the manufacturing site for a period of 5 years from the date of commencement of manufacture or import.

(2) The records must include the following to demonstrate compliance with the terms of this section:

(i) Chemical identity information as required in paragraph (g) of this section.

(ii) Information to demonstrate that the new polymer is not specifically excluded from the exemption.

(iii) Records of production volume for the first 3 years of manufacture and the date of commencement of manufacture.

(iv) Information to demonstrate that the new polymer meets the exemption criteria in paragraphs (e)(1), (e)(2), or (e)(3) of this section.

(v) Analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate that the polymer meets the number-average MW exemption criteria in paragraphs (e)(1) or (e)(2) of this section. The analytical tests may include gel permeation chromatography (GPC).vapor pressure osmometry (VPO), or other such tests which will demonstrate that the polymer meets the number-average MW criterion.

(vi) Analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate that the polymer meets the criteria in paragraphs (e)(1) or (e)(2) of this section, meets the low MW content criteria in paragraphs (e)(1) or (e)(2) of this section.

(vii) If applicable, analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary) required in paragraph (g) of this section for determining monomers or reactants charged to the reaction vessel at greater than 2 weight percent but incorporated at 2 weight percent or less in the manufactured polymer.

(viii) The certification statements as required under paragraph (h) of this section.

(3) The manufacturer must submit the records listed in paragraph (j)(2) of this section to EPA upon written request by EPA. The manufacturer must provide these records within 15 working days of receipt of this request. In addition, any person who manufactures a new chemical substance under the terms of this section, upon request of EPA, must permit such person at all reasonable times to have access to and to copy these records.

(k) *Submission of information.* Information submitted to EPA under this section must be sent in writing to: TSCA Document Control Officer, (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(l) *Compliance.* (1) A person who manufactures or imports a new chemical substance and fails to comply with any provision of this section is in violation of section 15 of the Act (15 U.S.C. 2614).

(2) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by this section and section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Failure or refusal to permit entry or inspection as required by section 11

of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(5) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this section may be subject to penalties calculated as if they never filed their notices.

(6) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section or act to seize any chemical substance manufactured or processed in violation of this section or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

(m) *Inspections.* EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 and this section, to verify that information submitted to EPA under this section is true and correct, and to audit data submitted to EPA under this section.

(n) *Confidentiality.* If a manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with ''CONFIDENTIAL'' or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in 40 CFR part 2. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

[60 FR 16332, Mar. 29, 1995, as amended at 62 FR 17932, Apr. 11, 1997; 75 FR 4305, Jan. 27, 2010]

PART 725—REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

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AUTHORITY: 15 U.S.C. 2604, 2607, 2613, and 2625.

SOURCE: 62 FR 17932, Apr. 11, 1997, unless otherwise noted.

Subpart A—General Provisions and Applicability

§ 725.1 Scope and purpose.

(a) This part establishes all reporting requirements under section 5 of TSCA for manufacturers, importers, and processors of microorganisms subject to TSCA jurisdiction for commercial purposes, including research and development for commercial purposes. New microorganisms for which manufacturers and importers are required to report under section 5(a)(1)(A) of TSCA are those that are intergeneric. In addition, under section 5(a)(1)(B) of TSCA, manufacturers, importers, and processors may be required to report for any microorganism that EPA determines by rule is being manufactured, imported, or processed for a significant new use.

(b) Any manufacturer, importer, or processor required to report under section 5 of TSCA (see §725.100 for new microorganisms and §725.900 for significant new uses) must file a Microbial Commercial Activity Notice (MCAN) with EPA, unless the activity is eligible for a specific exemption as described in this part. The general procedures for filing MCANs are described in subpart D of this part. The exemptions from the requirement to file a MCAN are for certain kinds of contained activities (see §§725.424 and 725.428), test marketing activities (see §725.300), and research and development activities described in paragraph (c) of this section.

(c) Any manufacturer, importer, or processor required to file a MCAN for research and development (R&D) activities may instead file a TSCA Experimental Release Application (TERA) for a specific test (see §725.250). A

TERA is not required for certain R&D activities; however a TERA exemption does not extend beyond the research and development stage, to general commercial use of the microorganism, for which compliance with MCAN requirements is required. The TERA exemptions are for R&D activities subject to other Federal agencies or programs (see § 725.232), certain kinds of contained R&D activities (see § 725.234), and R&D activities using certain listed microorganisms (see § 725.238).

(d) New microorganisms will be added to the Inventory established under section 8 of TSCA once a MCAN has been received, the MCAN review period has expired, and EPA receives a Notice of Commencement (NOC) indicating that manufacture or importation has actually begun. New microorganisms approved for use under a TERA will not be added to the Inventory until a MCAN has been received, the MCAN review period has expired, and EPA has received an NOC.

§ 725.3 Definitions.

Definitions in section 3 of the Act (15 U.S.C. 2602), as well as definitions contained in §§ 704.3, 720.3, and 721.3 of this chapter, apply to this part unless otherwise specified in this section. In addition, the following definitions apply to this part:

Consolidated microbial commercial activity notice or *consolidated MCAN* means any MCAN submitted to EPA that covers more than one microorganism (each being assigned a separate MCAN number by EPA) as a result of a prenotice agreement with EPA.

Containment and/or inactivation controls means any combination of engineering, mechanical, procedural, or biological controls designed and operated to restrict environmental release of viable microorganisms from a structure.

Director means the Director of the EPA Office of Pollution Prevention and Toxics.

Exemption request means any application submitted to EPA under subparts E, F, or G of this part.

General commercial use means use for commercial purposes other than research and development.

Genome means the sum total of chromosomal and extrachromosomal genetic material of an isolate and any descendants derived under pure culture conditions from that isolate.

Health and safety study of a microorganism or *health and safety study* means any study of any effect of a microorganism or microbial mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a microorganism or microbial mixture, toxicological, clinical, and ecological, or other studies of a microorganism or microbial mixture, and any test performed under the Act. Microorganism identity is always part of a health and safety study of a microorganism.

(1) It is intended that the term ''health and safety study of a microorganism'' be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a microorganism or microbial mixture on health or the environment is also included. Any data that bear on the effects of a microorganism on health or the environment would be included.

(2) Examples include:

(i) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: Acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(ii) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; dermatoxicity; cumulative, additive, and synergistic effects; and acute, subchronic, and chronic effects.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular microorganism or microbial mixture on the environment, including surveys, tests, and studies of: Survival and transport in air, water, and soil; ability to exchange genetic material with other microorganisms, ability to

colonize human or animal guts, and ability to colonize plants.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a microorganism.

(v) Any assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the microorganism.

Inactivation means that living microorganisms are rendered nonviable.

Institutional Biosafety Committee means the committees described in the NIH Guidelines in section IV.B.2.

Intergeneric microorganism means a microorganism that is formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera.

(1) The term ''intergeneric microorganism'' includes a microorganism which contains a mobile genetic element which was first identified in a microorganism in a genus different from the recipient microorganism.

(2) The term ''intergeneric microorganism'' does not include a microorganism which contains introduced genetic material consisting of only well-characterized, non-coding regulatory regions from another genus.

Introduced genetic material means genetic material that is added to, and remains as a component of, the genome of the recipient.

Manufacture, import, or process for commercial purposes means:

(1) To import, produce, manufacture, or process with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, importer, or processor, and includes, among other things, ''manufacture'' or ''processing'' of any amount of a microorganism or microbial mixture:

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development or as an intermediate.

(2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another microorganism or microbial mixture, including byproducts that are separated from that other microorganism or microbial mixture and impurities that remain in that microorganism or microbial mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture or processing of a microorganism for commercial purposes.

Microbial commercial activity notice or *MCAN* means a notice for microorganisms submitted to EPA pursuant to section 5(a)(1) of the Act in accordance with subpart D of this part.

Microbial mixture means any combination of microorganisms or microorganisms and other chemical substances, if the combination does not occur in nature and is not an article.

Microorganism means an organism classified, using the 5-kingdom classification system of Whittacker, in the kingdoms Monera (or Procaryotae), Protista, Fungi, and the Chlorophyta and the Rhodophyta of the Plantae, and a virus or virus-like particle.

Mobile genetic element or *MGE* means an element of genetic material that has the ability to move genetic material within and between organisms. ''Mobile genetic elements'' include all plasmids, viruses, transposons, insertion sequences, and other classes of elements with these general properties.

New microorganism means a microorganism not included on the Inventory.

NIH Guidelines means the National Institutes of Health (NIH) ''Guidelines for Research Involving Recombinant DNA Molecules'' (July 5, 1994).

Non-coding regulatory region means a segment of introduced genetic material for which:

(1) The regulatory region and any inserted flanking nucleotides do not code for protein, peptide, or functional ribonucleic acid molecules.

(2) The regulatory region solely controls the activity of other regions that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

Small quantities solely for research and development (or ''small quantities solely for purposes of scientific experimentation or analysis or research on, or analysis of, such substance or another

substance, including such research or analysis for development of a product'') means quantities of a microorganism manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that meet the requirements of § 725.234.

Structure means a building or vessel which effectively surrounds and encloses the microorganism and includes features designed to restrict the microorganism from leaving.

Submission means any MCAN or exemption request submitted to EPA under this part.

Technically qualified individual means a person or persons:

(1) Who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the microorganism which is used under his or her supervision,

(2) Who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or microbiological research to minimize such risks, and

(3) Who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the microorganism as may be appropriate or required within the scope of conducting a research and development activity.

TSCA Experimental Release Application or *TERA* means an exemption request for a research and development activity, which is not eligible for a full exemption from reporting under § 725.232, 725.234, or 725.238, submitted to EPA in accordance with subpart E of this part.

Well-characterized for introduced genetic material means that the following have been determined:

(1) The function of all of the products expressed from the structural gene(s).

(2) The function of sequences that participate in the regulation of expression of the structural gene(s).

(3) The presence or absence of associated nucleotide sequences and their associated functions, where associated nucleotide sequences are those sequences needed to move genetic material including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

§ 725.8 Coverage of this part.

(a) *Microorganisms subject to this part.* Only microorganisms which are manufactured, imported, or processed for commercial purposes, as defined in § 725.3, are subject to the requirements of this part.

(b) *Microorganisms automatically included on the Inventory.* Microorganisms that are not intergeneric are automatically included on the Inventory.

(c) *Microorganisms not subject to this part.* The following microorganisms are not subject to this part, either because they are not subject to jurisdiction under the Act or are not subject to reporting under section 5 of the Act.

(1) Any microorganism which would be excluded from the definition of ''chemical substance'' in section 3 of the Act and § 720.3(e) of this chapter.

(2) Any microbial mixture as defined in § 725.3. This exclusion applies only to a microbial mixture as a whole and not to any microorganisms and other chemical substances which are part of the microbial mixture.

(3) Any microorganism that is manufactured and processed solely for export if the following conditions are met:

(i) The microorganism is labeled in accordance with section 12(a)(1)(B) of the Act, when the microorganism is distributed in commerce.

(ii) The manufacturer and processor can document at the commencement of manufacturing or processing that the person to whom the microorganism will be distributed intends to export it or process it solely for export as defined in § 721.3 of this chapter.

§ 725.12 Identification of microorganisms for Inventory and other listing purposes.

To identify and list microorganisms on the Inventory, both taxonomic designations and supplemental information will be used. The supplemental information required in paragraph (b) of this section will be used to specifically describe an individual microorganism on the Inventory. Submitters must provide the supplemental information

required by paragraph (b) of this section to the extent necessary to enable a microorganism to be accurately and unambiguously identified on the Inventory.

(a) *Taxonomic designation.* The taxonomic designation of a microorganism must be provided for the donor organism and the recipient microorganism to the level of strain, as appropriate. These designations must be substantiated by a letter from a culture collection, literature references, or the results of tests conducted for the purpose of taxonomic classification. Upon EPA's request to the submitter, data supporting the taxonomic designation must be provided to EPA. The genetic history of the recipient microorganism should be documented back to the isolate from which it was derived.

(b) *Supplemental information.* The supplemental information described in paragraphs (b)(1) and (b)(2) of this section is required to the extent that it enables a microorganism to be accurately and unambiguously identified.

(1) *Phenotypic information.* Phenotypic information means pertinent traits that result from the interaction of a microorganism's genotype and the environment in which it is intended to be used and may include intentionally added biochemical and physiological traits.

(2) *Genotypic information.* Genotypic information means the pertinent and distinguishing genotypic characteristics of a microorganism, such as the identity of the introduced genetic material and the methods used to construct the reported microorganism. This also may include information on the vector construct, the cellular location, and the number of copies of the introduced genetic material.

§ 725.15 Determining applicability when microorganism identity or use is confidential or uncertain.

(a) *Consulting EPA.* Persons intending to conduct activities involving microorganisms may determine their obligations under this part by consulting the Inventory or the microorganisms and uses specified in § 725.239 or in subpart M of this part. This section establishes procedures for EPA to assist persons in determining whether the microorganism or the use is listed on the Inventory, in § 725.239 or in subpart M of this part.

(1) *Confidential identity or use.* In some cases it may not be possible to directly determine if a specific microorganism is listed, because portions of that entry may contain generic information to protect confidential business information (CBI). If any portion of the microorganism's identity or use has been claimed as CBI, that portion does not appear on the public version of the Inventory, in § 725.239 or in subpart M of this part. Instead, it is contained in a confidential version held in EPA's Confidential Business Information Center (CBIC). The public versions contain generic information which masks the confidential business information. A person who intends to conduct an activity involving a microorganism or use whose entry is described with generic information will need to inquire of EPA whether the unreported microorganism or use is on the confidential version.

(2) *Uncertain microorganism identity.* The current state of scientific knowledge leads to some imprecision in describing a microorganism. As the state of knowledge increases, EPA will be developing policies to determine whether one microorganism is equivalent to another. Persons intending to conduct activities involving microorganisms may inquire of EPA whether the microorganisms they intend to manufacture (including import) or process are equivalent to specific microorganisms described on the Inventory, in § 725.239, or in subpart M of this part.

(b) *Requirement of bona fide intent.* (1) EPA will answer the inquiries described in paragraph (a) of this section only if the Agency determines that the person has a *bona fide* intent to conduct the activity for which reporting is required or for which any exemption may apply.

(2) To establish a *bona fide* intent to manufacture (including import) or process a microorganism, the person who proposes to manufacture (including import) or process the microorganism must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such *bona fide* intents to manufacture (including import) or process

must be generated and completed using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software. A *bona fide* intent to manufacture (including import) or process must contain the following information:

(i) Taxonomic designations and supplemental information required by § 725.12.

(ii) A signed statement certifying that the submitter intends to manufacture (including import) or process the microorganism for commercial purposes.

(iii) A description of research and development activities conducted with the microorganism to date, demonstration of the submitter's ability to produce or obtain the microorganism from a foreign manufacturer, and the purpose for which the person will manufacture (including import) or process the microorganism.

(iv) An indication of whether a related microorganism was previously reviewed by EPA to the extent known by the submitter.

(v) A specific description of the major intended application or use of the microorganism.

(c) If an importer or processor cannot provide all the information required by paragraph (b) of this section, because it is claimed as confidential business information by its foreign manufacturer or supplier, the foreign manufacturer or supplier may supply the information directly to EPA.

(d) EPA will review the information submitted by the manufacturer (including importer) or processor under this paragraph to determine whether that person has shown a *bona fide* intent to manufacture (including import) or process the microorganism. If necessary, EPA will compare this information to the information requested for the confidential microorganism under § 725.85(b)(3)(iii).

(e) In order for EPA to make a conclusive determination of the microorganism's status, the proposed manufacturer (including importer) or processor must show a *bona fide* intent to manufacture (including import) or process the microorganism and must provide sufficient information to establish identity unambiguously. After sufficient information has been provided, EPA will inform the manufacturer (including importer) or processor whether the microorganism is subject to this part and if so, which sections of this part apply.

(f) If the microorganism is found on the confidential version of the Inventory, in § 725.239 or in subpart M of this part, EPA will notify the person(s) who originally reported the microorganism that another person (whose identity will remain confidential, if so requested) has demonstrated a *bona fide* intent to manufacture (including import) or process the microorganism and therefore was told that the microorganism is on the Inventory, in § 725.239, or in subpart M of this part.

(g) A disclosure to a person with a *bona fide* intent to manufacture (including import) or process a particular microorganism that the microorganism is on the Inventory, in § 725.239, or in subpart M of this part will not be considered a public disclosure of confidential business information under section 14 of the Act.

(h) EPA will answer an inquiry on whether a particular microorganism is subject to this part within 30 days after receipt of a complete submission under paragraph (b) of this section.

[62 FR 17932, Apr. 11, 1997, as amended at 80 FR 42747, July 20, 2015]

§ 725.17 Consultation with EPA.

Persons may consult with EPA, either in writing or by telephone, about their obligations under this part. Written consultation is preferred. Written inquiries should be sent to the following address: Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: Biotechnology Notice Consultation. Persons wishing to consult with EPA by telephone should call (202) 554–1404; hearing impaired TDD (202) 554–0551 or e-mail: *TSCA-Hotline@epamail.epa.gov*.

Subpart B—Administrative Procedures

§ 725.20 Scope and purpose.

This subpart describes general administrative procedures applicable to all persons who submit MCANs and exemption requests to EPA under section 5 of the Act for microorganisms.

§ 725.25 General administrative requirements.

(a) *General.* (1) Each person who is subject to the notification provisions of this part must complete, sign, and submit a MCAN or exemption request containing the information as required for the appropriate submission under this part. Except as otherwise provided, each submission must include all referenced attachments. All information in the submission (unless certain attachments appear in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) In addition to specific information required, the submitter should submit all information known to or reasonably ascertainable by the submitter that would permit EPA to make a reasoned evaluation of the human health and environmental effects of the microorganism and any microbial mixture or article that may contain the microorganism.

(b) *Certification.* Persons submitting MCANs and exemption requests to EPA under this part, and material related to their reporting obligations under this part, must attach the following statement to any information submitted to EPA. This statement must be signed and dated by an authorized official of the submitter:

I certify that to the best of my knowledge and belief: The company named in this submission intends to manufacture, import, or process for a commercial purpose, other than in small quantities solely for research and development, the microorganism identified in this submission. All information provided in this submission is complete and truthful as of the date of submission. I am including with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by 40 CFR 725.160 or 725.260.

(c) *Where to submit information under this part.* MCANs and exemption requests, and any support documents related to these submissions, may only be submitted in a manner set forth in this paragraph. MCANs and exemption requests, and any related support documents, must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(d) *General requirements for submission of data.* (1) Submissions under this part must include the information described in § 725.155, § 725.255, § 725.355, or § 725.455, as appropriate, to the extent such information is known to or reasonably ascertainable by the submitter.

(2) In accordance with § 725.160 or § 725.260, as appropriate, the submission must also include any test data in the submitter's possession or control and descriptions of other data which are known to or reasonably ascertainable by the submitter and which concern the health and environmental effects of the microorganism.

(e) *Agency or joint submissions.* (1) A manufacturer or importer may designate an agent to assist in submitting the MCAN. If so, only the manufacturer or importer, and not the agent, signs the certification on the form.

(2) A manufacturer or importer may authorize another person, (e.g., a supplier or a toll manufacturer) to report some of the information required in the MCAN to EPA on its behalf. The manufacturer or importer should indicate in a cover letter accompanying the MCAN which information will be supplied by another person and identify that other person as a joint submitter where indicated in their MCAN. The other person supplying information (i.e., the joint submitter) may submit the information to EPA either in the MCAN or a Letter of Support, except that if the joint submitter is not incorporated, licensed, or doing business in the United States, the joint submitter must submit the information to EPA in a Letter of Support only, rather than the MCAN. The joint submitter must indicate in the MCAN or Letter of Support the identity of the manufacturer or importer. Any person who submits the MCAN or Letter of Support for a joint

submission must sign and certify the MCAN or Letter of Support.

(3) If EPA receives a submission which does not include the information required, which the submitter indicates that it has authorized another person to provide, the review period will not begin until EPA receives all of the required information.

(f) *Microorganisms subject to a section 4 test rule.* (1) Except as provided in paragraph (f)(3) of this section, if a person intends to manufacture or import a new microorganism which is subject to the notification requirements of this part, and the microorganism is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with § 725.160. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in § 725.33.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the person may not file a MCAN or TERA until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

(i) The name, title, and address of the person who submitted the test data to EPA.

(ii) The date the test data were submitted to EPA.

(iii) A citation for the test rule.

(iv) A description of the exemption and a reference identifying it.

(g) *Microorganisms subject to a section 5(b)(4) rule.* (1) If a person:

(i) Intends to manufacture or import a microorganism which is subject to the notification requirements of this part and which is subject to a rule issued under section 5(b)(4) of the Act; and

(ii) Is not required by a rule issued under section 4 of the Act to submit test data for the microorganism before the filing of a submission, the person must submit to EPA data described in paragraph (g)(2) of this section at the time the submission is filed.

(2) Data submitted under paragraph (g)(1) of this section must be data which the person submitting the notice believes show that the manufacture, processing, distribution in commerce, use, and disposal of the microorganism, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

(h) *Data that need not be submitted.* Specific data requirements are listed in subparts D, E, F, G, and L of this part. The following is a list of data that need not be submitted under this part:

(1) *Data previously submitted to EPA.* (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the new submission includes: the office or person to whom the data were submitted; the date of submission; and, if appropriate, a standard literature citation as specified in § 725.160(a)(3)(ii).

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the new submission and any claim of confidentiality, under § 725.80.

(2) *Efficacy data.* This part does not require submission of any data related solely to product efficacy. However, including efficacy data will improve EPA's ability to assess the benefits of the use of the microorganism. This does not exempt a person from submitting any of the data specified in § 725.160 or § 725.260.

(3) *Non-U.S. exposure data.* This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

(i) *Fees.* Persons submitting MCANs and exemption requests to EPA under this part are subject to the applicable

fees and conditions specified in §§ 700.40, 700.45(c), and 700.49 of this chapter.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 788, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013; 83 FR 52723, Oct. 17, 2018]

§ 725.27 Submissions.

Each person who is required to submit information under this part must submit the information in the form and manner set forth in the appropriate subpart.

(a) Requirements specific to MCANs are described in §§ 725.150 through 725.160.

(b) Requirements specific to TERAs are described in §§ 725.250 through 725.260.

(c) Requirements specific to test marketing exemptions (TMEs) are described in §§ 725.350 and 725.355.

(d) Requirements specific to Tier I and Tier II exemptions for certain general commercial uses are described in §§ 725.424 through 725.470.

(e) Additional requirements specific to significant new uses for microorganisms are described at § 725.950.

§ 725.28 Notice that submission is not required.

When EPA receives a MCAN or exemption request, EPA will review it to determine whether the microorganism is subject to the requirements of this part. If EPA determines that the microorganism is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture, import, or processing of the microorganism and that the submission is not needed.

§ 725.29 EPA acknowledgement of receipt of submission.

(a) EPA will acknowledge receipt of each submission by sending a letter via CDX or U.S. mail to the submitter that identifies the number assigned to each MCAN or exemption request and the date on which the review period begins. The review period will begin on the date the MCAN or exemption request is received by the Office of Pollution Prevention and Toxics Document Control Officer.

(b) The acknowledgement does not constitute a finding by EPA that the submission is in compliance with this part.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 788, Jan. 6, 2010]

§ 725.32 Errors in the submission.

(a) Within 30 days of receipt of the submission, EPA may request that the submitter remedy errors in the submission. The following are examples of such errors:

(1) Failure to date the submission.

(2) Typographical errors that cause data to be misleading or answers to any questions to be unclear.

(3) Contradictory information.

(4) Ambiguous statements or information.

(b) In the request to correct the submission, EPA will explain the action which the submitter must take to correct the submission.

(c) If the submitter fails to correct the submission within 15 days of receipt of the request, EPA may extend the review period.

§ 725.33 Incomplete submissions.

(a) A submission under this part is not complete, and the review period does not begin, if:

(1) The wrong person files the submission.

(2) The submitter does not attach and sign the certification statement as required by § 725.25(b).

(3) Some or all of the information in the submission or any attachments are not in English, except for published scientific literature.

(4) The submitter does not provide information that is required by sections 5(d)(1)(B) and (C) of the Act and § 725.160 or 725.260, as appropriate.

(5) The submitter does not provide information required by § 725.25, § 725.155, § 725.255, § 725.355, or § 725.455, as appropriate, or indicate that it is not known to or reasonably ascertainable by the submitter.

(6) The submitter has asserted confidentiality claims and has failed to:

(i) Submit a second copy of the submission with all confidential information deleted for the public file, as required by § 725.80(b)(2).

(ii) Comply with the substantiation requirements as described in § 725.94.

(7) The submitter does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by § 725.25(f).

(8) The submitter does not submit data which the submitter believes show that the microorganism will not present an unreasonable risk of injury to health or the environment, if EPA has listed the microorganism under section 5(b)(4) of the Act, as required in § 725.25(g).

(9) The submitter does not remit the fees required by § 700.45(c) of this chapter.

(10) The submitter does not include an identifying number and a payment identity number.

(11) The submitter does not submit the notice in the manner set forth in § 725.25(c).

(b)(1) If EPA receives an incomplete submission under this part, the Director, or a designee, will notify the submitter within 30 days of receipt that the submission is incomplete and that the review period will not begin until EPA receives a complete submission.

(2) If EPA obtains additional information during the review period for any submission that indicates the original submission was incomplete, the Director, or a designee, may declare the submission incomplete within 30 days after EPA obtains the additional information and so notify the submitter.

(c) The notification that a submission is incomplete under paragraph (b) of this section will include:

(1) A statement of the basis of EPA's determination that the submission is incomplete.

(2) The requirements for correcting the incomplete submission.

(3) Information on procedures under paragraph (d) of this section for filing objections to the determination or requesting modification of the requirements for completing the submission.

(d) Within 10 days after receipt of notification by EPA that a submission is incomplete, the submitter may file written objections requesting that EPA accept the submission as complete or modify the requirements necessary to complete the submission.

(e)(1) EPA will consider the objections filed by the submitter. The Director, or a designee, will determine whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within 10 days of receiving the objections.

(2) If the Director, or a designee, determines, in response to the objection, that the submission was complete, the review period will be deemed suspended on the date EPA declared the submission incomplete, and will resume on the date that the submission is declared complete. The submitter need not correct the submission as EPA originally requested. If EPA can complete its review within the review period beginning on the date of the submission, the Director, or a designee, may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(3) If the Director, or a designee, modifies the requirements for completing the submission or concurs with EPA's original determination, the review period will begin when EPA receives a complete submission.

(f) If EPA discovers at any time that a person submitted materially false or misleading statements in information submitted under this part, EPA may find that the submission was incomplete from the date it was submitted, and take any other appropriate action.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 788, Jan. 6, 2010; 83 FR 52723, Oct. 17, 2018]

§ 725.36 New information.

(a) During the review period, if a submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the MCAN or exemption request, the submitter must send that information within 10 days of receiving the new information, but no later than 5 days before the end of the review period. The new information must be sent in the same manner the original notice or exemption was sent, as described in § 725.25(c)(1), (c)(2), and (c)(3).

(b) The new submission must clearly identify the submitter, the MCAN or exemption request to which the new information is related, and the number assigned to that submission by EPA, if known to the submitter.

(c) If the new information becomes available during the last 5 days of the review period, the submitter must immediately inform the EPA contact for that submission by telephone of the new information.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010]

§ 725.40 Notice in the Federal Register.

(a) *Filing of* FEDERAL REGISTER notice. After EPA receives a MCAN or an exemption request under this part, EPA will issue a notice in the FEDERAL REGISTER including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific microorganism identity listed in the submission will be published in the FEDERAL REGISTER unless the submitter has claimed the microorganism identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with § 725.85.

(2) The categories of use of the microorganism will be published as reported in the submission unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 725.88 will be published.

(3) A list of information submitted in accordance with § 725.160(a), § 725.255, § 725.260, § 725.355, or § 725.455, as appropriate, will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

(c) *Publication of exemption decisions.* Following the expiration of the appropriate review period for the exemption request, EPA will issue a notice in the FEDERAL REGISTER indicating whether the request has been approved or denied and the reasons for the decision.

§ 725.50 EPA review.

(a) *MCANs.* The review period specified in section 5(a) of the Act for MCANs runs for 90 days from the date the Document Control Officer receives a complete submission, or the date EPA determines the submission is complete under § 725.33, unless the Agency extends the review period under section 5(c) of the Act and § 725.56.

(b) *Exemption requests.* The review period starts on the date the Document Control Officer receives a complete exemption request, or the date EPA determines the request is complete under § 725.33, unless the Agency extends the review period under § 725.56. The review periods for exemption requests run as follows:

(1) *TERAs.* The review period for TERAs is 60 days.

(2) *TMEs.* The review period for TMEs is 45 days.

(3) *Tier II exemption requests.* The review period for Tier II exemption requests is 45 days.

§ 725.54 Suspension of the review period.

(a) A submitter may voluntarily suspend the running of the review period if the Director, or a designee, agrees. If the Director does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the review period. The suspension must be for a specified period of time.

(b)(1) *Request for suspension.* A request for suspension may only be submitted in a manner set forth in this paragraph. The request for suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice, subject to paragraph (c) of this section.

(2) *Submission of suspension notices.* EPA will accept requests for suspension only if submitted in accordance with this paragraph. Requests for suspension, must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(c) An oral request for suspension may be granted by EPA for a maximum of 15 days only. Requests for longer suspension must only be submitted in the manner set forth in this paragraph.

(d) If the submitter has not made a previous oral request, the running of the notice review period is suspended

as of the date of receipt of the CDX submission by EPA.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013]

§ 725.56 Extension of the review period.

(a) At any time during the review period, EPA may unilaterally determine that good cause exists to extend the review period specified for MCANs, or the exemption requests.

(b) If EPA makes such a determination, EPA:

(1) Will notify the submitter that EPA is extending the review period for a specified length of time and state the reasons for the extension.

(2) For MCANs, EPA may issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the review period and gives the reasons for the extension.

(c) The total period of the extension may be for a period of up to the same length of time as specified for each type of submission in § 725.50. If the initial extension is for less than the total time allowed, EPA may make additional extensions. However, the sum of the extensions may not exceed the total allowed.

(d) The following are examples of situations in which EPA may find that good cause exists for extending the review period:

(1) EPA has reviewed the submission and is seeking additional information.

(2) EPA has received significant additional information during the review period.

(3) The submitter has failed to correct a submission after receiving EPA's request under § 725.32.

(4) EPA has reviewed the submission and determined that there is a significant possibility that the microorganism will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial review period.

§ 725.60 Withdrawal of submission by the submitter.

(a)(1) *Withdrawal of notice by the submitter.* A submitter may withdraw a notice during the notice review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt of the CDX submission by EPA.

(2) *Submission of withdrawal notices.* EPA will accept statements of withdrawal only if submitted in accordance with this paragraph. Statements of withdrawal must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(b) If a manufacturer, importer, or processor who withdrew a submission later resubmits a submission for the same microorganism, a new review period begins.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013]

§ 725.65 Recordkeeping.

(a) *General provisions.* (1) Any person who submits a notice under this part must retain documentation of information in the submission, including:

(i) Any data in the submitter's possession or control; and

(ii) Records of production volume for the first 3 years of manufacture, import, or processing.

(2) Any person who submits a notice under this part must retain documentation of the date of commencement of testing, manufacture, import, or processing.

(3) Any person who is exempt from some or all of the reporting requirements of this part must retain documentation that supports the exemption.

(4) All information required by this section must be retained for 3 years from the date of commencement of each activity for which records are required under this part.

(b) *Specific requirements.* In addition to the requirements of paragraph (a) of this section, specific recordkeeping requirements included in certain subparts must also be followed.

(1) Additional recordkeeping requirements for activities conducted inside a structure are set forth in § 725.235(h).

(2) Additional recordkeeping requirements for TERAs are set forth in § 725.250(f).

(3) Additional recordkeeping requirements for TMEs are set forth in § 725.350(c).

(4) Additional recordkeeping requirements for Tier I exemptions under subpart G of this part are set forth in § 725.424(a)(5).

(5) Additional recordkeeping requirements for Tier II exemptions under subpart G of this part are set forth in § 725.450(d).

(6) Additional recordkeeping requirements for significant new uses of microorganisms reported under subpart L of this part are set forth in § 725.850. Recordkeeping requirements may also be included when a microorganism and significant new use are added to subpart M of this part.

§ 725.67 Applications to exempt new microorganisms from this part.

(a) *Submission.* (1) Any manufacturer or importer of a new microorganism may request, under TSCA section 5(h)(4), an exemption, in whole or in part, from this part by sending a Letter of Application in the manner set forth in § 725.25(c).

(2) *General provisions.* The Letter of Application should provide information to show that any activities affected by the requested exemption will not present an unreasonable risk of injury to health or the environment. This information should include data described in the following paragraphs.

(i) The effects of the new microorganism on health and the environment.

(ii) The magnitude of exposure of human beings and the environment to the new microorganism.

(iii) The benefits of the new microorganism for various uses and the availability of substitutes for such uses.

(iv) The reasonably ascertainable economic consequences of granting or denying the exemption, including effects on the national economy, small business, and technological innovation.

(3) *Specific requirements.* In addition to the requirements of paragraph (a)(2) of this section, the specific information requirements of the relevant subpart under which the exemption is sought should be met.

(i) *Exemption from MCAN reporting under subpart D.* Information requirements are set forth in §§ 725.155 and 725.160.

(ii) *Exemption from TERA reporting under subpart E.* Information requirements are set forth in §§ 725.255 and 725.260.

(iii) *Listing a recipient microorganism as eligible for exemption under subpart G.* Information regarding the following criteria should be addressed in an application to list a recipient microorganism under § 725.420:

(A) Identification and classification of the microorganism using available genotypic and phenotypic information;

(B) Information to evaluate the relationship of the microorganism to any other closely related microorganisms which have a potential for adverse effects on health or the environment;

(C) A history of safe commercial use for the microorganism;

(D) Commercial uses indicating that the microorganism products might be subject to TSCA;

(E) Studies which indicate the potential for the microorganism to cause adverse effects to health or the environment; and

(F) Studies which indicate the survival characteristics of the microorganism in the environment.

(b) *Processing of the Letter of Application by EPA*—(1) *Grant of the Application.* If, after consideration of the Letter of Application and any other relevant information available to EPA, the Assistant Administrator for Chemical Safety and Pollution Prevention makes a preliminary determination that the new microorganism will not present an unreasonable risk of injury to health or the environment, the Assistant Administrator will propose a rule to grant the exemption using the applicable procedures in part 750 of this chapter.

(2) *Denial of the application.* If the Assistant Administrator decides that the preliminary determination described in paragraph (b)(1) of this section cannot be made, the application will be denied by sending the applicant a written statement with the Assistant Administrator's reasons for denial.

(c) *Processing of the exemption*—(1) *Unreasonable risk standard.* Granting a section 5(h)(4) exemption requires a determination that the activities will not present an unreasonable risk of injury to health or the environment.

(i) An unreasonable risk determination under the Act is an administrative judgment that requires balancing of the harm to health or the environment that a chemical substance may cause and the magnitude and severity of that harm, against the social and economic effects on society of EPA action to reduce that harm.

(ii) A determination of unreasonable risk under section 5(h)(4) of the Act will examine the reasonably ascertainable economic and social consequences of granting or denying the exemption after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

(2) *Grant of the exemption.* The exemption will be granted if the Assistant Administrator determines, after consideration of all relevant evidence presented in the rulemaking proceeding described in paragraph (b)(1) of this section, that the new microorganism will not present an unreasonable risk of injury to health or the environment.

(3) *Denial of the exemption.* The exemption will be denied if the Assistant Administrator determines, after consideration of all relevant evidence presented in the rulemaking proceeding described in paragraph (b)(1) of this section, that the determination described in paragraph (c)(2) of this section cannot be made. A final decision terminating the rulemaking proceeding will be published in the FEDERAL REGISTER.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010; 77 FR 46292, Aug. 3, 2012]

§ 725.70 Compliance.

(a) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(b) A person who manufactures or imports a microorganism before a MCAN is submitted and the MCAN review period expires is in violation of section 15 of the Act even if that person was not required to submit the MCAN under § 725.105.

(c) Using a microorganism which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of the Act or this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(e) Failure or refusal to permit entry or inspection as required by section 11 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(f) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this part may be subject to penalties calculated as if they never filed their submissions.

(g) EPA may seek to enjoin the manufacture or processing of a microorganism in violation of this part or act to seize any microorganism manufactured or processed in violation of this part or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

§ 725.75 Inspections.

EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 of the Act and this part, to verify that information required by EPA under this part is true and correct, and to audit data submitted to EPA under this part.

Subpart C—Confidentiality and Public Access to Information

§ 725.80 General provisions for confidentiality claims.

(a) A person may assert a claim of confidentiality for any information submitted to EPA under this part. However,

(1) Any person who asserts a claim of confidentiality for portions of the specific microorganism identity must provide the information as described in § 725.85.

(2) Any person who asserts a claim of confidentiality for a use of a microorganism must provide the information as described in § 725.88.

(3) Any person who asserts a claim of confidentiality for information contained in a health and safety study of a

microorganism must provide the information described in § 725.92.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1) When a person submits any information under this part, including any attachments, for which claims of confidentiality are made, the claim(s) must be asserted by circling the specific information which is claimed and marking the page on which that information appears with an appropriate designation such as ''trade secret,'' ''TSCA CBI,'' or ''confidential business information.''

(2) If any information is claimed confidential, the person must submit two copies of the document including the claimed information.

(i) One copy of the document must be complete. In that copy, the submitter must mark the information which is claimed as confidential in the manner prescribed in paragraph (b)(1) of this section.

(ii) The second copy must be complete except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(iii) If the submitter does not provide the second copy, the submission is incomplete and the review period does not begin to run until EPA receives the second copy, in accordance with § 725.33.

(iv) Any information contained within the copy submitted under paragraph (b)(2)(ii) of this section which has been in the public file for more than 30 days will be presumed to be in the public domain, notwithstanding any assertion of confidentiality made under this section.

(3) A person who submits information to EPA under this part must reassert a claim of confidentiality and substantiate the claim each time the information is submitted to EPA.

(c) Any person asserting a claim of confidentiality under this part must substantiate each claim in accordance with the requirements in § 725.94.

(d) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent permitted by the Act, this subpart, and part 2 of this title.

(e) If a submitter does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public and place it in the public file without further notice to the submitter.

§ 725.85 Microorganism identity.

(a) *Claims applicable to the period prior to commencement of manufacture or import for general commercial use*—(1) *When to make a claim.* (i) A person who submits information to EPA under this part may assert a claim of confidentiality for portions of the specific microorganism identity at the time of submission of the information. This claim will apply only to the period prior to the commencement of manufacture or import for general commercial use.

(ii) A person who submits information to EPA under this part must reassert a claim of confidentiality and substantiate the claim each time the information is submitted to EPA. For example, if a person claims certain information confidential in a TERA submission and wishes the same information to remain confidential in a subsequent TERA or MCAN submission, the person must reassert and resubstantiate the claim in the subsequent submission.

(2) *Assertion of claim.* (i) A submitter may assert a claim of confidentiality only if the submitter believes that public disclosure prior to commencement of manufacture or import for general commercial use of the fact that anyone is initiating research and development activities pertaining to the specific microorganism or intends to manufacture or import the specific microorganism for general commercial use would reveal confidential business information. Claims must be substantiated in accordance with the requirements of § 725.94(a).

(ii) If the submission includes a health and safety study concerning the microorganism and if the claim for confidentiality with respect to the specific identity is denied in accordance with § 725.92(c), EPA will deny a claim asserted under paragraph (a) of this section.

(3) *Development of generic name.* Any person who asserts a claim of confidentiality for portions of the specific microorganism identity under this paragraph must provide one of the following items at the time the submission is filed:

(i) The generic name which was accepted by EPA in the prenotice consultation conducted under paragraph (a)(4) of this section.

(ii) One generic name that is only as generic as necessary to protect the confidential identity of the particular microorganism. The name should reveal the specific identity to the maximum extent possible. The generic name will be subject to EPA review and approval.

(4) *Determination by EPA.* (i) Any person who intends to assert a claim of confidentiality for the specific identity of a new microorganism may seek a determination by EPA of an appropriate generic name for the microorganism before filing a submission. For this purpose, the person should submit to EPA:

(A) The specific identity of the microorganism.

(B) A proposed generic name(s) which is only as generic as necessary to protect the confidential identity of the new microorganism. The name(s) should reveal the specific identity of the microorganism to the maximum extent possible.

(ii) Within 30 days, EPA will inform the submitter either that one of the proposed generic names is adequate or that none is adequate and further consultation is necessary.

(5) *Use of generic name.* If a submitter claims microorganism identity as confidential under paragraph (a) of this section, and if the submitter complies with paragraph (a)(2) of this section, EPA will issue for publication in the FEDERAL REGISTER notice described in § 725.40 the generic name proposed by the submitter or one agreed upon by EPA and the submitter.

(b) *Claims applicable to the period after commencement of manufacture or import for general commercial use*—(1) *Maintaining claim.* Any claim of confidentiality under paragraph (a) of this section is applicable only until the microorganism is manufactured or imported for general commercial use and becomes eligible for inclusion on the Inventory. To maintain the confidential status of the microorganism identity when the microorganism is added to the Inventory, a submitter must reassert the confidentiality claim and substantiate the claim in the notice of commencement of manufacture required under § 725.190.

(i) A submitter may not claim the microorganism identity confidential for the period after commencement of manufacture or import for general commercial use unless the submitter claimed the microorganism identity confidential under paragraph (a) of this section in the MCAN submitted for the microorganism.

(ii) A submitter may claim the microorganism identity confidential for the period after commencement of manufacture or import for general commercial use if the submitter did not claim the microorganism identity confidential under paragraph (a) of this section in any TERA submitted for the microorganism, but subsequently did claim microorganism identity confidential in the MCAN submitted for the microorganism.

(2) *Assertion of claim.* (i) A person who believes that public disclosure of the fact that anyone manufactures or imports the microorganism for general commercial use would reveal confidential business information may assert a claim of confidentiality under paragraph (b) of this section.

(ii) If the notice includes a health and safety study concerning the new microorganism, and if the claim for confidentiality with respect to the microorganism identity is denied in accordance with § 725.92(c), EPA will deny a claim asserted under paragraph (b) of this section.

(3) *Requirements for assertion.* Any person who asserts a confidentiality claim for microorganism identity must:

(i) Comply with the requirements of paragraph (a)(3) of this section regarding submission of a generic name.

(ii) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the microorganism

the fact that the particular microorganism is included on the confidential Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available and agree to furnish to EPA upon request the taxonomic designations and supplemental information required by § 725.12.

(iv) Provide a detailed written substantiation of the claim, in accordance with the requirements of § 725.94(b).

(4) *Denial of claim.* If the submitter does not meet the requirements of paragraph (b) of this section, EPA will deny the claim of confidentiality.

(5) *Acceptance of claim.* (i) EPA will publish a generic name on the public Inventory if:

(A) The submitter asserts a claim of confidentiality in accordance with this paragraph.

(B) No claim for confidentiality of the microorganism identity as part of a health and safety study has been denied in accordance with part 2 of this title or § 725.92.

(ii) Publication of a generic name on the public Inventory does not create a category for purposes of the Inventory. Any person who has a *bona fide* intent to manufacture or import a microorganism which is described by a generic name on the public Inventory may submit an inquiry to EPA under § 725.15(b) to determine whether the particular microorganism is included on the confidential Inventory.

(iii) Upon receipt of a request described in § 725.15(b), EPA may require the submitter who originally asserted confidentiality for a microorganism to submit to EPA the information listed in paragraph (b)(3)(iii) of this section.

(iv) Failure to submit any of the information required under paragraph (b)(3)(iii) of this section within 10 calendar days of receipt of a request by EPA under paragraph (b) of this section will constitute a waiver of the original submitter's confidentiality claim. In this event, EPA may place the specific microorganism identity on the public Inventory without further notice to the original submitter.

(6) *Use of generic name on the public Inventory.* If a submitter asserts a claim of confidentiality under paragraph (b) of this section, EPA will examine the generic microorganism name proposed by the submitter.

(i) If EPA determines that the generic name proposed by the submitter is only as generic as necessary to protect the confidential identity of the particular microorganism, EPA will place that generic name on the public Inventory.

(ii) If EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, EPA will propose in writing, for review by the submitter, an alternative generic name that will reveal the identity of the microorganism to the maximum extent possible.

(iii) If the generic name proposed by EPA is acceptable to the submitter, EPA will place that generic name on the public Inventory.

(iv) If the generic name proposed by EPA is not acceptable to the submitter, the submitter must explain in detail why disclosure of that generic name would reveal confidential business information and propose another generic name which is only as generic as necessary to protect the confidential identity of the microorganism. If EPA does not receive a response from the submitter within 30 days after the submitter receives the proposed name, EPA will place EPA's chosen generic name on the public Inventory. If the submitter does provide the information requested, EPA will review the response. If the submitter's proposed generic name is acceptable, EPA will publish that generic name on the public Inventory. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of EPA's choice of a generic name. Thirty days after this notification, EPA will place the chosen generic name on the public Inventory.

§ 725.88 Uses of a microorganism.

(a) *Assertion of claim.* A person who submits information to EPA under this part on the categories or proposed categories of use of a microorganism may assert a claim of confidentiality for this information.

(b) *Requirements for claim.* A submitter that asserts such a claim must:

(1) Report the categories or proposed categories of use of the microorganism.

(2) Provide, in nonconfidential form, a description of the uses that is only as generic as necessary to protect the confidential business information. The generic use description will be included in the FEDERAL REGISTER notice described in § 725.40.

(c) *Generic use description.* The person must submit the information required by paragraph (b) of this section by describing the uses as precisely as possible, without revealing the information which is claimed confidential, to disclose as much as possible how the use may result in human exposure to the microorganism or its release to the environment.

§ 725.92 Data from health and safety studies of microorganisms.

(a) *Information other than specific microorganism identity.* Except as provided in paragraph (b) of this section, EPA will deny any claim of confidentiality with respect to information included in a health and safety study of a microorganism, unless the information would disclose confidential business information concerning:

(1) Processes used in the manufacture or processing of a microorganism.

(2) Information which is not in any way related to the effects of a microorganism on health or the environment, such as, the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of confidentiality in accordance with § 725.80.

(b) *Microorganism identity*—(1) *Claims applicable to the period prior to commencement of manufacture or import for general commercial use.* A claim of confidentiality for the period prior to commencement of manufacture or import for general commercial use for the specific identity of a microorganism for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under § 725.85(a). The submitter must substantiate each claim in accordance with the requirements of § 725.94(a).

(2) *Claims applicable to the period after commencement of manufacture or import for general commercial use.* To maintain the confidential status of the specific identity of a microorganism for which a health and safety study was submitted after commencement of manufacture or import for general commercial use, the claim must be reasserted and substantiated in conjunction with a claim under § 725.85(b). The submitter must substantiate each claim in accordance with the requirements of § 725.94(b).

(c) *Denial of confidentiality claim.* EPA will deny a claim of confidentiality for microorganism identity under paragraph (b) of this section, unless:

(1) The information would disclose processes used in the manufacture or processing of a microorganism.

(2) The microorganism identity is not necessary to interpret a health and safety study.

(d) *Use of generic names.* When EPA discloses a health and safety study containing a microorganism identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the microorganism by the generic name selected under § 725.85.

§ 725.94 Substantiation requirements.

(a) *Claims applicable to the period prior to commencement of manufacture or import for general commercial use*—(1) *MCAN, TME, Tier I certification, and Tier II exemption request requirements.* Any person who submits a MCAN, TME, Tier I certification, or Tier II exemption request should strictly limit confidentiality claims to that information which is confidential and proprietary to the business.

(i) If any information in the submission is claimed as confidential business information, the submitter must substantiate each claim by submitting written answers to the questions in paragraphs (c), (d), and (e) of this section at the time the person submits the information.

(ii) If the submitter does not provide written substantiation as required in paragraph (a)(1)(i) of this section, the submission will be considered incomplete and the review period will not begin in accordance with § 725.33.

(2) *TERA requirements.* Any person who submits a TERA, should strictly limit confidentiality claims to that information which is confidential and proprietary to the business. If any information in such a submission is claimed as confidential business information, the submitter must have available for each of those claims, and agree to furnish to EPA upon request, written answers to the questions in paragraphs (d) and (e) of this section.

(b) *Claims applicable to the period after commencement of manufacture or import for general commercial use.* (1) If a submitter claimed portions of the microorganism identity confidential in the MCAN and wants the identity to be listed on the confidential Inventory, the claim must be reasserted and substantiated at the time the Notice of Commencement (NOC) is submitted under §725.190. Otherwise, EPA will list the specific microorganism identity on the public Inventory.

(2) The submitter must substantiate the claim for confidentiality of the microorganism identity by answering all of the questions in paragraphs (c), (d), and (e) in this section. In addition, the following questions must be answered:

(i) What harmful effects to the company's or institution's competitive position, if any, would result if EPA publishes on the Inventory the identity of the microorganism? How could a competitor use such information given the fact that the identity of the microorganism otherwise would appear on the TSCA Inventory with no link between the microorganism and the company or institution? How substantial would the harmful effects of disclosure be? What is the causal relationship between the disclosure and the harmful effects?

(ii) Has the identity of the microorganism been kept confidential to the extent that competitors do not know it is being manufactured or imported for general commercial use by anyone?

(c) *General questions.* The following questions must be answered in detail for each confidentiality claim:

(1) For what period of time is a claim of confidentiality being asserted? If the claim is to extend until a certain event or point in time, indicate that event or time period. Explain why the information should remain confidential until such point.

(2) Briefly describe any physical or procedural restrictions within the company or institution relating to the use and storage of the information claimed as confidential. What other steps, if any, apply to use or further disclosure of the information?

(3) Has the information claimed as confidential been disclosed to individuals outside of the company or institution? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

(4) Does the information claimed as confidential appear, or is it referred to, in any of the following questions? If the answer is yes to any of these questions, indicate where the information appears and explain why it should nonetheless be treated as confidential.

(i) Advertising or promotional materials for the microorganism or the resulting end product?

(ii) Material safety data sheets or other similar materials for the microorganism or the resulting end product?

(iii) Professional or trade publications?

(iv) Any other media available to the public or to competitors?

(v) Patents?

(vi) Local, State, or Federal agency public files?

(5) Has EPA, another Federal agency, a Federal court, or a State made any confidentiality determination regarding the information claimed as confidential? If so, provide copies of such determinations.

(6) For each type of information claimed confidential, describe the harm to the company's or institution's competitive position that would result if this information were disclosed. Why would this harm be substantial? How could a competitor use such information? What is the causal connection between the disclosure and harm?

(7) If EPA disclosed to the public the information claimed as confidential, how difficult would it be for the competitor to enter the market for the resulting product? Consider such constraints as capital and marketing cost, specialized technical expertise, or unusual processes.

(d) *Microorganism identity and production method.* If confidentiality claims are asserted for the identity of the microorganism or information on how the microorganism is produced, the following questions must be answered:

(1) Has the microorganism or method of production been patented in the U.S. or elsewhere? If so, why is confidentiality necessary?

(2) Does the microorganism leave the site of production or testing in a form which is accessible to the public or to competitors? What is the cost to a competitor, in time and money, to develop appropriate use conditions? What factors facilitate or impede product analysis?

(3) For each additional type of information claimed as confidential, explain what harm would result from disclosure of each type of information if the identity of the microorganism were to remain confidential.

(e) *Health and safety studies of microorganisms.* If confidentiality claims are asserted for information in a health or safety study of a microorganism, the following questions must be answered:

(1) Would the disclosure of the information claimed confidential reveal: confidential process information, or information unrelated to the effects of the microorganism on health and the environment. Describe the causal connection between the disclosure and harm.

(2) Does the company or institution assert that disclosure of the microorganism identity is not necessary to interpret any health and safety studies which have been submitted? If so, explain how a less specific identity would be sufficient to interpret the studies.

§ 725.95 Public file.

All information submitted, including any health and safety study of a microorganism and other supporting documentation, will become part of the public file for that submission, unless such materials are claimed confidential. In addition, EPA may add materials to the public file, unless such materials are claimed confidential. Publically available docket materials are available at the addresses in § 700.17(b)(1) and (2) of this chapter

[62 FR 17932, Apr. 11, 1997, 77 FR 46292, Aug. 3, 2012]

Subpart D—Microbial Commercial Activities Notification Requirements

§ 725.100 Scope and purpose.

(a) This subpart establishes procedures for submission of a notice to EPA under section 5(a) of the Act for persons who manufacture, import, or process microorganisms for commercial purposes. This notice is called a Microbial Commercial Activity Notice (MCAN). It is expected that MCANs will in general only be submitted for microorganisms intended for general commercial use. Persons who manufacture, import, or process a microorganism in small quantities solely for research and development as defined in § 725.3 are not required to submit a notice to EPA. Persons who manufacture, import, or process a microorganism for research and development activities that do not fit the definition of small quantities solely for research and development may nonetheless qualify for more limited reporting requirements in subpart E, including the TERA which can be used for review of research and development involving environmental release.

(b) Persons subject to MCAN submission are described in § 725.105.

(c) Exclusions and exemptions specific to MCAN submissions are described in § 725.110.

(d) Submission requirements applicable specifically to MCANs are described at § 725.150.

(e) Data requirements for MCANs are set forth in §§ 725.155 and 725.160.

(f) EPA review procedures specific to MCANs are set forth in § 725.170.

(g) Subparts A through C of this part apply to any MCAN submitted under this subpart.

§ 725.105 Persons who must report.

(a) *Manufacturers of new microorganisms.* (1) MCAN submission is required for any person who intends to manufacture for commercial purposes in the

United States a new microorganism. Exclusions are described in § 725.110.

(2) If a person contracts with a manufacturer to produce or process a new microorganism and the manufacturer produces or processes the microorganism exclusively for that person, and that person specifies the identity of the microorganism, and controls the total amount produced and the basic technology for the plant process, then that person must submit the MCAN. If it is unclear who must report, EPA should be contacted to determine who must submit the MCAN.

(3) Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a MCAN.

(b) *Importers of new microorganisms.* (1) MCAN submission is required for a person who intends to import into the United States for commercial purposes a new microorganism. Exclusions are described in § 725.110.

(2) When several persons are involved in an import transaction, the MCAN must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the MCAN for that transaction.

(3) Except as otherwise provided in paragraph (b)(4) of this section, the provisions of this subpart D apply to each person who submits a MCAN for a new microorganism which such person intends to import for a commercial purpose. In addition, each importer must comply with paragraph (b)(4) of this section.

(4) EPA will hold the principal importer, or the importer that EPA determines must submit the MCAN when there is no principal importer under paragraph (b)(2) of this section, liable for complying with this part, for completing the MCAN, and for the completeness and truthfulness of all information which it submits.

(c) *Manufacturers, importers, or processors of microorganisms for a significant new use.* MCAN submission is required for any person who intends to manufacture, import, or process for commercial purposes a microorganism identified as having one or more significant new uses in subpart M of this part, and who intends either to engage in a designated significant new use of the microorganism or intends to distribute it in commerce. Persons excluded from reporting on significant new uses of microorganisms and additional procedures for reporting are described in subpart L of this part.

§ 725.110 Persons not subject to this subpart.

Persons are not subject to the requirements of this subpart for the following activities:

(a) Manufacturing, importing, or processing solely for research and development microorganisms that meet the requirements for an exemption under subpart E of this part.

(b) Manufacturing, importing, or processing microorganisms for test marketing activities which have been granted an exemption under subpart F of this part.

(c) Manufacturing or importing new microorganisms under the conditions of a Tier I or Tier II exemption under subpart G of this part.

§ 725.150 Procedural requirements for this subpart.

General requirements for all MCANs under this part are contained in subparts A through C of this part. In addition, the following requirements apply to MCANs submitted under this subpart:

(a) *When to submit a MCAN.* A MCAN must be submitted at least 90 calendar days prior to manufacturing or importing a new microorganism and at least 90 calendar days prior to manufacturing, importing, or processing a microorganism for a significant new use.

(b) *Section 5(b) of the Act.* The submitter must comply with any applicable requirement of section 5(b) of the Act for the submission of test data.

(c) *Contents of a MCAN.* Each person who submits a MCAN under this subpart must provide the information and test data described in §§ 725.155 and 725.160.

(d) *Recordkeeping.* Each person who submits a MCAN under this subpart must comply with the recordkeeping requirements of § 725.65.

§ 725.155 Information to be included in the MCAN.

(a) Each person who is required by this part to submit a MCAN must include the information specified in paragraphs (c) through (h) of this section, to the extent it is known to or reasonably ascertainable by that person. However, no person is required to include information which relates solely to exposure of humans or ecological populations outside of the United States.

(b) Each person should also submit, in writing, all other information known to or reasonably ascertainable by that person that would permit EPA to make a reasoned evaluation of the health and environmental effects of the microorganism, or any microbial mixture or article, including information on its effects on humans, animals, plants, and other microorganisms, and in the environment. The information to be submitted under this subpart includes the information listed in paragraphs (c) through (h) of this section relating to the manufacture, processing, distribution in commerce, use, and disposal of the new microorganism.

(c) *Submitter identification.* (1) The name and headquarters address of the submitter.

(2) The name, address, and office telephone number (including area code) of the principal technical contact representing the submitter.

(d) *Microorganism identity information.* Persons must submit sufficient information to allow the microorganism to be accurately and unambiguously identified for listing purposes as required by § 725.12.

(1) *Description of the recipient microorganism and the new microorganism.* (i) Data substantiating the taxonomy of the recipient microorganism and the new microorganism to the level of strain, as appropriate. In lieu of data, EPA will accept a letter from a culture collection substantiating taxonomy, provided EPA, upon request to the submitter, may have access to the data supporting the taxonomic designation.

(ii) Information on the morphological and physiological features of the new microorganism.

(iii) Other specific data by which the new microorganism may be uniquely identified for Inventory purposes.

(2) *Genetic construction of the new microorganism.* (i) Data substantiating the taxonomy of the donor organism(s). In lieu of data, EPA will accept a letter from a culture collection substantiating taxonomy, provided EPA, upon request to the submitter, may have access to the data supporting the taxonomic designation.

(ii) Description of the traits for which the new microorganism has been selected or developed and other traits known to have been added or modified.

(iii) A detailed description of the genetic construction of the new microorganism, including the technique used to modify the microorganism (e.g., fusion of cells, injection of DNA, electroporation or chemical poration, or methods used for induced mutation and selection). The description should include, for example, a description of the introduced genetic material, including any regulatory sequences and structural genes and the products of those genes; how the introduced genetic material is expected to affect behavior of the recipient; expression, alteration, and stability of the introduced genetic material; methods for vector construction and introduction; and a description of the regulatory and structural genes that are components of the introduced genetic material, including genetic maps of the introduced sequences.

(3) *Phenotypic and ecological characteristics.* (i) Habitat, geographical distribution, and source of the recipient microorganism.

(ii) Survival and dissemination under relevant environmental conditions including a description of methods for detecting the new or recipient microorganism(s) in the environment and the sensitivity limit of detection for these techniques.

(iii) A description of anticipated biological interactions with and effects on target organisms and other organisms such as competitors, prey, hosts, symbionts, parasites, and pathogens; a description of host range; a description of pathogenicity, infectivity, toxicity, virulence, or action as a vector of pathogens; and capacity for genetic

transfer under laboratory and relevant environmental conditions.

(iv) A description of anticipated involvement in biogeochemical or biological cycling processes, involvement in rate limiting steps in mineral or nutrient cycling, or involvement in inorganic compounds cycling (such as possible sequestration or transformation of heavy metals).

(e) *Byproducts.* A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new microorganism.

(f) *Total production volume.* The estimated maximum amount of the new microorganism intended to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any consecutive 12–month period during the first 3 years of production. This estimate may be by weight or volume and should include an estimation of viability (i.e., viable cells per unit volume or colony forming units per unit dry weight).

(g) *Use information.* A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new microorganism in the formulation for each commercial or consumer use.

(h) *Worker exposure and environmental release.* (1) For sites controlled by the submitter:

(i) The identity of sites where the new microorganism will be manufactured, processed, or used. For purposes of this section, the site for a person who imports a new microorganism is the site of the operating unit within the person's organization which is directly responsible for importing the new microorganism and which controls the import transaction. The import site may in some cases be the organization's headquarters office in the United States.

(ii) A process description of each manufacture, processing, and use operation, which includes a diagram of the major unit operations and conversions, the identity and entry point of all feedstocks, and the identity of any possible points of release of the new microorganism from the process, including a description of all controls, including engineering controls, used to prevent such releases.

(iii) Worker exposure information, including worker activities, physical form of process streams which contain the new microorganism to which workers may be exposed, the number of workers, and the duration of activities.

(iv) Information on release of the new microorganism to the environment, including the quantity and media of release and type of control technology used.

(v) A narrative description of the intended transport of the new microorganism, including the means of transport, containment methods to be used during transport, and emergency containment procedures to be followed in case of accidental release.

(vi) Procedures for disposal of any articles, waste, clothing, or other equipment involved in the activity, including procedures for inactivation of the new microorganism, containment, disinfection, and disposal of contaminated items.

(2) For sites not controlled by the submitter, a description of each type of processing and use operation involving the new microorganism, including identification of the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new microorganism will occur, the number of workers exposed and the duration of exposure; procedures for transport of the new microorganism and for disposal, including procedures for inactivation of the new microorganism; and control measures which limit worker exposure and environmental release.

§ 725.160 Submission of health and environmental effects data.

(a) *Test data on the new microorganism in the possession or control of the submitter.* (1) Except as provided in § 725.25(h), and in addition to the information required by § 725.155(d)(3), each MCAN must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new microorganism or any microbial mixture or article containing the new

microorganism, or any combination of such activities. This includes test data concerning the new microorganism in a pure culture or formulated form as used or as intended to be used in one of the activities listed above.

(2) A full report or standard literature citation must be submitted for the following types of test data:

(i) Health effects data.

(ii) Ecological effects data.

(iii) Physical and chemical properties data.

(iv) Environmental fate characteristics.

(v) Monitoring data and other test data related to human exposure to or environmental release of the new microorganism.

(3)(i) If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4)(i) If a study, report, or test is incomplete when a person submits a MCAN, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected, significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the MCAN review period ends, the person must submit the study, report, or test, as specified in paragraph (a)(3)(i) of this section, to the address listed in § 725.25(c) within 10 days of receiving it, but no later than 5 days before the end of the review period. If the test or experiment is completed during the last 5 days of the review period, the submitter must immediately inform its EPA contact for that submission by telephone.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within 10 days of the request, but no later than 5 days before the end of the review period.

(6) All test data described under paragraph (a) of this section are subject to these requirements, regardless of their age, quality, or results.

(b) *Other data concerning the health and environmental effects of the new microorganism that are known to or reasonably ascertainable by the submitter.* (1) Except as provided in § 725.25(h), and in addition to the information required by § 725.155(c)(3), any person who submits a MCAN must describe the following data, including any data from a health and safety study of a microorganism, if the data are related to effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the microorganism, of any microbial mixture or article containing the new microorganism, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the microorganism.

(2) Data that must be described include data concerning the new microorganism in a pure culture or formulated form as used or as intended to be used in one of the activities listed in paragraph (b)(1) of this section.

(3) The description of data reported under paragraph (b) of this section must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not available in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described in paragraph (b) of this section are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the MCAN is submitted.

§ 725.170 EPA review of the MCAN.

General procedures for review of all submissions under this part are contained in §§ 725.28 through 725.60. In addition, the following procedures apply to EPA review of MCANs submitted under this subpart:

(a) Length of the review period. The MCAN review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete MCAN, or the date EPA determines the MCAN is complete under § 725.33, unless the Agency extends the period under section 5(c) of the Act and § 725.56.

(b) Notice of expiration of MCAN review period. (1) EPA will notify the submitter that the MCAN review period has expired or that EPA has completed its review of the MCAN. Expiration of the review period does not constitute EPA approval or certification of the new microorganism, and does not mean that EPA may not take regulatory action against the microorganism in the future.

(2) After expiration of the MCAN review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the microorganism even if the submitter has not received notice of expiration.

(3) Early notification that EPA has completed its review does not permit commencement of manufacture or import prior to the expiration of the 90–day MCAN review period.

(c) No person submitting a MCAN in response to the requirements of this subpart may manufacture, import, or process a microorganism subject to this subpart until the review period, including all extensions and suspensions, has expired.

§ 725.190 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences the manufacture or import of a new microorganism for nonexempt, commercial purposes for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement (NOC) of manufacture or import.

(b) *When to report.* (1) If manufacture or import for nonexempt, commercial purposes begins on or after May 27, 1997, the submitter must submit the NOC to EPA no later than 30 calendar days after the first day of such manufacture or import.

(2) If manufacture or import for nonexempt, commercial purposes began or will begin before May 27, 1997, the submitter must submit the NOC by May 27, 1997.

(3) Submission of an NOC prior to the commencement of manufacture or import is a violation of section 15 of the Act.

(c) *Information to be reported.* The NOC must contain the following information: Specific microorganism identity, MCAN number, and the date when manufacture or import commences. If the person claimed microorganism identity confidential in the MCAN, and wants the identity to be listed on the confidential Inventory, the claim must be reasserted and resubstantiated in accordance with § 725.85(b). Otherwise, EPA will list the specific microorganism identity on the public Inventory.

(d) *How to submit.* All notices of commencement must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013]

Subpart E—Exemptions for Research and Development Activities

§ 725.200 Scope and purpose.

(a) This subpart describes exemptions from the reporting requirements under

subpart D of this part for research and development activities involving microorganisms.

(b) In lieu of complying with subpart D of this part, persons described in § 725.205 may submit a TSCA Experimental Release Application (TERA) for research and development activities involving microorganisms or otherwise comply with this subpart.

(c) Exemptions from part 725 are provided at §§ 725.232, 725.234, and 725.238.

(d) Submission requirements specific for TERAs are described at § 725.250.

(e) Data requirements for TERAs are set forth in §§ 725.255 and 725.260.

(f) EPA review procedures specific for TERAs are set forth in §§ 725.270 and 725.288.

(g) Subparts A through C of this part apply to any submission under this subpart.

§ 725.205 Persons who may report under this subpart.

(a) Commercial research and development activities involving new microorganisms or significant new uses of microorganisms are subject to reporting under this part unless they qualify for an exemption under this part.

(b) Commercial purposes for research and development means that the activities are conducted with the purpose of obtaining an immediate or eventual commercial advantage for the researcher and would include:

(1) All research and development activities which are funded directly, in whole or in part, by a commercial entity regardless of who is actually conducting the research. Indications that the research and development activities are funded directly, in whole or in part, may include, but are not limited to:

(i) Situations in which a commercial entity contracts directly with a university or researcher; or

(ii) Situations in which a commercial entity gives a conditional grant where the commercial entity holds patent rights, or establishes a joint venture where the commercial entity holds patent or licensing rights; or

(iii) Any other situation in which the commercial entity intends to obtain an immediate or eventual commercial advantage for the commercial entity and/or the researcher.

(2) Research and development activities that are not funded directly by a commercial entity, if the researcher intends to obtain an immediate or eventual commercial advantage. Indications that the researcher intends to obtain an immediate or eventual commercial advantage may include, but are not limited to:

(i) The research is directed toward developing a commercially viable improvement of a product already on the market; or

(ii) The researcher has sought or is seeking commercial funding for the purpose of developing a commercial application; or

(iii) The researcher or university has sought or is seeking a patent to protect a commercial application which the research is developing; or

(iv) Other evidence that the researcher is aware of a commercial application for the research and has directed the research toward developing that application.

(c) Certain research and development activities involving microorganisms subject to jurisdiction under the Act are exempt from reporting under this part. A person conducting research and development activities which meet the conditions for the exemptions described in §§ 725.232, 725.234, or 725.238 is exempt from TERA reporting under this subpart.

(d) A microorganism is not exempt from reporting under subpart D of this part if any amount of the microorganism, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development.

(e) Quantities of the inactivated microorganism, or mixtures or articles containing the inactivated microorganism, remaining after completion of research and development activities may be disposed of as a waste in accordance with applicable Federal, State, and local regulations.

(f) A person who manufactures, imports, or processes a microorganism solely for research and development is not required to comply with the requirements of this section if:

(1) The person is manufacturing a microbial pesticide identified in §172.45(c), or

(2) The person is manufacturing a microbial pesticide for which an Experimental Use Permit is required, pursuant to §172.3; or

(3) The person is manufacturing a microbial pesticide for which a notification or an Experimental Use Permit is not required to be submitted.

§ 725.232 Activities subject to the jurisdiction of other Federal programs or agencies.

This part does not apply to any research and development activity that meets all of the following conditions.

(a) The microorganism is manufactured, imported, or processed solely for research and development activities.

(b) There is no intentional testing of a microorganism outside of a structure, as structure is defined in §725.3.

(c)(1) The person receives research funds from another Federal agency, and the funds are awarded on the condition that the research will be conducted in accordance with the relevant portions of the NIH Guidelines, or

(2) A Federal agency or program otherwise imposes the legally binding requirement that the research is to be conducted in accordance with relevant portions of the NIH Guidelines.

§ 725.234 Activities conducted inside a structure.

A person who manufactures, imports, or processes a microorganism is not subject to the reporting requirements under subpart D of this part if all of the following conditions are met:

(a) The microorganism is manufactured, imported, or processed solely for research and development activities.

(b) The microorganism is used by, or directly under the supervision of, a technically qualified individual, as defined in §725.3. The technically qualified individual must maintain documentation of the procedures selected to comply with paragraph (d) of this section and must ensure that the procedures are used.

(c) There is no intentional testing of a microorganism outside of a structure, as structure is defined in §725.3.

(d) Containment and/or inactivation controls. (1) Selection and use of containment and/or inactivation controls inside a structure for a particular microorganism shall take into account the following:

(i) Factors relevant to the organism's ability to survive in the environment.

(ii) Potential routes of release in air, solids and liquids; in or on waste materials and equipment; in or on people, including maintenance and custodial personnel; and in or on other organisms, such as insects and rodents.

(iii) Procedures for transfer of materials between facilities.

(2) The technically qualified individual's selection of containment and/or inactivation controls shall be approved and certified by an authorized official (other than the TQI) of the institution that is conducting the test prior to the commencement of the test.

(3) Records shall be developed and maintained describing the selection and use of containment and/or inactivation controls, as specified in §725.235(c). These records, which must be maintained at the location where the research and development activity is being conducted, shall be submitted to EPA upon written request and within the time frame specified in EPA's request.

(4) Subsequent to EPA review of records in accordance with paragraph (d)(3) of this section, changes to the containment/inactivation controls selected under paragraph (d)(1) of this section must be made upon EPA order. Failure to comply with EPA's order shall result in automatic loss of eligibility for an exemption under this section.

(e) The manufacturer, importer, or processor notifies all persons in its employ or to whom it directly distributes the microorganism, who are engaged in experimentation, research, or analysis on the microorganism, including the manufacture, processing, use, transport, storage, and disposal of the microorganism associated with research and development activities, of any risk to health, identified under §725.235(a), which may be associated with the microorganism. The notification must be made in accordance with §725.235(b).

§ 725.235 Conditions of exemption for activities conducted inside a structure.

(a) *Determination of risks.* To determine whether notification under § 725.234(e) is required, the manufacturer, importer, or processor must do one of the following:

(1) For research conducted in accordance with the NIH Guidelines, the manufacturer, importer, or processor must meet the conditions laid out at IV-B-4-d of the NIH Guidelines; or

(2) For all other research conducted in accordance with § 725.234, the manufacturer, importer, or processor must review and evaluate the following information to determine whether there is reason to believe there is any risk to health which may be associated with the microorganism:

(i) Information in its possession or control concerning any significant adverse reaction of persons exposed to the microorganism which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer, importer, or processor by a supplier or any other person concerning a health risk believed to be associated with the microorganism.

(iii) Health and environmental effects data in its possession or control concerning the microorganism.

(iv) Information on health effects which accompanies any EPA rule or order issued under TSCA section 4, 5, or 6 of the Act that applies to the microorganism and of which the manufacturer, importer, or processor has knowledge.

(b) *Notification to employees and others.* (1) The manufacturer, importer, or processor must notify the persons identified in § 725.234(e) by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer, importer, or processor has reason to believe may be associated with the microorganism, as determined under paragraph (a) of this section.

(2) If the manufacturer, importer, or processor distributes a microorganism manufactured, imported, or processed under this section to persons not in its employ, the manufacturer, importer, or processor must in written form:

(i) Notify those persons that the microorganism is to be used only for research and development purposes and the requirements of § 725.234 are to be met.

(ii) Provide the notice of health risks specified in paragraph (b)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer, importer, or processor.

(c) *Recordkeeping.* (1) For research conducted in accordance with the NIH Guidelines, a person who manufactures, imports, or processes a microorganism under this section must retain the following records:

(i) Documentation that the NIH Guidelines have been adhered to. Such documentation shall include:

(A) For experiments subject to Institutional Biosafety Committee review, or notification simultaneous with initiation of the experiment, the information submitted for review or notification, along with standard laboratory records, shall satisfy the recordkeeping requirements specified in § 725.234(d)(3).

(B) For experiments exempt from Institutional Biosafety Committee review or notification simultaneous with initiation of the experiment, documentation of the exemption, along with standard laboratory records, shall satisfy the recordkeeping requirement specified in § 725.234(d)(3).

(ii) Documentation of how the following requirements are satisfied under the NIH Guidelines:

(A) Copies or citations to information reviewed and evaluated to determine the need to make any notification of risk.

(B) Documentation of the nature and method of notification of risk, including copies of any labels or written notices used.

(C) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the microorganism, the amount distributed, and copies of the notifications required.

(2) For all other research conducted in accordance with §725.234, a person who manufacturers, imports, or processes a microorganism under this section, must maintain the following records:

(i) Records describing selection and use of containment and/or inactivation controls required by §725.234(d)(3) and certification by an authorized official required by §725.234(d)(2) for each microorganism.

(ii) Copies or citations to information reviewed and evaluated under paragraph (a) of this section to determine the need to make any notification of risk.

(iii) Documentation of the nature and method of notification under paragraph (b)(1) of this section, including copies of any labels or written notices used.

(iv) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the microorganism, the amount distributed, and copies of the notifications required under paragraph (b)(2) of this section.

§ 725.238 Activities conducted outside a structure.

(a) *Exemption.* (1) Research and development activities involving intentional testing in the environment of certain microorganisms listed in §725.239 may be conducted without prior review by EPA if all of the conditions of this section and §725.239 are met.

(2) The research and development activity involving a microorganism listed in §725.239 must be conducted by, or directly under the supervision of, a technically qualified individual, as defined in §725.3.

(b) *Certification.* To be eligible for the exemption under this section, a manufacturer or importer must submit to EPA prior to initiation of the activity a document signed by an authorized official containing the following information:

(1) Name, address, and telephone number of the manufacturer or importer.

(2) Location, estimated duration, and planned start date of the test.

(3) Certification of the following:

(i) Compliance with the conditions of the exemption specified for the microorganism in §725.239.

(ii) If state and/or local authorities have been notified of the activity, evidence of notification.

(c) *Recordkeeping.* Persons who conduct research and development activities under this section must comply with the recordkeeping requirements of §725.65 and retain documentation that supports their compliance with the requirements of this section and the specific requirements for the microorganism listed in §725.239.

§ 725.239 Use of specific microorganisms in activities conducted outside a structure.

(a) *Bradyrhizobium japonicum.* To qualify for an exemption under this section, all of the following conditions must be met for a test involving *Bradyrhizobium japonicum:*

(1) *Characteristics of recipient microorganism.* The recipient microorganism is limited to strains of *Bradyrhizobium japonicum.*

(2) *Modification of traits.* (i) The introduced genetic material must meet the criteria for poorly mobilizable listed in §725.421(c).

(ii) The introduced genetic material must consist only of the following components:

(A) The structural gene(s) of interest, which have the following limitations:

(*1*) For structural genes encoding marker sequences, the gene is limited to the *aadH* gene, which confers resistance to the antibiotics streptomycin and spectinomycin.

(*2*) For traits other than antibiotic resistance, the structural gene must be limited to the genera *Bradyrhizobium* and *Rhizobium.*

(B) The regulatory sequences permitting the expression of solely the gene(s) of interest.

(C) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

(D) The vector nucleotide sequences needed for vector transfer.

(E) The vector nucleotide sequences needed for vector maintenance.

(3) *Limitations on exposure.* (i) The test site area must be no more than 10 terrestrial acres.

(ii) The technically qualified individual must select appropriate methods to limit the dissemination of modified *Bradyrhizobium japonicum.*

(b) *Rhizobium meliloti.* To qualify for an exemption under this section, all of the following conditions must be met for a test involving *Rhizobium meliloti:*

(1) *Characteristics of recipient microorganism.* The recipient microorganism is limited to strains of *Rhizobium meliloti.*

(2) *Modification of traits.* (i) The introduced genetic material must meet the criteria for poorly mobilizable listed in § 725.421(c) of this part.

(ii) The introduced genetic material must consist only of the following components:

(A) The structural gene(s) of interest, which have the following limitations:

(*1*) For structural genes encoding marker sequences, the gene is limited to the *aadH* gene, which confers resistance to the antibiotics streptomycin and spectinomycin.

(*2*) For traits other than antibiotic resistance, the structural gene must be limited to the genera *Bradyrhizobium* and *Rhizobium.*

(B) The regulatory sequences permitting the expression of solely the gene(s) of interest.

(C) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

(D) The vector nucleotide sequences needed for vector transfer.

(E) The vector nucleotide sequences needed for vector maintenance.

(3) *Limitations on exposure.* (i) The test site area must be no more than 10 terrestrial acres.

(ii) The technically qualified individual must select appropriate methods to limit the dissemination of modified *Rhizobium meliloti.*

§ 725.250 Procedural requirements for the TERA.

General requirements for all submissions under this part are contained in subparts A through C of this part. In addition, the following requirements apply to TERAs submitted under this subpart:

(a) *When to submit the TERA.* Each person who is eligible to submit a TERA under this subpart must submit the TERA at least 60 calendar days before the person intends to initiate the proposed research and development activity.

(b) *Contents of the TERA.* Each person who submits a TERA under this subpart must provide the information and test data described in §§ 725.255 and 725.260. In addition, the submitter must supply sufficient information to enable EPA to evaluate the effects of all activities for which approval is requested.

(c) A person may submit a TERA for one or more microorganisms and one or more research and development activities, including a research program.

(d) EPA will either approve the TERA, with or without conditions, or disapprove it under procedures established in this subpart.

(e) The manufacturer, importer, or processor who receives a TERA approval must comply with all terms of the approval, as well as conditions described in the TERA, and remains liable for compliance with all terms and conditions, regardless of who conducts the research and development activity. Any person conducting the research and development activity approved under the TERA must comply with all terms of the TERA approval, as well as the conditions described in the TERA.

(f) *Recordkeeping.* Persons submitting a TERA must comply with the recordkeeping requirements of § 725.65. In addition, the following requirements apply to TERAs:

(1) Each person submitting a TERA under this part must retain documentation of information contained in the TERA for a period of 3 years from the date that the results of the study are submitted to the Agency.

(2) Summaries of all data, conclusions, and reports resulting from the conduct of the research and development activity under the TERA must be submitted to the EPA address identified in § 725.25(c) within 1 year of the termination of the activity.

§ 725.255 Information to be included in the TERA.

(a) To review a TERA, EPA must have sufficient information to permit a reasoned evaluation of the health and environmental effects of the planned test in the environment. The person seeking EPA approval must submit all information known to or reasonably ascertainable by the submitter on the microorganism(s) and the research and development activity, including information not listed in paragraphs (c), (d), and (e) of this section that the person believes will be useful for EPA's risk assessment. The TERA must be in writing and must include at least the information described in the following paragraphs.

(b) When specific information is not submitted, an explanation of why such information is not available or not applicable must be included.

(c) Persons applying for a TERA, must include the submitter identification and microorganism identity information required for MCANs in § 725.155(c), (d)(1), and (d)(2).

(d) Persons applying for a TERA must submit phenotypic and ecological characteristics information required in § 725.155(d)(3) as it relates directly to the conditions of the proposed research and development activity.

(e) Persons applying for a TERA must also submit the following information about the proposed research and development activity:

(1) *A detailed description of the proposed research and development activity.* (i) The objectives and significance of the activity and a rationale for testing the microorganisms in the environment.

(ii) Number of microorganisms released (including viability per volume if applicable) and the method(s) of application or release.

(iii) Characteristics of the test site(s), including location, geographical, physical, chemical, and biological features, proximity to human habitation or activity, and description of site characteristics that would influence dispersal or confinement.

(iv) Target organisms (if the microorganism(s) to be tested has an intended target), including identification of each target organism and anticipated mechanism and result of interaction.

(v) Planned start date and duration of each activity.

(vi) If State and/or local authorities have been notified of the activity, evidence of notification.

(2) *Information on monitoring, confinement, mitigation, and emergency termination procedures.* (i) Confinement procedures for the activity, access and security measures, and procedures for routine termination of the activity.

(ii) Mitigation and emergency procedures.

(iii) Measures to detect and control potential adverse effects.

(iv) Name of principal investigator and chief of site personnel responsible for emergency procedures.

(v) Personal protective equipment, engineering controls, and procedures to be followed to minimize dispersion of the microorganism(s) by people, machinery, or equipment.

(vi) Procedures for disposal of any articles, waste, clothing, machinery, or other equipment involved in the experimental release, including methods for inactivation of the microorganism(s), containment, disinfection, and disposal of contaminated items.

§ 725.260 Submission of health and environmental effects data.

Each TERA must contain all available data concerning actual or potential effects on health or the environment of the new microorganism that are in the possession or control of the submitter and a description of other data known to or reasonably ascertainable by the submitter that will permit a reasoned evaluation of the planned test in the environment. The data must be reported in the manner described in § 725.160(a)(3) and (b)(3).

§ 725.270 EPA review of the TERA.

General procedures for review of all submissions under this part are contained in §§ 725.28 through 725.60. In addition, the following procedures apply to EPA review of applications submitted under this subpart:

(a) *Length of the review period.* (1) The review period for the TERA will be 60 days from the date the Document Control Officer for the Office of Pollution

Prevention and Toxics receives a complete TERA, or the date EPA determines the TERA is complete under § 725.33, unless EPA finds good cause for an extension under § 725.56.

(2) A submitter shall not proceed with the research and development activity described in the TERA unless and until EPA provides written approval of the TERA. A submitter may receive early approval if a review is completed in less than 60 days.

(b) *EPA decision regarding proposed TERA activity.* (1) A decision concerning a TERA under this subpart will be made by the Administrator, or a designee.

(2) If EPA determines that the proposed research and development activity for the microorganism does not present an unreasonable risk of injury to health or the environment, EPA will notify the submitter that the TERA is approved and that the submitter can proceed with the proposed research and development activity described in the TERA.

(3) EPA may include requirements and conditions in its approval of the TERA that would be stated in the TERA approval under paragraph (c) of this section.

(4) If EPA concludes that it cannot determine that the proposed research and development activity described in the TERA will not present an unreasonable risk of injury to health or the environment, EPA will deny the TERA and will provide reasons for the denial in writing.

(c) *TERA approval.* (1) A TERA approval issued by EPA under this section is legally binding on the TERA submitter.

(2) When EPA approves a TERA, the submitter must conduct the research and development activity only as described in the TERA and in accordance with any requirements and conditions prescribed by EPA in its approval of the TERA.

(3) Any person who fails to conduct the research and development activity as described in the TERA and in accordance with any requirements and conditions prescribed by EPA in its approval of the TERA under this section, shall be in violation of sections 5 and 15 of the Act and be subject to civil and criminal penalties under section 16 of the Act.

§ 725.288 Revocation or modification of TERA approval.

(a) *Significant questions about risk.* (1) If, after approval of a TERA under this subpart, EPA receives information which raises significant questions about EPA's determination that the activity does not present an unreasonable risk of injury to health or the environment, EPA will notify the submitter in writing of those questions.

(2) The submitter may, within 10 days of receipt of EPA's notice, provide in writing additional information or arguments concerning the significance of the questions and whether EPA should modify or revoke the approval of the TERA.

(3) After considering any such information and arguments, EPA will decide whether to change its determination regarding approval of the TERA.

(i) If EPA determines that the activity will not present an unreasonable risk of injury to health or the environment, it will notify the submitter in writing. To make this finding, EPA may prescribe additional conditions which must be followed by the submitter.

(ii) If EPA determines that it can no longer conclude that the activity will not present an unreasonable risk of injury to health or the environment, it will notify the submitter in writing that EPA is revoking its approval and state its reasons. In that event, the submitter must terminate the research and development activity within 48 hours of receipt of the notice in accordance with directions provided by EPA in the notice.

(b) *Evidence of unreasonable risk.* (1) If, after approval of a TERA under this subpart, EPA determines that the proposed research and development activity will present an unreasonable risk of injury to health or the environment, EPA will notify the submitter in writing and state its reasons.

(2) In the notice, EPA may prescribe additional safeguards to address or reduce the risk, or may instruct the submitter to suspend the research and development activities.

(3) Within 48 hours, the submitter must implement the instructions contained in the notice. The submitter may then submit additional information or arguments concerning the matters raised by EPA and whether EPA should modify or revoke the approval of the TERA in accordance with paragraph (a)(2) of this section.

(4) EPA will consider the information and arguments in accordance with paragraph (a)(3) of this section.

(5) Following consideration of the information and arguments under paragraph (a)(3) of this section, if EPA notifies the submitter that the R&D activity must be suspended or terminted, the submitter may resume the activity only upon written notice from EPA that EPA has approved resumption of the activity. In approving resumption of an activity, EPA may prescribe additional conditions which must be followed by the submitter.

(c) *Modifications.* If, after approval of a TERA under this subpart, the submitter concludes that it is necessary to alter the conduct of the research and development activity in a manner which would result in the activity being different from that described in the TERA agreement and any conditions EPA prescribed in its approval, the submitter must inform the EPA contact for the TERA and may not modify the activity without the approval of EPA.

Subpart F—Exemptions for Test Marketing

§ 725.300 Scope and purpose.

(a) This subpart describes exemptions from the reporting requirements under subpart D of this part for test marketing activities involving microorganisms.

(b) In lieu of complying with subpart D of this part, persons described in § 725.305 may submit an application for a test marketing exemption (TME).

(c) Submission requirements specific for TME applications are described at § 725.350.

(d) Data requirements for TME applications are set forth in § 725.355.

(e) EPA review procedures specific for TMEs are set forth in § 725.370.

(f) Subparts A through C of this part apply to any submission under this subpart.

§ 725.305 Persons who may apply under this subpart.

A person identified in this section may apply for a test marketing exemption. EPA may grant the exemption if the person demonstrates that the microorganism will not present an unreasonable risk of injury to health or the environment as a result of the test marketing. A person may apply under this subpart for the following test marketing activities:

(a) A person who intends to manufacture or import for commercial purposes a new microorganism.

(b) A person who intends to manufacture, import, or process for commercial purposes a microorganism identified in subpart M of this part for a significant new use.

§ 725.350 Procedural requirements for this subpart.

General requirements for all submissions under this part are contained in subparts A through C of this part. In addition, the following requirements apply to applications submitted under this subpart:

(a) *Prenotice consultation.* EPA strongly suggests that for a TME, the applicant contact EPA for a prenotice consultation regarding eligibility for a TME.

(b) *When to submit a TME application.* Each person who is eligible to apply for a TME under this subpart must submit the application at least 45 calendar days before the person intends to commence the test marketing activity.

(c) *Recordkeeping.* Each person who is granted a TME must comply with the recordkeeping requirements of § 725.65. In addition, any person who obtains a TME must retain documentation of compliance with any restrictions imposed by EPA when it grants the TME. This information must be retained for 3 years from the final date of manufacture or import under the exemption.

§ 725.355 Information to be included in the TME application.

(a) To review a TME application, EPA must have sufficient information

to permit a reasoned evaluation of the health and environmental effects of the planned test marketing activity. The person seeking EPA approval must submit all information known to or reasonably ascertainable by the person on the microorganism and the test marketing activity, including information not listed in paragraphs (c), (d), and (e) of this section that the person believes will demonstrate that the microorganism will not present an unreasonable risk of injury to health or the environment as a result of the test marketing. The TME application must be in writing and must include at least the information described in paragraphs (b), (c), (d), and (e) of this section.

(b) When specific information is not submitted, an explanation of why such information is not available or not applicable must be included.

(c) Persons applying for a TME must submit the submitter identification and microorganism identity information required for MCANs in §725.155(c), (d)(1), and (d)(2).

(d) Persons applying for a TME must submit phenotypic and ecological characteristics information required in §725.155(d)(3) as it relates directly to the conditions of the proposed test marketing activity.

(e) Persons applying for a TME must also submit the following information about the proposed test marketing activity:

(1) *Proposed test marketing activity*. (i) The maximum quantity of the microorganism which the applicant will manufacture or import for test marketing.

(ii) The maximum number of persons who may be provided the microorganism during test marketing.

(iii) The maximum number of persons who may be exposed to the microorganism as a result of test marketing, including information regarding duration and route of such exposures.

(iv) A description of the test marketing activity, including its duration and how it can be distinguished from full-scale commercial production and research and development activities.

(2) *Health and environmental effects data*. All existing data regarding health and environmental effects of the microorganism must be reported in accordance with §725.160.

§ 725.370 EPA review of the TME application.

General procedures for review of all submissions under this part are contained in §§725.28 through 725.60. In addition, the following procedures apply to EPA review of TME applications submitted under this subpart:

(a) No later than 45 days after EPA receives a TME, the Agency will either approve or deny the application.

(b) A submitter may only proceed with test marketing activities after receipt of EPA approval.

(c) In approving a TME application, EPA may impose any restrictions necessary to ensure that the microorganism will not present an unreasonable risk of injury to health and the environment as a result of test marketing.

Subpart G—General Exemptions for New Microorganisms

§ 725.400 Scope and purpose.

(a) This subpart describes exemptions from reporting under subpart D of this part, and from review under this part altogether, for manufacturing and importing of certain new microorganisms for commercial purposes.

(b) Recipient microorganisms eligible for the tiered exemption from review under this part are listed in §725.420.

(c) Criteria for the introduced genetic material contained in the new microorganisms are described in §725.421.

(d) Physical containment and control technologies are described in §725.422.

(e) The conditions for the Tier I exemption are listed in §725.424.

(f) In lieu of complying with subpart D of this part, persons using recipient microorganisms eligible for the tiered exemption may submit a Tier II exemption request. The limited reporting requirements for the Tier II exemption, including data requirements, are described in §§725.450 and 725.455.

(g) EPA review procedures for the Tier II exemption are set forth in §725.470.

(h) Subparts A through C of this part apply to any submission under this subpart.

§ 725.420 Recipient microorganisms.

The following recipient microorganisms are eligible for either exemption under this subpart:

(a) *Acetobacter aceti*.
(b) *Aspergillus niger*.
(c) *Aspergillus oryzae*.
(d) *Bacillus licheniformis*.
(e) *Bacillus subtilis*.
(f) *Clostridium acetobutylicum*.
(g) *Escherichia coli* K-12.
(h) *Penicillium roqueforti*.
(i) *Saccharomyces cerevisiae*.
(j) *Saccharomyces uvarum*.

§ 725.421 Introduced genetic material.

For a new microorganism to qualify for either exemption under this subpart, introduced genetic material must meet all of the criteria listed in this section.

(a) *Limited in size*. The introduced genetic material must consist only of the following:

(1) The structural gene(s) of interest.

(2) The regulatory sequences permitting the expression of solely the gene(s) of interest.

(3) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

(4) The nucleotide sequences needed for vector transfer.

(5) The nucleotide sequences needed for vector maintenance.

(b) *Well-characterized*. For introduced genetic material, well-characterized means that the following have been determined:

(1) The function of all of the products expressed from the structural gene(s).

(2) The function of sequences that participate in the regulation of expression of the structural gene(s).

(3) The presence or absence of associated nucleotide sequences and their associated functions, where associated nucleotide sequences are those sequences needed to move genetic material including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

(c) *Poorly mobilizable*. The ability of the introduced genetic material to be transferred and mobilized is inactivated, with a resulting frequency of transfer of less than 10^{-8} transfer events per recipient.

(d) *Free of certain sequences*. (1) The introduced genetic material must not contain a functional portion of any of the toxin-encoding sequences described in this paragraph (d).

(i) For the purposes of this section, a functional portion of a toxin-encoding sequence means any sequence which codes for a polypeptide that has one of the following effects:

(A) It directly or indirectly contributes to toxic effects in humans. Directly contributes to toxic effects in humans means those sequences encoding polypeptides that have direct toxicity to target cells. An example of a sequence which directly contributes to toxic effects in humans is one which encodes the portion of diphtheria toxin, listed in paragraph (d)(2) of this section, capable of interacting with elongation factor 2, leading to inhibition of protein synthesis in target respiratory, heart, kidney, and nerve tissues. Indirectly contributes to toxic effects in humans means a sequence whose encoded polypeptide is not directly toxic to target cells, yet still adversely affects humans. An example of a sequence which indirectly contributes to toxic effects is the sequence which encodes the portion of the botulinum toxin, listed in paragraph (d)(3) of this section, capable of blocking the release of acetylcholine from gangliosides. Botulinum toxin affects neuromuscular junctions by its blockage of acetylcholine release, leading to irreversible relaxation of muscles and respiratory arrest.

(B) It binds a toxin or toxin precursor to target human cells.

(C) It facilitates intracellular transport of a toxin in target human cells.

(ii) While these toxins are listed (with synonyms in parentheses) in paragraphs (d)(2) through (d)(7) of this section according to the source organism, it is use of the nucleotide sequences that encode the toxins that is being restricted and not the use of the source organisms. The source organisms are listed to provide specificity in identification of sequences whose use is restricted. Although similar or identical sequences may be isolated from organisms other than those listed

below in paragraphs (d)(2) through (d)(7) of this section, these comparable toxin sequences, regardless of the organism from which they are derived, must not be included in the introduced genetic material.

(2) *Sequences for protein synthesis inhibitor.*

Sequence Source	Toxin Name
Corynebacterium diphtheriae & *C. ulcerans*	Diphtheria toxin
Pseudomonas aeruginosa	Exotoxin A
Shigella dysenteriae	Shigella toxin (Shiga toxin, Shigella dysenteriae type I toxin, Vero cell toxin)
Abrus precatorius, seeds	Abrin
Ricinus communis, seeds	Ricin

(3) *Sequences for neurotoxins.*

Sequence Source	Toxin Name
Clostridium botulinum	Neurotoxins A, B, C1, D, E, F, G (Botulinum toxins, botulinal toxins)
Clostridium tetani	Tetanus toxin (tetanospasmin)
Proteus mirabilis	Neurotoxin
Staphylococcus aureus	Alpha toxin (alpha lysin)
Yersinia pestis	Murine toxin
Snake toxins	
Bungarus caeruleus	Caeruleotoxin
Bungarus multicinctus	Beta-bungarotoxin (phospholipase)
Crotalus spp.	Crotoxin (phospholipase)
Dendroaspis viridis	Neurotoxin
Naja naja varieties	Neurotoxin
Notechia scutatus	Notexin (phospholipase)
Oxyuranus scutellatus	Taipoxin
Invertebrate toxins	
Chironex fleckeri	Neurotoxin
Androctnus australis	Neurotoxin
Centruroides sculpturatus	Neurotoxin

(4) *Sequences for oxygen labile cytolysins.*

Sequence Source	Toxin Name
Bacillus alve	Alveolysin
Bacillus cereus	Cereolysin
Bacillus laterosporus	Laterosporolysin
Bacillus thuringiensis	Thuringiolysin
Clostridium bifermentans	Lysin
Clostridium botulinum	Lysin
Clostridium caproicum	Lysin
Clostridium chauvoei	Delta-toxin
Clostridium histolyticum	Epsilon-toxin
Clostridium novyi	Gamma-toxin
Clostridium oedematiens	Delta-toxin
Clostridium perfringens	Theta-toxin (Perfringolysin)
Clostridium septicum	Delta-toxin
Clostridium sordellii	Lysin
Clostridium tetani	Tetanolysin
Listeria monocytogenes	Listeriolysin (A B)
Streptococcus pneumoniae	Pneumolysin
Streptococcus pyogene	Streptolysin O (SLO)

(5) *Sequences for toxins affecting membrane function.*

Sequence Source	Toxin Name
Bacillus anthracis	Edema factor (Factors I II); Lethal factor (Factors II III)
Bacillus cereus	Enterotoxin (diarrheagenic toxin, mouse lethal factor)
Bordetella pertussis	Adenylate cyclase (Heat-labile factor); Pertussigen (pertussis toxin, islet activating factor, histamine sensitizing factor, lymphocytosis promoting factor)
Clostridium botulinum	C2 toxin
Clostridium difficile	Enterotoxin (toxin A)
Clostridium perfringens	Beta-toxin; Delta-toxin
Escherichia coli & other Enterobacteriaceae spp.	Heat-labile enterotoxins (LT); Heat-stable enterotoxins (STa, ST1 subtypes ST1a ST1b; also STb, STII)
Legionella pneumophila	Cytolysin
Vibrio cholerae & Vibrio mimicus	Cholera toxin (choleragen)

(6) Sequences that affect membrane integrity.

Sequence Source	Toxin Name
Clostridium bifermentans & other *Clostridium spp*	Lecithinase
Clostridium perfringens	Alpha-toxin (phospholipase C, lecithinase); Enterotoxin
Corynebacterium pyogenes & other Corynebacterium spp.	Cytolysin (phospholipase C), Ovis toxin (sphingomyelinase D)
Staphylococcus aureus	Beta-lysin (beta toxin)

(7) *Sequences that are general cytotoxins.*

Sequence Source	Toxin Name
Adenia digitata	Modeccin
Aeromonas hydrophila	Aerolysin (beta-lysin, cytotoxic lysin)
Clostridium difficile	Cytotoxin (toxin B)
Clostridium perfringens	Beta-toxin; Epsilon-toxin; Kappa-toxin
Escherichia coli & other Enterobacteriaceae spp.	Cytotoxin (Shiga-like toxin, Vero cell toxin)
Pseudomonas aeruginosa	Proteases
Staphylococcus aureus	Gamma lysin (Gamma toxin); Enterotoxins (SEA, SEB, SEC, SED SEE); Pyrogenic exotoxins A B; Toxic shock syndrome toxins (TSST-1)
Staphylococcus aureus & Pseudomonas aeruginosa	Leucocidin (leukocidin, cytotoxin)
Streptococcus pyogenes	Streptolysin S (SLS); Erythrogenic toxins (scarlet fever toxins, pyrogenic exotoxins)
Yersinia enterocolitica	Heat-stable enterotoxins (ST)

§ 725.422 Physical containment and control technologies.

The manufacturer must meet all of the following criteria for physical containment and control technologies for

any facility in which the new microorganism will be used for a Tier I exemption; these criteria also serve as guidance for a Tier II exemption.

(a) Use a structure that is designed and operated to contain the new microorganism.

(b) Control access to the structure.

(c) Provide written, published, and implemented procedures for the safety of personnel and control of hygiene.

(d) Use inactivation procedures demonstrated and documented to be effective against the new microorganism contained in liquid and solid wastes prior to disposal of the wastes. The inactivation procedures must reduce viable microbial populations by at least 6 logs in liquid and solid wastes.

(e) Use features known to be effective in minimizing viable microbial populations in aerosols and exhaust gases released from the structure, and document use of such features.

(f) Use systems for controlling dissemination of the new microorganism through other routes, and document use of such features.

(g) Have in place emergency clean-up procedures.

§ 725.424 Requirements for the Tier I exemption.

(a) *Conditions of exemption.* The manufacture or import of a new microorganism for commercial purposes is not subject to review under this part if all of the following conditions are met for all activities involving the new microorganism:

(1) The recipient microorganism is listed in and meets any requirements specified in § 725.420.

(2) The introduced genetic material meets the criteria under § 725.421.

(3) The physical containment and control technologies of any facility in which the microorganism will be manufactured, processed, or used meet the criteria under § 725.422.

(4) The manufacturer or importer submits a certification described in paragraph (b) of this section to EPA at least 10 days before commencing initial manufacture or import of a new microorganism derived from a recipient microorganism listed in § 725.420.

(5) The manufacturer or importer complies with the recordkeeping requirements of § 725.65 and maintains records for the initial and subsequent uses of the new microorganism that verify compliance with the following:

(i) The certifications made in paragraph (b) of this section.

(ii) All the eligibility criteria for the Tier I exemption including the criteria for the recipient microorganism, the introduced genetic material, the physical containment and control technologies.

(b) *Certification.* To be eligible for the Tier I exemption under this subpart, the manufacturer or importer must submit to EPA a document signed by a responsible company official containing the information listed in this paragraph.

(1) Name and address of manufacturer or importer.

(2) Date when manufacture or import is expected to begin.

(3) The identification (genus, species) of the recipient microorganism listed in § 725.420 which is being used to create the new microorganism which will be used under the conditions of the Tier I exemption.

(4) Certification of the following:

(i) Compliance with the introduced genetic material criteria described in § 725.421.

(ii) Compliance with the containment requirements described in § 725.422, including the provision in paragraph (a)(3) of this section.

(5) The site of waste disposal and the type of permits for disposal, the permit numbers and the institutions issuing the permits.

(6) The certification statement required in § 725.25(b). Certification of submission of test data is not required for the Tier I exemption.

§ 725.426 Applicability of the Tier I exemption.

The Tier I exemption under § 725.424 applies only to a manufacturer or importer of a new microorganism that certifies that the microorganism will be used in all cases in compliance with §§ 725.420, 725.421, and 725.422.

§ 725.428 Requirements for the Tier II exemption.

The manufacturer or importer of a new microorganism for commercial

purposes may submit to EPA a Tier II exemption request in lieu of a MCAN under subpart D of this part if all of the following conditions are met:

(a) The recipient microorganism is listed in and meets any requirements specified in § 725.420.

(b) The introduced genetic material meets the criteria under § 725.421.

(c) Adequate physical containment and control technologies are used. The criteria listed under § 725.422 for physical containment and control technologies of facilities should be used as guidance to satisfy the Tier II exemption request data requirements listed at § 725.455(d). EPA will review proposed process and containment procedures as part of the submission for a Tier II exemption under this section.

§ 725.450 Procedural requirements for the Tier II exemption.

General requirements for all submissions under this part are contained in § 725.25. In addition, the following requirements apply to requests submitted under this subpart:

(a) *Prenotice consultation.* EPA strongly suggests that for a Tier II exemption, the submitter contact the Agency for a prenotice consultation regarding eligibility for the exemption.

(b) *When to submit the Tier II exemption request.* Each person who is eligible to submit a Tier II exemption request under this subpart must submit the request at least 45 calendar days before the person intends to commence manufacture or import.

(c) *Contents of the Tier II exemption request.* Each person who submits a request under this subpart must provide the information described in §§ 725.428 and 725.455, as well as information known to or reasonably ascertainable by the person that would permit EPA to determine that use of the microorganism, under the conditions specified in the request, will not present an unreasonable risk of injury to health or the environment.

(d) *Recordkeeping.* Each person who submits a request under this subpart must comply with the recordkeeping requirements of § 725.65. In addition, the submitter should maintain records which contain information that verifies compliance with the following:

(1) The certifications made in the request.

(2) All the eligibility criteria for the Tier II exemption request including the criteria for the recipient microorganism, the introduced genetic material, the physical containment and control technologies.

§ 725.455 Information to be included in the Tier II exemption request.

The submitter must indicate clearly that the submission is a Tier II exemption request for a microorganism instead of the MCAN under subpart D of this part and must submit the following information:

(a) *Submitter identification.* (1) The name and headquarters address of the submitter.

(2) The name, address, and office telephone number (including area code) of the principal technical contact representing the submitter.

(b) *Microorganism identity information.* (1) Identification (genus, species, and strain) of the recipient microorganism. Genus, species designation should be substantiated by a letter from a culture collection or a brief summary of the results of tests conducted for taxonomic identification.

(2) Type of genetic modification and the function of the introduced genetic material.

(3) Site of insertion.

(4) Certification of compliance with the introduced genetic material criteria described in § 725.421.

(c) *Production volume.* Production volume, including total liters per year, and the maximum cell concentration achieved during the production process.

(d) *Process and containment information.* (1) A description of the process including the following:

(i) Identity and location of the manufacturing site(s).

(ii) Process flow diagram illustrating the production process, including downstream separations, and indicating the containment envelope around the appropriate equipment.

(iii) Identities and quantities of feedstocks.

(iv) Sources and quantities of potential releases to both the workplace and

environment, and a description of engineering controls, inactivation procedures, and other measures which will reduce worker exposure and environmental releases.

(v) A description of procedures which will be undertaken to prevent fugitive emissions, i.e. leak detection and repair program.

(vi) A description of procedures/safeguards to prevent and mitigate accidental releases to the workplace and the environment.

(2) Certification of those elements of the containment criteria described in §725.422 with which the manufacturer is in compliance, including stating by number the elements with which the manufacturer is in full compliance.

(e) The site of waste disposal and the type of permits for disposal, the permit numbers and the institutions issuing the permits.

(f) The certification statement required in §725.25(b). Certification of submission of test data is not required for the Tier II exemption.

§ 725.470 EPA review of the Tier II exemption request.

General procedures for review of all submissions under this part are contained in §§725.28 through 725.60. In addition, the following procedures apply to EPA review of Tier II exemption requests submitted under this subpart:

(a) *Length of the review period.* The review period for the request will be 45 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete request, or the date EPA determines the request is complete under §725.33, unless the Agency extends the review period for good cause under §725.56.

(b) *Criteria for review.* EPA will review the request to determine that the new microorganism complies with §725.428 and that its manufacture, processing, use, and disposal as described in the request will not present an unreasonable risk of injury to health or the environment.

(c) *EPA decision regarding the Tier II exemption request.* A decision concerning a request under this subpart will be made by the Administrator, or a designee.

(d) *Determination that the microorganism is ineligible for a Tier II review.* (1) EPA may determine that the manufacturer or importer is not eligible for Tier II review, because the microorganism does not meet the criteria under §725.428 or the Administrator, or a designee, decides that there is insufficient information to determine that the conditions of manufacture, processing, use, or disposal of the microorganism as described in the request will not present an unreasonable risk to health or the environment.

(2) If the Agency makes this determination, the Administrator, or a designee will notify the manufacturer or importer by telephone, followed by a letter, that the request has been denied. The letter will explain reasons for the denial.

(3) If the request is denied, the manufacturer or importer may submit the information necessary to constitute a MCAN under subpart D of this part.

(e) *Approval or denial of the Tier II exemption request.* (1) No later than 45 days after EPA receives a request, the Agency will either approve or deny the request.

(2) In approving a request, EPA may impose any restrictions necessary to ensure that the microorganism will not present an unreasonable risk of injury to health and the environment as a result of general commercial use.

(f) EPA may seek to enjoin the manufacture or import of a microorganism in violation of this subpart, or act to seize any microorganism manufactured or imported in violation of this section or take other actions under the authority of sections 7 or 17 of the Act.

(g) A manufacturer or importer may only proceed after receipt of EPA approval.

Subparts H–K [Reserved]

Subpart L—Additional Procedures for Reporting on Significant New Uses of Microorganisms

§ 725.900 Scope and purpose.

(a) This subpart describes additional provisions governing submission of MCANs for microorganisms subject to

significant new use rules identified in subpart M of this part.

(b) Manufacturers, importers, and processors described in § 725.105(c) must submit a MCAN under subpart D of this part for significant new uses of microorganisms described in subpart M of this part, unless they are excluded under § 725.910 or § 725.912.

(c) Section 725.920 discusses exports and imports.

(d) Additional recordkeeping requirements specific to significant new uses of microorganisms are described in § 725.950.

(e) Section 725.975 describes how EPA will approve alternative means of complying with significant new use requirements designated in subpart M of this part.

(f) Expedited procedures for promulgating significant new use requirements under subpart M of this part for microorganisms subject to section 5(e) orders are discussed in §§ 725.980 and 725.984.

(g) This subpart L contains provisions governing submission and review of notices for the microorganisms and significant new uses identified in subpart M of this part. The provisions of this subpart L apply to the microorganisms and significant new uses identified in subpart M of this part, except to the extent that they are specifically modified or supplanted by specific requirements in subpart M of this part. In the event of a conflict between the provisions of this subpart L and the provisions of subpart M of this part, the provisions of subpart M of this part shall govern.

(h) The provisions of subparts A through F of this part also apply to subparts L and M of this part. For purposes of subparts L and M of this part, wherever the words ''microorganism'' or ''new microorganism'' appear in subparts A through F of this part, it shall mean the microorganism subject to subparts L and M of this part. In the event of a conflict between the provisions of subparts A through F and the provisions of subparts L and M of this part, the provisions of subparts L and M of this part shall govern.

§ 725.910 Persons excluded from reporting significant new uses.

(a) A person who intends to manufacture, import, or process a microorganism identified in subpart M of this part and who intends to distribute it in commerce is not required to submit a MCAN under subpart D of this part, if that person can document one or more of the following as to each recipient of the microorganism from that person:

(1) That the person has notified the recipient, in writing, of the specific section in subpart M of this part which identifies the microorganism and its designated significant new uses, or

(2) That the recipient has knowledge of the specific section in subpart M of this part which identifies the microorganism and its designated significant new uses, or

(3) That the recipient cannot undertake any significant new use described in the specific section in subpart M of this part.

(b) The manufacturer, importer, or processor described in paragraph (a) of this section must submit a MCAN under subpart D of this part, if such person has knowledge at the time of commercial distribution of the microorganism identified in the specific section in subpart M of this part that a recipient intends to engage in a designated significant new use of that microorganism without submitting a MCAN under this part.

(c) A person who processes a microorganism identified in a specific section in subpart M of this part for a significant new use of that microorganism is not required to submit a MCAN if that person can document each of the following:

(1) That the person does not know the specific microorganism identity of the microorganism being processed, and

(2) That the person is processing the microorganism without knowledge that the microorganism is identified in subpart M of this part.

(d)(1) If at any time after commencing distribution in commerce of a microorganism identified in a specific section in subpart M of this part, a person who manufactures, imports, or processes a microorganism described in subpart M of this part and distributes it in commerce has knowledge that a

recipient of the microorganism is engaging in a significant new use of that microorganism designated in that section without submitting a MCAN under this part, the person is required to cease supplying the microorganism to that recipient and to submit a MCAN for that microorganism and significant new use, unless the person is able to document each of the following:

(i) That the person has notified the recipient and EPA enforcement authorities (at the address in paragraph (d)(1)(iii) of this section), in writing within 15 working days of the time the person develops knowledge that the recipient is engaging in a significant new use, that the recipient is engaging in a significant new use without submitting a MCAN.

(ii) That, within 15 working days of notifying the recipient as described in paragraph (d)(1)(i) of this section, the person received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the applicable section in subpart M of this part and will not engage in the significant new use.

(iii) That the person has promptly provided EPA enforcement authorities with a copy of the recipient's statement of assurance described in paragraph (d)(1)(ii) of this section. The copy must be sent to the Director, Office of Compliance (2221A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(2) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use after providing the statement of assurance described in paragraph (d)(1)(ii) of this section and without submitting a MCAN under this part, the manufacturer, importer, or processor shall immediately cease distribution to that recipient until the manufacturer, importer, or processor or the recipient has submitted a MCAN under this part and the MCAN review period has ended.

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a MCAN under this part, the manufacturer, importer, or processor must immediately cease distributing the microorganism to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a MCAN under this part and the MCAN review period has ended.

(ii) The recipient has submitted a MCAN under this part and the MCAN review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

§ 725.912 Exemptions.

Persons identified in § 725.105(c) are not required to submit a MCAN under subpart D of this part for a microorganism identified in subpart M of this part, unless otherwise specified in a specific section in subpart M, if:

(a) The person submits a MCAN for the microorganism prior to the promulgation date of the section in subpart M of this part which identifies the microorganism, and the person receives written notification of compliance from EPA prior to the effective date of such section. The MCAN submitter must comply with any applicable requirement of section 5(b) of the Act. The MCAN must include the information and test data specified in section 5(d)(1) of the Act. For purposes of this exemption, the specific section in subpart M of this part which identifies the microorganism and §§ 725.3, 725.15, 725.65, 725.70, 725.75, 725.100, and 725.900 apply; after the effective date of the section in subpart M of this part which identifies the microorganism, §§ 725.105 and 725.910 apply and § 725.920 continues to apply. EPA will provide the MCAN submitter with written notification of compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the MCAN will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances, or

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart M of this part which identifies the microorganism.

(b) The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in subpart M of this part, abiding by the provision of the section 5(e) order exempts the person from submitting a MCAN for that specific significant new use.

§ 725.920 Exports and imports.

(a) *Exports.* Persons who intend to export a microorganism identified in subpart M of this part, or in any proposed rule which would amend subpart M of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at part 707 of this chapter.

(b) *Imports.* Persons who import a substance identified in a specific section in subpart M of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR §§ 12.118 through 12.127 and 127.28(i). The EPA policy in support of the import certification requirements appears at part 707 of this chapter.

§ 725.950 Additional recordkeeping requirements.

Persons submitting a MCAN for a significant new use of a microorganism must comply with the recordkeeping requirements of § 725.65. In addition, the following requirements apply:

(a) At the time EPA adds a microorganism to subpart M of this part, EPA may specify appropriate recordkeeping requirements. Each manufacturer, importer, and processor of the microorganism shall maintain the records for 3 years from the date of their creation.

(b) The records required to be maintained under this section may include the following:

(1) Records documenting the information contained in the MCAN submitted to EPA.

(2) Records documenting the manufacture and importation volume of the microorganism and the corresponding dates of manufacture and import.

(3) Records documenting volumes of the microorganism purchased domestically by processors of the microorganism, names and addresses of suppliers and corresponding dates of purchase.

(4) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the manufacturer, importer, or processor directly sells or transfers the microorganism, the date of each sale or transfer, and the quantity of the microorganism sold or transferred on such date.

§ 725.975 EPA approval of alternative control measures.

(a) In certain sections of subpart M of this part, significant new uses for the identified microorganisms are described as the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or release of microorganisms which are identified in such sections, or alternative measures to control worker exposure or environmental release which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a microorganism identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination of equivalency before commencing manufacture, import, or processing involving the alternative control measures.

(b) Persons submitting a request for a determination of equivalency to EPA under this part must submit the request to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software.

A request for a determination of equivalency must contain:

(1) The name of the submitter.

(2) The specific identity of the microorganism.

(3) The citation for the specific section in subpart M of this part which pertains to the microorganism for which the request is being submitted.

(4) A detailed description of the activities involved.

(5) The specifications of the alternative worker exposure control measures or environmental release control measures.

(6) A detailed analysis explaining why such alternative control measures provide substantially the same degree of protection as the specific control measures identified in the specific section in subpart M of this part which pertains to the microorganism for which the request is being submitted.

(7) The data and information described in §§ 725.155 and 725.160. If such data and information have already been submitted to EPA's Office of Pollution Prevention and Toxics, the submitter need only document that it was previously submitted, to whom, and the date it was submitted.

(c) Requests for determinations of equivalency will be reviewed by EPA within 45 days. Determinations under this paragraph will be made by the Director, or a designee. Notice of the results of such determinations will be mailed to the submitter.

(d) If EPA notifies the submitter under paragraph (c) of this section that EPA has determined that the alternative control measures provide substantially the same degree of protection as the specified control measures identified in the specific section of subpart M of this part which pertains to the microorganism for which the request is being submitted, the submitter may commence manufacture, import, or processing in accordance with the specifications for alternative worker exposure control measures or environmental release control measures identified in the submitter's request, and may alter any corresponding notification to workers to reflect such alternative controls. Deviations from the activities described in the EPA notification constitute a significant new use and are subject to the requirements of this part.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 790, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013]

§ 725.980 Expedited procedures for issuing significant new use rules for microorganisms subject to section 5(e) orders.

(a) *Selection of microorganisms.* (1) In accordance with the expedited process specified in this section, EPA will issue significant new use notification requirements for each new microorganism that, after MCAN review under subpart D of this part, becomes subject to a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture and import of the microorganism, unless EPA determines that significant new use notification requirements are not needed for the microorganism.

(2) If EPA determines that significant new use notifications requirements are not needed for a microorganism that is subject to a final order issued under section 5(e) of the Act, EPA will issue a notice in the FEDERAL REGISTER explaining why the significant new use requirements are not needed.

(b) *Designation of requirements.* (1) The significant new use notification and other specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. EPA may also designate additional activities as significant new uses which will be subject to notification.

(2) Significant new use requirements and other specific requirements designated under this section will be listed in subpart M of this part. For each microorganism, subpart M of this part will identify:

(i) The microorganism name.

(ii) The activities designated as significant new uses.

(iii) Other specific requirements applicable to the microorganism, including recordkeeping requirements or any other requirements included in the final section 5(e) order.

(c) *Procedures for issuing significant new use rules*—(1) *Possible processes.* EPA will issue significant new use

rules (SNURs) under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(2) *Notice in the Federal Register.* FEDERAL REGISTER documents issued to propose or establish significant new uses under this section will contain the following:

(i) The microorganism identity or, if its specific identity is claimed confidential, an appropriate generic microorganism name and an accession number assigned by EPA.

(ii) The MCAN number.

(iii) A summary of EPA's findings under section 5(e)(1)(A) of the Act for the final order issued under section 5(e).

(iv) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(v) Any modification of subpart L of this part applicable to the specific microorganism and significant new uses.

(vi) If the FEDERAL REGISTER document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(3) *Direct final rulemaking.* (i) EPA will use direct final rulemaking to issue a significant new use rule, when specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. EPA will issue a final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new microorganism.

(ii) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days of publication that someone wishes to submit adverse or critical comments, the rule will be effective 60 days from the date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and a proposal will be published in the proposed rule section of the FEDERAL REGISTER. The proposal will establish a 30–day comment period.

(iii) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the microorganism to subpart M of this part and designating the significant new uses subject to notification.

(4) *Interim final rulemaking.* (i) EPA will use the interim final rulemaking procedure to issue a significant new use rule, when specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. The Agency will issue an interim final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new microorganism. The document will state EPA's reasons for using the interim final rulemaking procedure.

(A) The significant new use rule will take effect on the date of publication.

(B) Persons will be given 30 days from the date of publication to submit comments.

(ii) Interim final rules issued under this section shall cease to be in effect 180 days after publication unless, within the 180–day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30–day comment period specified in paragraph (c)(4)(i)(B) of this section and promulgating final significant new use notification requirements and other requirements for the microorganism.

(5) *Notice and comment rulemaking.* (i) EPA will use a notice and comment procedure to issue a significant new use rule, when EPA is designating additional activities which are not provisions included in the final order issued for the microorganism under section 5(e) of the Act as significant new uses which will be subject to notification. EPA will issue a proposal in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new microorganism. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the microorganism under this part.

(ii) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the microorganism to subpart M of this part and designating the significant new uses subject to notification.

(d) *Schedule for issuing significant new use rules.* (1) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 180 days of receipt of a valid notice of commencement under § 725.190.

(2) If EPA receives adverse or critical significant comments following publication of a proposed or interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

§ 725.984 Modification or revocation of certain notification requirements.

(a) *Criteria for modification or revocation.* EPA may at any time modify or revoke significant new use notification requirements for a microorganism which has been added to subpart M of this part using the procedures of § 725.980. Such action may be taken under this section if EPA makes one of the following determinations, unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the microorganism will not present an unreasonable risk of injury to health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law, for the microorganism that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received MCANs for some or all of the activities designated as significant new uses of the microorganism and, after reviewing such MCANs, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data or other information supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act and has concluded that a rational basis no longer exists for the findings that activities involving the microorganism may present an unreasonable risk of injury to health or the environment required under section 5(e)(1)(A) of the Act.

(5) Certain activities involving the microorganism have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) *Procedures for limitation or revocation.* Modification or revocation of significant new use notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in § 725.980 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in § 725.980. The request must be accompanied by information sufficient to support the request. Persons submitting a request to EPA under this part must submit the request to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Support documents related to these requests

must also be submitted to EPA via CDX using e-PMN software.

(2) The Director, or a designee, will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that microorganism should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a microorganism should be limited or revoked, EPA will propose the changes in a notice in the FEDERAL REGISTER, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 790, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013]

Subpart M—Significant New Uses for Specific Microorganisms

§ 725.1000 Scope.

This subpart identifies uses of microorganisms which EPA has determined to be significant new uses under the authority of section 5(a)(2) of the Toxic Substances Control Act.

§ 725.1075 Burkholderia cepacia complex.

(a) *Microorganism and significant new uses subject to reporting.* (1) The microorganisms identified as the *Burkholderia cepacia* complex defined as containing the following nine species, *Burkholderia cepacia*, *Burkholderia multivorans*, *Burkholderia stabilis*, *Burkholderia vietnamiensis*, *Burkholderia ambifaria*, *Burkholderia pyrrocinia*, *Burkholderia cepacia* genomovar VIII (*Burkholderia anthina*), and *Burkholderia cepacia* genomovars III and VI are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is any use other than research and development in the degradation of chemicals via injection into subsurface groundwater.

(b) [Reserved]

[68 FR 35320, June 13, 2003]

PART 745—LEAD-BASED PAINT POISONING PREVENTION IN CERTAIN RESIDENTIAL STRUCTURES

Subparts A–C [Reserved]

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AUTHORITY: 15 U.S.C. 2605, 2607, 2681–2692 and 42 U.S.C. 4852d.

SOURCE: 61 FR 9085, Mar. 6, 1996, unless otherwise noted.

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Subpart D—Lead-Based Paint Hazards

SOURCE: 66 FR 1237, Jan. 5, 2001, unless otherwise noted.

§ 745.61 Scope and applicability.

(a) This subpart identifies lead-based paint hazards.

(b) The standards for lead-based paint hazards apply to target housing and child-occupied facilities.

(c) Nothing in this subpart requires the owner of property(ies) subject to these standards to evaluate the property(ies) for the presence of lead-based paint hazards or take any action to control these conditions if one or more of them is identified.

§ 745.63 Definitions.

The following definitions apply to part 745.

Arithmetic mean means the algebraic sum of data values divided by the number of data values (e.g., the sum of the concentration of lead in several soil samples divided by the number of samples).

Chewable surface means an interior or exterior surface painted with lead-based paint that a young child can mouth or chew. A chewable surface is the same as an ''accessible surface'' as defined in 42 U.S.C. 4851b(2)). Hard metal substrates and other materials that cannot be dented by the bite of a young child are not considered chewable.

Common area group means a group of common areas that are similar in design, construction, and function. Common area groups include, but are not limited to hallways, stairwells, and laundry rooms.

Concentration means the relative content of a specific substance contained within a larger mass, such as the amount of lead (in micrograms per gram or parts per million by weight) in a sample of dust or soil.

Deteriorated paint means any interior or exterior paint or other coating that is peeling, chipping, chalking or cracking, or any paint or coating located on an interior or exterior surface or fixture that is otherwise damaged or separated from the substrate.

Dripline means the area within 3 feet surrounding the perimeter of a building.

Friction surface means an interior or exterior surface that is subject to abrasion or friction, including, but not limited to, certain window, floor, and stair surfaces.

Impact surface means an interior or exterior surface that is subject to damage by repeated sudden force such as certain parts of door frames.

Interior window sill means the portion of the horizontal window ledge that protrudes into the interior of the room.

Lead-based paint hazard means hazardous lead-based paint, dust-lead hazard or soil-lead hazard as identified in § 745.65.

Loading means the quantity of a specific substance present per unit of surface area, such as the amount of lead in micrograms contained in the dust collected from a certain surface area divided by the surface area in square feet or square meters.

Mid-yard means an area of a residential yard approximately midway between the dripline of a residential building and the nearest property boundary or between the driplines of a residential building and another building on the same property.

Play area means an area of frequent soil contact by children of less than 6 years of age as indicated by, but not limited to, such factors including the following: the presence of play equipment (e.g., sandboxes, swing sets, and sliding boards), toys, or other children's possessions, observations of play patterns, or information provided by parents, residents, care givers, or property owners.

Residential building means a building containing one or more residential dwellings.

Room means a separate part of the inside of a building, such as a bedroom, living room, dining room, kitchen, bathroom, laundry room, or utility room. To be considered a separate room, the room must be separated from adjoining rooms by built-in walls or archways that extend at least 6 inches from an intersecting wall. Half walls or bookcases count as room separators if built-in. Movable or collapsible partitions or partitions consisting solely of shelves or cabinets are not considered built-in walls. A screened in porch that is used as a living area is a room.

Soil sample means a sample collected in a representative location using ASTM E1727, ''Standard Practice for Field Collection of Soil Samples for Lead Determination by Atomic Spectrometry Techniques,'' or equivalent method.

Weighted arithmetic mean means the arithmetic mean of sample results weighted by the number of subsamples in each sample. Its purpose is to give influence to a sample relative to the surface area it represents. A single surface sample is comprised of a single subsample. A composite sample may contain from two to four subsamples of the same area as each other and of each single surface sample in the composite. The weighted arithmetic mean is obtained by summing, for all samples, the product of the sample's result multiplied by the number of subsamples in the sample, and dividing the sum by the total number of subsamples contained in all samples. For example, the weighted arithmetic mean of a single surface sample containing 60 $\mu g/ft^2$, a composite sample (three subsamples) containing 100 $\mu g/ft^2$, and a composite sample (4 subsamples) containing 110 $\mu g/ft^2$ is 100 $\mu g/ft^2$. This result is based on the equation [60 + (3*100) + (4*110)]/(1 + 3 + 4).

Window trough means, for a typical double-hung window, the portion of the exterior window sill between the interior window sill (or stool) and the frame of the storm window. If there is no storm window, the window trough is the area that receives both the upper and lower window sashes when they are both lowered. The window trough is sometimes referred to as the window ''well.''

Wipe sample means a sample collected by wiping a representative surface of known area, as determined by ASTM E1728, ''Standard Practice for Field Collection of Settled Dust Samples Using Wipe Sampling Methods for Lead Determination by Atomic Spectrometry Techniques, or equivalent method, with an acceptable wipe material as defined in ASTM E 1792, ''Standard Specification for Wipe Sampling Materials for Lead in Surface Dust.''

§ 745.65 Lead-based paint hazards.

(a) *Paint-lead hazard.* A paint-lead hazard is any of the following:

(1) Any lead-based paint on a friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (e.g., the window sill, or floor) are equal to or greater than the dust-lead hazard levels identified in paragraph (b) of this section.

(2) Any damaged or otherwise deteriorated lead-based paint on an impact surface that is caused by impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against its door frame.

(3) Any chewable lead-based painted surface on which there is evidence of teeth marks.

(4) Any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(b) *Dust-lead hazard.* A dust-lead hazard is surface dust in a residential dwelling or child-occupied facility that contains a mass-per-area concentration of lead equal to or exceeding 40 μg/ft^2 on floors or 250 μg/ft^2 on interior window sills based on wipe samples.

(c) *Soil-lead hazard.* A soil-lead hazard is bare soil on residential real property or on the property of a child-occupied facility that contains total lead equal to or exceeding 400 parts per million (μg/g) in a play area or average of 1,200 parts per million of bare soil in the rest of the yard based on soil samples.

(d) *Work practice requirements.* Applicable certification, occupant protection, and clearance requirements and work practice standards are found in regulations issued by EPA at 40 CFR part 745, subpart L and in regulations issued by the Department of Housing and Urban Development (HUD) at 24 CFR part 35, subpart R. The work practice standards in those regulations do not apply when treating paint-lead hazards of less than:

(1) Two square feet of deteriorated lead-based paint per room or equivalent,

(2) Twenty square feet of deteriorated paint on the exterior building, or

(3) Ten percent of the total surface area of deteriorated paint on an interior or exterior type of component with a small surface area.

Subpart E—Residential Property Renovation

SOURCE: 63 FR 29919, June 1, 1998, unless otherwise noted.

§ 745.80 Purpose.

This subpart contains regulations developed under sections 402 and 406 of the Toxic Substances Control Act (15 U.S.C. 2682 and 2686) and applies to all renovations performed for compensation in target housing and child-occupied facilities. The purpose of this subpart is to ensure the following:

(a) Owners and occupants of target housing and child-occupied facilities receive information on lead-based paint hazards before these renovations begin; and

(b) Individuals performing renovations regulated in accordance with §745.82 are properly trained; renovators and firms performing these renovations are certified; and the work practices in §745.85 are followed during these renovations.

[73 FR 21758, Apr. 22, 2008]

§ 745.81 Effective dates.

(a) *Training, certification and accreditation requirements and work practice standards.* The training, certification and accreditation requirements and work practice standards in this subpart are applicable in any State or Indian Tribal area that does not have a renovation program that is authorized under subpart Q of this part. The training, certification and accreditation requirements and work practice standards in this subpart will become effective as follows:

(1) *Training programs.* Effective June 23, 2008, no training program may provide, offer, or claim to provide training or refresher training for EPA certification as a renovator or a dust sampling technician without accreditation from EPA under §745.225. Training programs may apply for accreditation under §745.225 beginning April 22, 2009.

(2) *Firms.* (i) Firms may apply for certification under §745.89 beginning October 22, 2009.

(ii) On or after April 22, 2010, no firm may perform, offer, or claim to perform renovations without certification from EPA under §745.89 in target housing or child-occupied facilities, unless the renovation qualifies for one of the exceptions identified in §745.82(a) or (c).

(3) *Individuals.* On or after April 22, 2010, all renovations must be directed by renovators certified in accordance with §745.90(a) and performed by certified renovators or individuals trained in accordance with §745.90(b)(2) in target housing or child-occupied facilities, unless the renovation qualifies for one of the exceptions identified in §745.82(a) or (c).

(4) *Work practices.* (i) On or after April 22, 2010 and before July 6, 2010 all renovations must be performed in accordance with the work practice standards in §745.85 and the associated recordkeeping requirements in §745.86 (b)(6) in target housing or child-occupied facilities, unless the renovation qualifies for one of the exceptions identified in §745.82(a). This does not apply to renovations in target housing for which the firm performing the renovation has obtained a statement signed by the owner that the renovation will occur in the owner's residence, no child under age 6 resides there, the housing is not a child-occupied facility, and the owner acknowledges that the work practices to be used during the renovation will not necessarily include all of the lead-safe work practices contained in EPA's renovation, repair, and painting rule. For the purposes of this section, a child resides in the primary residence of his or her custodial parents, legal guardians, and foster parents. A child also resides in the primary residence of an informal caretaker if the child lives and sleeps most of the time at the caretaker's residence.

(ii) On or after July 6, 2010, all renovations must be performed in accordance with the work practice standards in §745.85 and the associated recordkeeping requirements in §745.86(b)(1) and (b)(6) in target housing or child-occupied facilities, unless the renovation qualifies for the exception identified in §745.82(a).

(5) The suspension and revocation provisions in §745.91 are effective April 22, 2010.

(b) *Renovation-specific pamphlet.* Before December 22, 2008, renovators or firms performing renovations in States and Indian Tribal areas without an authorized program may provide owners and occupants with either of the following EPA pamphlets: *Protect Your Family From Lead in Your Home* or *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools.* After that date, *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools* must be used exclusively.

(c) *Pre-Renovation Education Rule.* With the exception of the requirement to use the pamphlet entitled *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools*, the provisions of the Pre-Renovation Education Rule in this subpart have been in effect since June 1999.

[73 FR 21758, Apr. 22, 2008, as amended at 75 FR 24818, May 6, 2010]

§745.82 Applicability.

(a) This subpart applies to all renovations performed for compensation in target housing and child-occupied facilities, except for the following:

(1) Renovations in target housing or child-occupied facilities in which a written determination has been made by an inspector or risk assessor (certified pursuant to either Federal regulations at §745.226 or a State or Tribal certification program authorized pursuant to §745.324) that the components affected by the renovation are free of paint or other surface coatings that contain lead equal to or in excess of 1.0 milligrams/per square centimeter (mg/cm^2) or 0.5% by weight, where the firm performing the renovation has obtained a copy of the determination.

(2) Renovations in target housing or child-occupied facilities in which a certified renovator, using an EPA recognized test kit as defined in §745.83 and following the kit manufacturer's instructions, has tested each component affected by the renovation and determined that the components are free of paint or other surface coatings that contain lead equal to or in excess of 1.0 mg/cm^2 or 0.5% by weight. If the components make up an integrated whole, such as the individual stair treads and risers of a single staircase, the renovator is required to test only one of the individual components, unless the individual components appear to have been repainted or refinished separately.

(3) Renovations in target housing or child-occupied facilities in which a certified renovator has collected a paint chip sample from each painted component affected by the renovation and a laboratory recognized by EPA pursuant to section 405(b) of TSCA as being capable of performing analyses for lead compounds in paint chip samples has determined that the samples are free of paint or other surface coatings that contain lead equal to or in excess of 1.0 mg/cm^2 or 0.5% by weight. If the components make up an integrated whole, such as the individual stair treads and risers of a single staircase, the renovator is required to test only one of the individual components, unless the individual components appear to have been repainted or refinished separately.

(b) The information distribution requirements in §745.84 do not apply to emergency renovations, which are renovation activities that were not planned but result from a sudden, unexpected event (such as non-routine failures of equipment) that, if not immediately attended to, presents a safety or public health hazard, or threatens equipment and/or property with significant damage. Interim controls performed in response to an elevated blood lead level in a resident child are also emergency renovations. Emergency renovations other than interim controls are also exempt from the warning sign, containment, waste handling, training, and certification requirements in §§745.85, 745.89, and 745.90 to the extent necessary to respond to the emergency. Emergency renovations are not exempt from the cleaning requirements of §745.85(a)(5), which must be performed by certified renovators or individuals trained in accordance with §745.90(b)(2), the cleaning verification requirements of §745.85(b), which must be performed by certified renovators, and the recordkeeping requirements of §745.86(b)(6) and (b)(7).

[73 FR 21758, Apr. 22, 2008, as amended at 75 FR 24818, May 6, 2010; 76 FR 47938, Aug. 5, 2011]

§745.83 Definitions.

For purposes of this part, the definitions in §745.103 as well as the following definitions apply:

Administrator means the Administrator of the Environmental Protection Agency.

Child-occupied facility means a building, or portion of a building, constructed prior to 1978, visited regularly by the same child, under 6 years of age, on at least two different days within any week (Sunday through Saturday period), provided that each day's visit lasts at least 3 hours and the combined weekly visits last at least 6 hours, and the combined annual visits last at least 60 hours. Child-occupied facilities may include, but are not limited to, day care centers, preschools and kindergarten classrooms. Child-occupied facilities may be located in target housing or in public or commercial buildings. With respect to common areas in public or commercial buildings that contain child-occupied facilities, the child-occupied facility encompasses only those common areas that are routinely used by children under age 6, such as restrooms and cafeterias. Common areas that children under age 6 only pass through, such as hallways, stairways, and garages are not included. In addition, with respect to exteriors of public or commercial buildings that contain child-occupied facilities, the child-occupied facility encompasses only the exterior sides of the building that are immediately adjacent to the child-occupied facility or the common areas routinely used by children under age 6.

Cleaning verification card means a card developed and distributed, or otherwise approved, by EPA for the purpose of determining, through comparison of wet and dry disposable cleaning cloths with the card, whether post-renovation cleaning has been properly completed.

Component or building component means specific design or structural elements or fixtures of a building or residential dwelling that are distinguished from each other by form, function, and location. These include, but are not limited to, interior components such as: Ceilings, crown molding, walls, chair rails, doors, door trim, floors, fireplaces, radiators and other heating units, shelves, shelf supports, stair treads, stair risers, stair stringers, newel posts, railing caps, balustrades,

windows and trim (including sashes, window heads, jambs, sills or stools and troughs), built in cabinets, columns, beams, bathroom vanities, counter tops, and air conditioners; and exterior components such as: Painted roofing, chimneys, flashing, gutters and downspouts, ceilings, soffits, fascias, rake boards, cornerboards, bulkheads, doors and door trim, fences, floors, joists, lattice work, railings and railing caps, siding, handrails, stair risers and treads, stair stringers, columns, balustrades, windowsills or stools and troughs, casings, sashes and wells, and air conditioners.

Dry disposable cleaning cloth means a commercially available dry, electrostatically charged, white disposable cloth designed to be used for cleaning hard surfaces such as uncarpeted floors or counter tops.

Firm means a company, partnership, corporation, sole proprietorship or individual doing business, association, or other business entity; a Federal, State, Tribal, or local government agency; or a nonprofit organization.

HEPA vacuum means a vacuum cleaner which has been designed with a high-efficiency particulate air (HEPA) filter as the last filtration stage. A HEPA filter is a filter that is capable of capturing particulates of 0.3 microns with 99.97% efficiency. The vacuum cleaner must be designed so that all the air drawn into the machine is expelled through the HEPA filter with none of the air leaking past it. HEPA vacuums must be operated and maintained in accordance with the manufacturer's instructions.

Interim controls means a set of measures designed to temporarily reduce human exposure or likely exposure to lead-based paint hazards, including specialized cleaning, repairs, maintenance, painting, temporary containment, ongoing monitoring of lead-based paint hazards or potential hazards, and the establishment and operation of management and resident education programs.

Minor repair and maintenance activities are activities, including minor heating, ventilation or air conditioning work, electrical work, and plumbing, that disrupt 6 square feet or less of painted surface per room for interior activities or 20 square feet or less of painted surface for exterior activities where none of the work practices prohibited or restricted by § 745.85(a)(3) are used and where the work does not involve window replacement or demolition of painted surface areas. When removing painted components, or portions of painted components, the entire surface area removed is the amount of painted surface disturbed. Jobs, other than emergency renovations, performed in the same room within the same 30 days must be considered the same job for the purpose of determining whether the job is a minor repair and maintenance activity.

Painted surface means a component surface covered in whole or in part with paint or other surface coatings.

Pamphlet means the EPA pamphlet titled *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools* developed under section 406(a) of TSCA for use in complying with section 406(b) of TSCA, or any State or Tribal pamphlet approved by EPA pursuant to 40 CFR 745.326 that is developed for the same purpose. This includes reproductions of the pamphlet when copied in full and without revision or deletion of material from the pamphlet (except for the addition or revision of State or local sources of information). Before December 22, 2008, the term ''pamphlet'' also means any pamphlet developed by EPA under section 406(a) of TSCA or any State or Tribal pamphlet approved by EPA pursuant to § 745.326.

Person means any natural or judicial person including any individual, corporation, partnership, or association; any Indian Tribe, State, or political subdivision thereof; any interstate body; and any department, agency, or instrumentality of the Federal Government.

Recognized test kit means a commercially available kit recognized by EPA under § 745.88 as being capable of allowing a user to determine the presence of lead at levels equal to or in excess of 1.0 milligrams per square centimeter, or more than 0.5% lead by weight, in a paint chip, paint powder, or painted surface.

Renovation means the modification of any existing structure, or portion

thereof, that results in the disturbance of painted surfaces, unless that activity is performed as part of an abatement as defined by this part (40 CFR 745.223). The term renovation includes (but is not limited to): The removal, modification or repair of painted surfaces or painted components (e.g., modification of painted doors, surface restoration, window repair, surface preparation activity (such as sanding, scraping, or other such activities that may generate paint dust)); the removal of building components (e.g., walls, ceilings, plumbing, windows); weatherization projects (e.g., cutting holes in painted surfaces to install blown-in insulation or to gain access to attics, planing thresholds to install weatherstripping), and interim controls that disturb painted surfaces. A renovation performed for the purpose of converting a building, or part of a building, into target housing or a child-occupied facility is a renovation under this subpart. The term renovation does not include minor repair and maintenance activities.

Renovator means an individual who either performs or directs workers who perform renovations. A certified renovator is a renovator who has successfully completed a renovator course accredited by EPA or an EPA-authorized State or Tribal program.

Training hour means at least 50 minutes of actual learning, including, but not limited to, time devoted to lecture, learning activities, small group activities, demonstrations, evaluations, and hands-on experience.

Wet disposable cleaning cloth means a commercially available, pre-moistened white disposable cloth designed to be used for cleaning hard surfaces such as uncarpeted floors or counter tops.

Vertical containment means a vertical barrier consisting of plastic sheeting or other impermeable material over scaffolding or a rigid frame, or an equivalent system of containing the work area. Vertical containment is required for some exterior renovations but it may be used on any renovation.

Wet mopping system means a device with the following characteristics: A long handle, a mop head designed to be used with disposable absorbent cleaning pads, a reservoir for cleaning solution, and a built-in mechanism for distributing or spraying the cleaning solution onto a floor, or a method of equivalent efficacy.

Work area means the area that the certified renovator establishes to contain the dust and debris generated by a renovation.

[63 FR 29919, June 1, 1998, as amended at 73 FR 21758, Apr. 22, 2008; 76 FR 47938, Aug. 5, 2011]

§ 745.84 Information distribution requirements.

(a) *Renovations in dwelling units.* No more than 60 days before beginning renovation activities in any residential dwelling unit of target housing, the firm performing the renovation must:

(1) Provide the owner of the unit with the pamphlet, and comply with one of the following:

(i) Obtain, from the owner, a written acknowledgment that the owner has received the pamphlet.

(ii) Obtain a certificate of mailing at least 7 days prior to the renovation.

(2) In addition to the requirements in paragraph (a)(1) of this section, if the owner does not occupy the dwelling unit, provide an adult occupant of the unit with the pamphlet, and comply with one of the following:

(i) Obtain, from the adult occupant, a written acknowledgment that the occupant has received the pamphlet; or certify in writing that a pamphlet has been delivered to the dwelling and that the firm performing the renovation has been unsuccessful in obtaining a written acknowledgment from an adult occupant. Such certification must include the address of the unit undergoing renovation, the date and method of delivery of the pamphlet, names of the persons delivering the pamphlet, reason for lack of acknowledgment (e.g., occupant refuses to sign, no adult occupant available), the signature of a representative of the firm performing the renovation, and the date of signature.

(ii) Obtain a certificate of mailing at least 7 days prior to the renovation.

(b) *Renovations in common areas.* No more than 60 days before beginning renovation activities in common areas of multi-unit target housing, the firm performing the renovation must:

(1) Provide the owner with the pamphlet, and comply with one of the following:

(i) Obtain, from the owner, a written acknowledgment that the owner has received the pamphlet.

(ii) Obtain a certificate of mailing at least 7 days prior to the renovation.

(2) *Comply with one of the following.* (i) Notify in writing, or ensure written notification of, each affected unit and make the pamphlet available upon request prior to the start of renovation. Such notification shall be accomplished by distributing written notice to each affected unit. The notice shall describe the general nature and locations of the planned renovation activities; the expected starting and ending dates; and a statement of how the occupant can obtain the pamphlet and a copy of the records required by §745.86(c) and (d), at no cost to the occupants, or

(ii) While the renovation is ongoing, post informational signs describing the general nature and locations of the renovation and the anticipated completion date. These signs must be posted in areas where they are likely to be seen by the occupants of all of the affected units. The signs must be accompanied by a posted copy of the pamphlet or information on how interested occupants can review a copy of the pamphlet or obtain a copy from the renovation firm at no cost to occupants. The signs must also include information on how interested occupants can review a copy of the records required by §745.86(c) and (d) or obtain a copy from the renovation firm at no cost to the occupants.

(3) Prepare, sign, and date a statement describing the steps performed to notify all occupants of the intended renovation activities and to provide the pamphlet.

(4) If the scope, locations, or expected starting and ending dates of the planned renovation activities change after the initial notification, and the firm provided written initial notification to each affected unit, the firm performing the renovation must provide further written notification to the owners and occupants providing revised information on the ongoing or planned activities. This subsequent notification must be provided before the firm performing the renovation initiates work beyond that which was described in the original notice.

(c) *Renovations in child-occupied facilities.* No more than 60 days before beginning renovation activities in any child-occupied facility, the firm performing the renovation must:

(1)(i) Provide the owner of the building with the pamphlet, and comply with one of the following:

(A) Obtain, from the owner, a written acknowledgment that the owner has received the pamphlet.

(B) Obtain a certificate of mailing at least 7 days prior to the renovation.

(ii) If the child-occupied facility is not the owner of the building, provide an adult representative of the child-occupied facility with the pamphlet, and comply with one of the following:

(A) Obtain, from the adult representative, a written acknowledgment that the adult representative has received the pamphlet; or certify in writing that a pamphlet has been delivered to the facility and that the firm performing the renovation has been unsuccessful in obtaining a written acknowledgment from an adult representative. Such certification must include the address of the child-occupied facility undergoing renovation, the date and method of delivery of the pamphlet, names of the persons delivering the pamphlet, reason for lack of acknowledgment (e.g., representative refuses to sign), the signature of a representative of the firm performing the renovation, and the date of signature.

(B) Obtain a certificate of mailing at least 7 days prior to the renovation.

(2) Provide the parents and guardians of children using the child-occupied facility with the pamphlet, information describing the general nature and locations of the renovation and the anticipated completion date, and information on how interested parents or guardians of children frequenting the child-occupied facility can review a copy of the records required by §745.86(c) and (d) or obtain a copy from the renovation firm at no cost to the occupants by complying with one of the following:

(i) Mail or hand-deliver the pamphlet and the renovation information to each

parent or guardian of a child using the child-occupied facility.

(ii) While the renovation is ongoing, post informational signs describing the general nature and locations of the renovation and the anticipated completion date. These signs must be posted in areas where they can be seen by the parents or guardians of the children frequenting the child-occupied facility. The signs must be accompanied by a posted copy of the pamphlet or information on how interested parents or guardians of children frequenting the child-occupied facility can review a copy of the pamphlet or obtain a copy from the renovation firm at no cost to the parents or guardians. The signs must also include information on how interested parents or guardians of children frequenting the child-occupied facility can review a copy of the records required by § 745.86(c) and (d) or obtain a copy from the renovation firm at no cost to the parents or guardians.

(3) The renovation firm must prepare, sign, and date a statement describing the steps performed to notify all parents and guardians of the intended renovation activities and to provide the pamphlet.

(d) *Written acknowledgment.* The written acknowledgments required by paragraphs (a)(1)(i), (a)(2)(i), (b)(1)(i), (c)(1)(i)(A), and (c)(1)(ii)(A) of this section must:

(1) Include a statement recording the owner or occupant's name and acknowledging receipt of the pamphlet prior to the start of renovation, the address of the unit undergoing renovation, the signature of the owner or occupant as applicable, and the date of signature.

(2) Be either a separate sheet or part of any written contract or service agreement for the renovation.

(3) Be written in the same language as the text of the contract or agreement for the renovation or, in the case of non-owner occupied target housing, in the same language as the lease or rental agreement or the pamphlet.

[63 FR 29919, June 1, 1998. Redesignated and amended at 73 FR 21760, Apr. 22, 2008; 75 FR 24818, May 6, 2010]

§ 745.85 Work practice standards.

(a) *Standards for renovation activities.* Renovations must be performed by certified firms using certified renovators as directed in § 745.89. The responsibilities of certified firms are set forth in § 745.89(d) and the responsibilities of certified renovators are set forth in § 745.90(b).

(1) *Occupant protection.* Firms must post signs clearly defining the work area and warning occupants and other persons not involved in renovation activities to remain outside of the work area. To the extent practicable, these signs must be in the primary language of the occupants. These signs must be posted before beginning the renovation and must remain in place and readable until the renovation and the post-renovation cleaning verification have been completed. If warning signs have been posted in accordance with 24 CFR 35.1345(b)(2) or 29 CFR 1926.62(m), additional signs are not required by this section.

(2) *Containing the work area.* Before beginning the renovation, the firm must isolate the work area so that no dust or debris leaves the work area while the renovation is being performed. In addition, the firm must maintain the integrity of the containment by ensuring that any plastic or other impermeable materials are not torn or displaced, and taking any other steps necessary to ensure that no dust or debris leaves the work area while the renovation is being performed. The firm must also ensure that containment is installed in such a manner that it does not interfere with occupant and worker egress in an emergency.

(i) *Interior renovations.* The firm must:

(A) Remove all objects from the work area, including furniture, rugs, and window coverings, or cover them with plastic sheeting or other impermeable material with all seams and edges taped or otherwise sealed.

(B) Close and cover all ducts opening in the work area with taped-down plastic sheeting or other impermeable material.

(C) Close windows and doors in the work area. Doors must be covered with plastic sheeting or other impermeable material. Doors used as an entrance to

the work area must be covered with plastic sheeting or other impermeable material in a manner that allows workers to pass through while confining dust and debris to the work area.

(D) Cover the floor surface, including installed carpet, with taped-down plastic sheeting or other impermeable material in the work area 6 feet beyond the perimeter of surfaces undergoing renovation or a sufficient distance to contain the dust, whichever is greater. Floor containment measures may stop at the edge of the vertical barrier when using a vertical containment system consisting of impermeable barriers that extend from the floor to the ceiling and are tightly sealed at joints with the floor, ceiling and walls.

(E) Use precautions to ensure that all personnel, tools, and other items, including the exteriors of containers of waste, are free of dust and debris before leaving the work area.

(ii) *Exterior renovations.* The firm must:

(A) Close all doors and windows within 20 feet of the renovation. On multistory buildings, close all doors and windows within 20 feet of the renovation on the same floor as the renovation, and close all doors and windows on all floors below that are the same horizontal distance from the renovation.

(B) Ensure that doors within the work area that will be used while the job is being performed are covered with plastic sheeting or other impermeable material in a manner that allows workers to pass through while confining dust and debris to the work area.

(C) Cover the ground with plastic sheeting or other disposable impermeable material extending 10 feet beyond the perimeter of surfaces undergoing renovation or a sufficient distance to collect falling paint debris, whichever is greater, unless the property line prevents 10 feet of such ground covering. Ground containment measures may stop at the edge of the vertical barrier when using a vertical containment system.

(D) If the renovation will affect surfaces within 10 feet of the property line, the renovation firm must erect vertical containment or equivalent extra precautions in containing the work area to ensure that dust and debris from the renovation does not contaminate adjacent buildings or migrate to adjacent properties. Vertical containment or equivalent extra precautions in containing the work area may also be necessary in other situations in order to prevent contamination of other buildings, other areas of the property, or adjacent buildings or properties.

(3) *Prohibited and restricted practices.* The work practices listed below are prohibited or restricted during a renovation as follows:

(i) Open-flame burning or torching of painted surfaces is prohibited.

(ii) The use of machines designed to remove paint or other surface coatings through high speed operation such as sanding, grinding, power planing, needle gun, abrasive blasting, or sandblasting, is prohibited on painted surfaces unless such machines have shrouds or containment systems and are equipped with a HEPA vacuum attachment to collect dust and debris at the point of generation. Machines must be operated so that no visible dust or release of air occurs outside the shroud or containment system.

(iii) Operating a heat gun on painted surfaces is permitted only at temperatures below 1,100 degrees Fahrenheit.

(4) *Waste from renovations.* (i) Waste from renovation activities must be contained to prevent releases of dust and debris before the waste is removed from the work area for storage or disposal. If a chute is used to remove waste from the work area, it must be covered.

(ii) At the conclusion of each work day and at the conclusion of the renovation, waste that has been collected from renovation activities must be stored under containment, in an enclosure, or behind a barrier that prevents release of dust and debris out of the work area and prevents access to dust and debris.

(iii) When the firm transports waste from renovation activities, the firm must contain the waste to prevent release of dust and debris.

(5) *Cleaning the work area.* After the renovation has been completed, the firm must clean the work area until no dust, debris or residue remains.

(i) *Interior and exterior renovations.* The firm must:

(A) Collect all paint chips and debris and, without dispersing any of it, seal this material in a heavy-duty bag.

(B) Remove the protective sheeting. Mist the sheeting before folding it, fold the dirty side inward, and either tape shut to seal or seal in heavy-duty bags. Sheeting used to isolate contaminated rooms from non-contaminated rooms must remain in place until after the cleaning and removal of other sheeting. Dispose of the sheeting as waste.

(ii) *Additional cleaning for interior renovations.* The firm must clean all objects and surfaces in the work area and within 2 feet of the work area in the following manner, cleaning from higher to lower:

(A) *Walls.* Clean walls starting at the ceiling and working down to the floor by either vacuuming with a HEPA vacuum or wiping with a damp cloth.

(B) *Remaining surfaces.* Thoroughly vacuum all remaining surfaces and objects in the work area, including furniture and fixtures, with a HEPA vacuum. The HEPA vacuum must be equipped with a beater bar when vacuuming carpets and rugs.

(C) Wipe all remaining surfaces and objects in the work area, except for carpeted or upholstered surfaces, with a damp cloth. Mop uncarpeted floors thoroughly, using a mopping method that keeps the wash water separate from the rinse water, such as the 2-bucket mopping method, or using a wet mopping system.

(b) *Standards for post-renovation cleaning verification*—(1) *Interiors.* (i) A certified renovator must perform a visual inspection to determine whether dust, debris or residue is still present. If dust, debris or residue is present, these conditions must be removed by re-cleaning and another visual inspection must be performed.

(ii) After a successful visual inspection, a certified renovator must:

(A) Verify that each windowsill in the work area has been adequately cleaned, using the following procedure.

(*1*) Wipe the windowsill with a wet disposable cleaning cloth that is damp to the touch. If the cloth matches or is lighter than the cleaning verification card, the windowsill has been adequately cleaned.

(*2*) If the cloth does not match and is darker than the cleaning verification card, re-clean the windowsill as directed in paragraphs (a)(5)(ii)(B) and (a)(5)(ii)(C) of this section, then either use a new cloth or fold the used cloth in such a way that an unused surface is exposed, and wipe the surface again. If the cloth matches or is lighter than the cleaning verification card, that windowsill has been adequately cleaned.

(*3*) If the cloth does not match and is darker than the cleaning verification card, wait for 1 hour or until the surface has dried completely, whichever is longer.

(*4*)After waiting for the windowsill to dry, wipe the windowsill with a dry disposable cleaning cloth. After this wipe, the windowsill has been adequately cleaned.

(B) Wipe uncarpeted floors and countertops within the work area with a wet disposable cleaning cloth. Floors must be wiped using an application device with a long handle and a head to which the cloth is attached. The cloth must remain damp at all times while it is being used to wipe the surface for post-renovation cleaning verification. If the surface within the work area is greater than 40 square feet, the surface within the work area must be divided into roughly equal sections that are each less than 40 square feet. Wipe each such section separately with a new wet disposable cleaning cloth. If the cloth used to wipe each section of the surface within the work area matches the cleaning verification card, the surface has been adequately cleaned.

(*1*) If the cloth used to wipe a particular surface section does not match the cleaning verification card, re-clean that section of the surface as directed in paragraphs (a)(5)(ii)(B) and (a)(5)(ii)(C) of this section, then use a new wet disposable cleaning cloth to wipe that section again. If the cloth matches the cleaning verification card, that section of the surface has been adequately cleaned.

(*2*) If the cloth used to wipe a particular surface section does not match the cleaning verification card after the surface has been re-cleaned, wait for 1

hour or until the entire surface within the work area has dried completely, whichever is longer.

(*3*) After waiting for the entire surface within the work area to dry, wipe each section of the surface that has not yet achieved post-renovation cleaning verification with a dry disposable cleaning cloth. After this wipe, that section of the surface has been adequately cleaned.

(iii) When the work area passes the post-renovation cleaning verification, remove the warning signs.

(2) *Exteriors.* A certified renovator must perform a visual inspection to determine whether dust, debris or residue is still present on surfaces in and below the work area, including windowsills and the ground. If dust, debris or residue is present, these conditions must be eliminated and another visual inspection must be performed. When the area passes the visual inspection, remove the warning signs.

(c) *Optional dust clearance testing.* Cleaning verification need not be performed if the contract between the renovation firm and the person contracting for the renovation or another Federal, State, Territorial, Tribal, or local law or regulation requires:

(1) The renovation firm to perform dust clearance sampling at the conclusion of a renovation covered by this subpart.

(2) The dust clearance samples are required to be collected by a certified inspector, risk assessor or dust sampling technician.

(3) The renovation firm is required to re-clean the work area until the dust clearance sample results are below the clearance standards in §745.227(e)(8) or any applicable State, Territorial, Tribal, or local standard.

(d) *Activities conducted after post-renovation cleaning verification.* Activities that do not disturb paint, such as applying paint to walls that have already been prepared, are not regulated by this subpart if they are conducted after post-renovation cleaning verification has been performed.

[73 FR 21761, Apr. 22, 2008, as amended at 76 FR 47938, Aug. 5, 2011]

§745.86 Recordkeeping and reporting requirements.

(a) Firms performing renovations must retain and, if requested, make available to EPA all records necessary to demonstrate compliance with this subpart for a period of 3 years following completion of the renovation. This 3–year retention requirement does not supersede longer obligations required by other provisions for retaining the same documentation, including any applicable State or Tribal laws or regulations.

(b) Records that must be retained pursuant to paragraph (a) of this section shall include (where applicable):

(1) Records or reports certifying that a determination had been made that lead-based paint was not present on the components affected by the renovation, as described in §745.82(a). These records or reports include:

(i) Reports prepared by a certified inspector or certified risk assessor (certified pursuant to either Federal regulations at §745.226 or an EPA-authorized State or Tribal certification program).

(ii) Records prepared by a certified renovator after using EPA-recognized test kits, including an identification of the manufacturer and model of any test kits used, a description of the components that were tested including their locations, and the result of each test kit used.

(iii) Records prepared by a certified renovator after collecting paint chip samples, including a description of the components that were tested including their locations, the name and address of the NLLAP-recognized entity performing the analysis, and the results for each sample.

(2) Signed and dated acknowledgments of receipt as described in §745.84(a)(1)(i), (a)(2)(i), (b)(1)(i), (c)(1)(i)(A), and (c)(1)(ii)(A).

(3) Certifications of attempted delivery as described in §745.84(a)(2)(i) and (c)(1)(ii)(A).

(4) Certificates of mailing as described in §745.84(a)(1)(ii), (a)(2)(ii), (b)(1)(ii), (c)(1)(i)(B), and (c)(1)(ii)(B).

(5) Records of notification activities performed regarding common area renovations, as described in §745.84(b)(3)

and (b)(4), and renovations in child-occupied facilities, as described in §745.84(c)(2).

(6) Documentation of compliance with the requirements of §745.85, including documentation that a certified renovator was assigned to the project, that the certified renovator provided on-the-job training for workers used on the project, that the certified renovator performed or directed workers who performed all of the tasks described in §745.85(a), and that the certified renovator performed the post-renovation cleaning verification described in §745.85(b). If the renovation firm was unable to comply with all of the requirements of this rule due to an emergency as defined in §745.82, the firm must document the nature of the emergency and the provisions of the rule that were not followed. This documentation must include a copy of the certified renovator's training certificate, and a certification by the certified renovator assigned to the project that:

(i) Training was provided to workers (topics must be identified for each worker).

(ii) Warning signs were posted at the entrances to the work area.

(iii) If test kits were used, that the specified brand of kits was used at the specified locations and that the results were as specified.

(v) The work area was contained by:

(A) Removing or covering all objects in the work area (interiors).

(B) Closing and covering all HVAC ducts in the work area (interiors).

(C) Closing all windows in the work area (interiors) or closing all windows in and within 20 feet of the work area (exteriors).

(D) Closing and sealing all doors in the work area (interiors) or closing and sealing all doors in and within 20 feet of the work area (exteriors).

(E) Covering doors in the work area that were being used to allow passage but prevent spread of dust.

(F) Covering the floor surface, including installed carpet, with taped-down plastic sheeting or other impermeable material in the work area 6 feet beyond the perimeter of surfaces undergoing renovation or a sufficient distance to contain the dust, whichever is greater (interiors) or covering the ground with plastic sheeting or other disposable impermeable material anchored to the building extending 10 feet beyond the perimeter of surfaces undergoing renovation or a sufficient distance to collect falling paint debris, whichever is greater, unless the property line prevents 10 feet of such ground covering, weighted down by heavy objects (exteriors).

(G) Installing (if necessary) vertical containment to prevent migration of dust and debris to adjacent property (exteriors).

(iv) If paint chip samples were collected, that the samples were collected at the specified locations, that the specified NLLAP-recognized laboratory analyzed the samples, and that the results were as specified.

(vi) Waste was contained on-site and while being transported off-site.

(vii) The work area was properly cleaned after the renovation by:

(A) Picking up all chips and debris, misting protective sheeting, folding it dirty side inward, and taping it for removal.

(B) Cleaning the work area surfaces and objects using a HEPA vacuum and/or wet cloths or mops (interiors).

(viii) The certified renovator performed the post-renovation cleaning verification (the results of which must be briefly described, including the number of wet and dry cloths used).

(c)(1) When the final invoice for the renovation is delivered or within 30 days of the completion of the renovation, whichever is earlier, the renovation firm must provide information pertaining to compliance with this subpart to the following persons:

(i) The owner of the building; and, if different,

(ii) An adult occupant of the residential dwelling, if the renovation took place within a residential dwelling, or an adult representative of the child-occupied facility, if the renovation took place within a child-occupied facility.

(2) When performing renovations in common areas of multi-unit target housing, renovation firms must post the information required by this subpart or instructions on how interested occupants can obtain a copy of this information. This information must be

posted in areas where it is likely to be seen by the occupants of all of the affected units.

(3) The information required to be provided by paragraph (c) of this section may be provided by completing the sample form titled ''Sample Renovation Recordkeeping Checklist'' or a similar form containing the test kit information required by §745.86(b)(1)(ii) and the training and work practice compliance information required by §745.86(b)(6).

(d) If dust clearance sampling is performed in lieu of cleaning verification as permitted by §745.85(c), the renovation firm must provide, when the final invoice for the renovation is delivered or within 30 days of the completion of the renovation, whichever is earlier, a copy of the dust sampling report to:

(1) The owner of the building; and, if different,

(2) An adult occupant of the residential dwelling, if the renovation took place within a residential dwelling, or an adult representative of the child-occupied facility, if the renovation took place within a child-occupied facility.

(3) When performing renovations in common areas of multi-unit target housing, renovation firms must post these dust sampling reports or information on how interested occupants of the housing being renovated can obtain a copy of the report. This information must be posted in areas where they are likely to be seen by the occupants of all of the affected units.

[73 FR 21761, Apr. 22, 2008, as amended at 75 FR 24819, May 6, 2010; 76 FR 47939, Aug. 5, 2011]

§745.87 Enforcement and inspections.

(a) Failure or refusal to comply with any provision of this subpart is a violation of TSCA section 409 (15 U.S.C. 2689).

(b) Failure or refusal to establish and maintain records or to make available or permit access to or copying of records, as required by this subpart, is a violation of TSCA sections 15 and 409 (15 U.S.C. 2614 and 2689).

(c) Failure or refusal to permit entry or inspection as required by 40 CFR 745.87 and TSCA section 11 (15 U.S.C. 2610) is a violation of sections 15 and 409 (15 U.S.C. 2614 and 2689).

(d) Violators may be subject to civil and criminal sanctions pursuant to TSCA section 16 (15 U.S.C. 2615) for each violation.

(e) Lead-based paint is assumed to be present at renovations covered by this subpart. EPA may conduct inspections and issue subpoenas pursuant to the provisions of TSCA section 11 (15 U.S.C. 2610) to ensure compliance with this subpart.

[63 FR 29919, June 1, 1998, as amended at 73 FR 21763, Apr. 22, 2008]

§745.88 Recognized test kits.

(a) Effective June 23, 2008, EPA recognizes the test kits that have been determined by National Institute of Standards and Technology research to meet the negative response criteria described in paragraph (c)(1) of this section. This recognition will last until EPA publicizes its recognition of the first test kit that meets both the negative response and positive response criteria in paragraph (c) of this section.

(b) No other test kits will be recognized until they are tested through EPA's Environmental Technology Verification Program or other equivalent EPA approved testing program.

(1) Effective September 1, 2008, to initiate the testing process, a test kit manufacturer must submit a sufficient number of kits, along with the instructions for using the kits, to EPA. The test kit manufacturer should first visit the following website for information on where to apply: *http://www.epa.gov/etv/howtoapply.html*.

(2) After the kit has been tested through the Environmental Technology Verification Program or other equivalent approved EPA testing program, EPA will review the report to determine whether the required criteria have been met.

(3) Before September 1, 2010, test kits must meet only the negative response criteria in paragraph (c)(1) of this section. The recognition of kits that meet only this criteria will last until EPA publicizes its recognition of the first test kits that meets both of the criteria in paragraph (c) of this section.

(4) After September 1, 2010, test kits must meet both of the criteria in paragraph (c) of this section.

(5) If the report demonstrates that the kit meets the required criteria, EPA will issue a notice of recognition to the kit manufacturer, provide them with the report, and post the information on EPA's website.

(6) If the report demonstrates that the kit does not meet the required criteria, EPA will notify the kit manufacturer and provide them with the report.

(c) *Response criteria*—(1) *Negative response criteria*. For paint containing lead at or above the regulated level, 1.0 mg/cm^2 or 0.5% by weight, a demonstrated probability (with 95% confidence) of a negative response less than or equal to 5% of the time.

(2) *Positive response criteria*. For paint containing lead below the regulated level, 1.0 mg/cm^2 or 0.5% by weight, a demonstrated probability (with 95% confidence) of a positive response less than or equal to 10% of the time.

[73 FR 21763, Apr. 22, 2008]

§ 745.89 Firm certification.

(a) *Initial certification*. (1) Firms that perform renovations for compensation must apply to EPA for certification to perform renovations or dust sampling. To apply, a firm must submit to EPA a completed ''Application for Firms,'' signed by an authorized agent of the firm, and pay at least the correct amount of fees. If a firm pays more than the correct amount of fees, EPA will reimburse the firm for the excess amount.

(2) After EPA receives a firm's application, EPA will take one of the following actions within 90 days of the date the application is received:

(i) EPA will approve a firm's application if EPA determines that it is complete and that the environmental compliance history of the firm, its principals, or its key employees does not show an unwillingness or inability to maintain compliance with environmental statutes or regulations. An application is complete if it contains all of the information requested on the form and includes at least the correct amount of fees. When EPA approves a firm's application, EPA will issue the firm a certificate with an expiration date not more than 5 years from the date the application is approved. EPA certification allows the firm to perform renovations covered by this section in any State or Indian Tribal area that does not have a renovation program that is authorized under subpart Q of this part.

(ii) EPA will request a firm to supplement its application if EPA determines that the application is incomplete. If EPA requests a firm to supplement its application, the firm must submit the requested information or pay the additional fees within 30 days of the date of the request.

(iii) EPA will not approve a firm's application if the firm does not supplement its application in accordance with paragraph (a)(2)(ii) of this section or if EPA determines that the environmental compliance history of the firm, its principals, or its key employees demonstrates an unwillingness or inability to maintain compliance with environmental statutes or regulations. EPA will send the firm a letter giving the reason for not approving the application. EPA will not refund the application fees. A firm may reapply for certification at any time by filing a new, complete application that includes the correct amount of fees.

(b) *Re-certification*. To maintain its certification, a firm must be re-certified by EPA every 5 years.

(1) *Timely and complete application*. To be re-certified, a firm must submit a complete application for re-certification. A complete application for re-certification includes a completed ''Application for Firms'' which contains all of the information requested by the form and is signed by an authorized agent of the firm, noting on the form that it is submitted as a re-certification. A complete application must also include at least the correct amount of fees. If a firm pays more than the correct amount of fees, EPA will reimburse the firm for the excess amount.

(i) An application for re-certification is timely if it is postmarked 90 days or more before the date the firm's current certification expires. If the firm's application is complete and timely, the firm's current certification will remain in effect until its expiration date or until EPA has made a final decision to

approve or disapprove the re-certification application, whichever is later.

(ii) If the firm submits a complete re-certification application less than 90 days before its current certification expires, and EPA does not approve the application before the expiration date, the firm's current certification will expire and the firm will not be able to conduct renovations until EPA approves its re-certification application.

(iii) If the firm fails to obtain recertification before the firm's current certification expires, the firm must not perform renovations or dust sampling until it is certified anew pursuant to paragraph (a) of this section.

(2) *EPA action on an application.* After EPA receives a firm's application for re-certification, EPA will review the application and take one of the following actions within 90 days of receipt:

(i) EPA will approve a firm's application if EPA determines that it is timely and complete and that the environmental compliance history of the firm, its principals, or its key employees does not show an unwillingness or inability to maintain compliance with environmental statutes or regulations. When EPA approves a firm's application for re-certification, EPA will issue the firm a new certificate with an expiration date 5 years from the date that the firm's current certification expires. EPA certification allows the firm to perform renovations or dust sampling covered by this section in any State or Indian Tribal area that does not have a renovation program that is authorized under subpart Q of this part.

(ii) EPA will request a firm to supplement its application if EPA determines that the application is incomplete.

(iii) EPA will not approve a firm's application if it is not received or is not complete as of the date that the firm's current certification expires, or if EPA determines that the environmental compliance history of the firm, its principals, or its key employees demonstrates an unwillingness or inability to maintain compliance with environmental statutes or regulations. EPA will send the firm a letter giving the reason for not approving the application. EPA will not refund the application fees. A firm may reapply for certification at any time by filing a new application and paying the correct amount of fees.

(c) *Amendment of certification.* A firm must amend its certification within 90 days of the date a change occurs to information included in the firm's most recent application. If the firm fails to amend its certification within 90 days of the date the change occurs, the firm may not perform renovations or dust sampling until its certification is amended.

(1) To amend a certification, a firm must submit a completed ''Application for Firms,'' signed by an authorized agent of the firm, noting on the form that it is submitted as an amendment and indicating the information that has changed. The firm must also pay at least the correct amount of fees.

(2) If additional information is needed to process the amendment, or the firm did not pay the correct amount of fees, EPA will request the firm to submit the necessary information or fees. The firm's certification is not amended until the firm complies with the request.

(3) Amending a certification does not affect the certification expiration date.

(d) *Firm responsibilities.* Firms performing renovations must ensure that:

(1) All individuals performing renovation activities on behalf of the firm are either certified renovators or have been trained by a certified renovator in accordance with § 745.90.

(2) A certified renovator is assigned to each renovation performed by the firm and discharges all of the certified renovator responsibilities identified in § 745.90.

(3) All renovations performed by the firm are performed in accordance with the work practice standards in § 745.85.

(4) The pre-renovation education requirements of § 745.84 have been performed.

(5) The recordkeeping requirements of § 745.86 are met.

[73 FR 21764, Apr. 22, 2008]

§ 745.90 Renovator certification and dust sampling technician certification.

(a) *Renovator certification and dust sampling technician certification.* (1) To

become a certified renovator or certified dust sampling technician, an individual must successfully complete the appropriate course accredited by EPA under §745.225 or by a State or Tribal program that is authorized under subpart Q of this part. The course completion certificate serves as proof of certification. EPA renovator certification allows the certified individual to perform renovations covered by this section in any State or Indian Tribal area that does not have a renovation program that is authorized under subpart Q of this part. EPA dust sampling technician certification allows the certified individual to perform dust clearance sampling under §745.85(c) in any State or Indian Tribal area that does not have a renovation program that is authorized under subpart Q of this part.

(2) Individuals who have successfully completed an accredited abatement worker or supervisor course, or individuals who successfully completed an EPA, HUD, or EPA/HUD model renovation training course before October 4, 2011 may take an accredited refresher renovator training course that includes hands-on training in lieu of the initial renovator training course to become a certified renovator.

(3) Individuals who have successfully completed an accredited lead-based paint inspector or risk assessor course October 4, 2011 may take an accredited refresher dust sampling technician course in lieu of the initial training to become a certified dust sampling technician. Individuals who are currently certified as lead-based paint inspectors or risk assessors may act as certified dust sampling technicians without further training.

(4) To maintain renovator certification or dust sampling technician certification, an individual must complete a renovator or dust sampling technician refresher course accredited by EPA under §745.225 or by a State or Tribal program that is authorized under subpart Q of this part within 5 years of the date the individual completed the initial course described in paragraph (a)(1) of this section. If the individual does not complete a refresher course within this time, the individual must re-take the initial course to become certified again. Individuals who complete a renovator course accredited by EPA or an EPA authorized program on or before March 31, 2010, must complete a renovator refresher course accredited by EPA or an EPA authorized program on or before March 31, 2016, to maintain renovator certification. Individuals who completed a renovator course accredited by EPA or an EPA authorized program between April 1, 2010 and March 31, 2011, will have one year added to their original 5-year certification. Individuals who take a renovator refresher course that does not include hands-on training will be certified for 3 years from the date they complete the training. Individuals who take a refresher training course that includes hands-on training will be certified for 5 years. Individuals who take the renovator refresher without hands-on training must, for their next refresher course, take a refresher course that includes hands-on training to maintain renovator certification.

(b) *Renovator responsibilities.* Certified renovators are responsible for ensuring compliance with §745.85 at all renovations to which they are assigned. A certified renovator:

(1) Must perform all of the tasks described in §745.85(b) and must either perform or direct workers who perform all of the tasks described in §745.85(a).

(2) Must provide training to workers on the work practices required by §745.85(a) that they will be using in performing their assigned tasks.

(3) Must be physically present at the work site when the signs required by §745.85(a)(1) are posted, while the work area containment required by §745.85(a)(2) is being established, and while the work area cleaning required by §745.85(a)(5) is performed.

(4) Must regularly direct work being performed by other individuals to ensure that the work practices required by §745.85(a) are being followed, including maintaining the integrity of the containment barriers and ensuring that dust or debris does not spread beyond the work area.

(5) Must be available, either on-site or by telephone, at all times that renovations are being conducted.

(6) When requested by the party contracting for renovation services, must

use an acceptable test kit to determine whether components to be affected by the renovation contain lead-based paint.

(7) Must have with them at the work site copies of their initial course completion certificate and their most recent refresher course completion certificate.

(8) Must prepare the records required by § 745.86(b)(1)(ii) and (6).

(c) *Dust sampling technician responsibilities.* When performing optional dust clearance sampling under § 745.85(c), a certified dust sampling technician:

(1) Must collect dust samples in accordance with § 745.227(e)(8), must send the collected samples to a laboratory recognized by EPA under TSCA section 405(b), and must compare the results to the clearance levels in accordance with § 745.227(e)(8).

(2) Must have with them at the work site copies of their initial course completion certificate and their most recent refresher course completion certificate.

[73 FR 21765, Apr. 22, 2008, as amended at 75 FR 24819, May 6, 2010; 76 FR 47939, Aug. 5, 2011; 80 FR 20446, Apr. 16, 2015; 81 FR 7995, Feb. 17, 2016]

§ 745.91 Suspending, revoking, or modifying an individual's or firm's certification.

(a)(1) *Grounds for suspending, revoking, or modifying an individual's certification.* EPA may suspend, revoke, or modify an individual's certification if the individual fails to comply with Federal lead-based paint statutes or regulations. EPA may also suspend, revoke, or modify a certified renovator's certification if the renovator fails to ensure that all assigned renovations comply with § 745.85. In addition to an administrative or judicial finding of violation, execution of a consent agreement in settlement of an enforcement action constitutes, for purposes of this section, evidence of a failure to comply with relevant statutes or regulations.

(2) *Grounds for suspending, revoking, or modifying a firm's certification.* EPA may suspend, revoke, or modify a firm's certification if the firm:

(i) Submits false or misleading information to EPA in its application for certification or re-certification.

(ii) Fails to maintain or falsifies records required in § 745.86.

(iii) Fails to comply, or an individual performing a renovation on behalf of the firm fails to comply, with Federal lead-based paint statutes or regulations. In addition to an administrative or judicial finding of violation, execution of a consent agreement in settlement of an enforcement action constitutes, for purposes of this section, evidence of a failure to comply with relevant statutes or regulations.

(b) *Process for suspending, revoking, or modifying certification.* (1) Prior to taking action to suspend, revoke, or modify an individual's or firm's certification, EPA will notify the affected entity in writing of the following:

(i) The legal and factual basis for the proposed suspension, revocation, or modification.

(ii) The anticipated commencement date and duration of the suspension, revocation, or modification.

(iii) Actions, if any, which the affected entity may take to avoid suspension, revocation, or modification, or to receive certification in the future.

(iv) The opportunity and method for requesting a hearing prior to final suspension, revocation, or modification.

(2) If an individual or firm requests a hearing, EPA will:

(i) Provide the affected entity an opportunity to offer written statements in response to EPA's assertions of the legal and factual basis for its proposed action.

(ii) Appoint an impartial official of EPA as Presiding Officer to conduct the hearing.

(3) The Presiding Officer will:

(i) Conduct a fair, orderly, and impartial hearing within 90 days of the request for a hearing.

(ii) Consider all relevant evidence, explanation, comment, and argument submitted.

(iii) Notify the affected entity in writing within 90 days of completion of the hearing of his or her decision and order. Such an order is a final agency action which may be subject to judicial review. The order must contain the commencement date and duration of

the suspension, revocation, or modification.

(4) If EPA determines that the public health, interest, or welfare warrants immediate action to suspend the certification of any individual or firm prior to the opportunity for a hearing, it will:

(i) Notify the affected entity in accordance with paragraph (b)(1)(i) through (b)(1)(iii) of this section, explaining why it is necessary to suspend the entity's certification before an opportunity for a hearing.

(ii) Notify the affected entity of its right to request a hearing on the immediate suspension within 15 days of the suspension taking place and the procedures for the conduct of such a hearing.

(5) Any notice, decision, or order issued by EPA under this section, any transcript or other verbatim record of oral testimony, and any documents filed by a certified individual or firm in a hearing under this section will be available to the public, except as otherwise provided by section 14 of TSCA or by part 2 of this title. Any such hearing at which oral testimony is presented will be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow presentation of information which may be entitled to confidential treatment under section 14 of TSCA or part 2 of this title.

(6) EPA will maintain a publicly available list of entities whose certification has been suspended, revoked, modified, or reinstated.

(7) Unless the decision and order issued under paragraph (b)(3)(iii) of this section specify otherwise:

(i) An individual whose certification has been suspended must take a refresher training course (renovator or dust sampling technician) in order to make his or her certification current.

(ii) An individual whose certification has been revoked must take an initial renovator or dust sampling technician course in order to become certified again.

(iii) A firm whose certification has been revoked must reapply for certification after the revocation ends in order to become certified again. If the firm's certification has been suspended and the suspension ends less than 5 years after the firm was initially certified or re-certified, the firm does not need to do anything to re-activate its certification.

[73 FR 21765, Apr. 22, 2008]

§ 745.92 Fees for the accreditation of renovation and dust sampling technician training and the certification of renovation firms.

(a) *Persons who must pay fees.* Fees in accordance with paragraph (b) of this section must be paid by:

(1) *Training programs*—(i) *Non-exempt training programs.* All non-exempt training programs applying to EPA for the accreditation and re-accreditation of training programs in one or more of the following disciplines: Renovator, dust sampling technician.

(ii) *Exemption.* No fee shall be imposed on any training program operated by a State, federally recognized Indian Tribe, local government, or nonprofit organization. This exemption does not apply to the certification of firms or individuals.

(2) *Firms.* All firms applying to EPA for certification and re-certification to conduct renovations.

(b) *Fee amounts*—(1) *Certification and accreditation fees.* Initial and renewal certification and accreditation fees are specified in the following table:

Training Program	Accreditation	Re-accreditation (every 4 years, see 40 CFR 745.225(f)(1) for details)
Initial Renovator or Dust Sampling Technician Course	$560	$340
Refresher Renovator or Dust Sampling Technician Course	$400	$310
Renovation Firm	Certification	Re-certification (every 5 years see 40 CFR 745.89(b))
Firm	$300	$300

Training Program	Accreditation	Re-accreditation (every 4 years, see 40 CFR 745.225(f)(1) for details)
Combined Renovation and Lead-based Paint Activities Firm Application	$550	$550
Combined Renovation and Lead-based Paint Activities Tribal Firm Application	$20	$20
Tribal Firm	$20	$20

(2) *Lost certificate.* A $15 fee will be charged for the replacement of a firm certificate.

(c) *Certificate replacement.* Firms seeking certificate replacement must:

(1) Complete the applicable portions of the ''Application for Firms'' in accordance with the instructions provided.

(2) Submit the application and a payment of $15 in accordance with the instructions provided with the application package.

(3) *Accreditation or certification amendments.* No fee will be charged for accreditation or certification amendments.

(d) *Failure to remit fees.* (1) EPA will not provide certification, re-certification, accreditation, or re-accreditation for any firm or training program that does not remit fees described in paragraph (b) of this section in accordance with the procedures specified in 40 CFR 745.89.

(2) EPA will not replace a certificate for any firm that does not remit the $15 fee in accordance with the procedures specified in paragraph (c) of this section.

[74 FR 11869, Mar. 20, 2009, as amended at 76 FR 47939, Aug. 5, 2011]

Subpart F—Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards Upon Sale or Lease of Residential Property

§ 745.100 Purpose.

This subpart implements the provisions of 42 U.S.C. 4852d, which impose certain requirements on the sale or lease of target housing. Under this subpart, a seller or lessor of target housing shall disclose to the purchaser or lessee the presence of any known lead-based paint and/or lead-based paint hazards; provide available records and reports; provide the purchaser or lessee with a lead hazard information pamphlet; give purchasers a 10-day opportunity to conduct a risk assessment or inspection; and attach specific disclosure and warning language to the sales or leasing contract before the purchaser or lessee is obligated under a contract to purchase or lease target housing.

§ 745.101 Scope and applicability.

This subpart applies to all transactions to sell or lease target housing, including subleases, with the exception of the following:

(a) Sales of target housing at foreclosure.

(b) Leases of target housing that have been found to be lead-based paint free by an inspector certified under the Federal certification program or under a federally accredited State or tribal certification program. Until a Federal certification program or federally accredited State certification program is in place within the State, inspectors shall be considered qualified to conduct an inspection for this purpose if they have received certification under any existing State or tribal inspector certification program. The lessor has the option of using the results of additional test(s) by a certified inspector to confirm or refute a prior finding.

(c) Short-term leases of 100 days or less, where no lease renewal or extension can occur.

(d) Renewals of existing leases in target housing in which the lessor has previously disclosed all information required under § 745.107 and where no new information described in § 745.107 has come into the possession of the lessor. For the purposes of this paragraph, renewal shall include both renegotiation of existing lease terms and/or ratification of a new lease.

§ 745.102 Effective dates.

The requirements in this subpart take effect in the following manner:

(a) For owners of more than four residential dwellings, the requirements shall take effect on September 6, 1996.

(b) For owners of one to four residential dwellings, the requirements shall take effect on December 6, 1996.

§ 745.103 Definitions.

The following definitions apply to this subpart.

The Act means the Residential Lead-Based Paint Hazard Reduction Act of 1992, 42 U.S.C. 4852d.

Agent means any party who enters into a contract with a seller or lessor, including any party who enters into a contract with a representative of the seller or lessor, for the purpose of selling or leasing target housing. This term does not apply to purchasers or any purchaser's representative who receives all compensation from the purchaser.

Available means in the possession of or reasonably obtainable by the seller or lessor at the time of the disclosure.

Common area means a portion of a building generally accessible to all residents/users including, but not limited to, hallways, stairways, laundry and recreational rooms, playgrounds, community centers, and boundary fences.

Contract for the purchase and sale of residential real property means any contract or agreement in which one party agrees to purchase an interest in real property on which there is situated one or more residential dwellings used or occupied, or intended to be used or occupied, in whole or in part, as the home or residence of one or more persons.

EPA means the Environmental Protection Agency.

Evaluation means a risk assessment and/or inspection.

Foreclosure means any of the various methods, statutory or otherwise, known in different jurisdictions, of enforcing payment of a debt, by the taking and selling of real property.

Housing for the elderly means retirement communities or similar types of housing reserved for households composed of one or more persons 62 years of age or more at the time of initial occupancy.

HUD means the U.S. Department of Housing and Urban Development.

Inspection means:

(1) A surface-by-surface investigation to determine the presence of lead-based paint as provided in section 302(c) of the Lead-Based Paint Poisoning and Prevention Act [42 U.S.C. 4822], and

(2) The provision of a report explaining the results of the investigation.

Lead-based paint means paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram per square centimeter or 0.5 percent by weight.

Lead-based paint free housing means target housing that has been found to be free of paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram per square centimeter or 0.5 percent by weight.

Lead-based paint hazard means any condition that causes exposure to lead from lead-contaminated dust, lead-contaminated soil, or lead-contaminated paint that is deteriorated or present in accessible surfaces, friction surfaces, or impact surfaces that would result in adverse human health effects as established by the appropriate Federal agency.

Lessee means any entity that enters into an agreement to lease, rent, or sublease target housing, including but not limited to individuals, partnerships, corporations, trusts, government agencies, housing agencies, Indian tribes, and nonprofit organizations.

Lessor means any entity that offers target housing for lease, rent, or sublease, including but not limited to individuals, partnerships, corporations, trusts, government agencies, housing agencies, Indian tribes, and nonprofit organizations.

Owner means any entity that has legal title to target housing, including but not limited to individuals, partnerships, corporations, trusts, government agencies, housing agencies, Indian tribes, and nonprofit organizations, except where a mortgagee holds legal title to property serving as collateral for a mortgage loan, in which case the owner would be the mortgagor.

Purchaser means an entity that enters into an agreement to purchase an

interest in target housing, including but not limited to individuals, partnerships, corporations, trusts, government agencies, housing agencies, Indian tribes, and nonprofit organizations.

Reduction means measures designed to reduce or eliminate human exposure to lead-based paint hazards through methods including interim controls and abatement.

Residential dwelling means:

(1) A single-family dwelling, including attached structures such as porches and stoops; or

(2) A single-family dwelling unit in a structure that contains more than one separate residential dwelling unit, and in which each such unit is used or occupied, or intended to be used or occupied, in whole or in part, as the residence of one or more persons.

Risk assessment means an on-site investigation to determine and report the existence, nature, severity, and location of lead-based paint hazards in residential dwellings, including:

(1) Information gathering regarding the age and history of the housing and occupancy by children under age 6;

(2) Visual inspection;

(3) Limited wipe sampling or other environmental sampling techniques;

(4) Other activity as may be appropriate; and

(5) Provision of a report explaining the results of the investigation.

Secretary means the Secretary of Housing and Urban Development.

Seller means any entity that transfers legal title to target housing, in whole or in part, in return for consideration, including but not limited to individuals, partnerships, corporations, trusts, government agencies, housing agencies, Indian tribes, and nonprofit organizations. The term ''seller'' also includes:

(1) An entity that transfers shares in a cooperatively owned project, in return for consideration; and

(2) An entity that transfers its interest in a leasehold, in jurisdictions or circumstances where it is legally permissible to separate the fee title from the title to the improvement, in return for consideration.

Target housing means any housing constructed prior to 1978, except housing for the elderly or persons with disabilities (unless any child who is less than 6 years of age resides or is expected to reside in such housing) or any 0-bedroom dwelling.

TSCA means the Toxic Substances Control Act, 15 U.S.C. 2601.

0-bedroom dwelling means any residential dwelling in which the living area is not separated from the sleeping area. The term includes efficiencies, studio apartments, dormitory housing, military barracks, and rentals of individual rooms in residential dwellings.

§ 745.107 Disclosure requirements for sellers and lessors.

(a) The following activities shall be completed before the purchaser or lessee is obligated under any contract to purchase or lease target housing that is not otherwise an exempt transaction pursuant to §745.101. Nothing in this section implies a positive obligation on the seller or lessor to conduct any evaluation or reduction activities.

(1) The seller or lessor shall provide the purchaser or lessee with an EPA-approved lead hazard information pamphlet. Such pamphlets include the EPA document entitled *Protect Your Family From Lead in Your Home* (EPA #747-K-94-001) or an equivalent pamphlet that has been approved for use in that State by EPA.

(2) The seller or lessor shall disclose to the purchaser or lessee the presence of any known lead-based paint and/or lead-based paint hazards in the target housing being sold or leased. The seller or lessor shall also disclose any additional information available concerning the known lead-based paint and/or lead-based paint hazards, such as the basis for the determination that lead-based paint and/or lead-based paint hazards exist, the location of the lead-based paint and/or lead-based paint hazards, and the condition of the painted surfaces.

(3) The seller or lessor shall disclose to each agent the presence of any known lead-based paint and/or lead-based paint hazards in the target housing being sold or leased and the existence of any available records or reports pertaining to lead-based paint and/or lead-based paint hazards. The seller or lessor shall also disclose any additional information available concerning the

known lead-based paint and/or lead-based paint hazards, such as the basis for the determination that lead-based paint and/or lead-based paint hazards exist, the location of the lead-based paint and/or lead-based paint hazards, and the condition of the painted surfaces.

(4) The seller or lessor shall provide the purchaser or lessee with any records or reports available to the seller or lessor pertaining to lead-based paint and/or lead-based paint hazards in the target housing being sold or leased. This requirement includes records or reports regarding common areas. This requirement also includes records or reports regarding other residential dwellings in multifamily target housing, provided that such information is part of an evaluation or reduction of lead-based paint and/or lead-based paint hazards in the target housing as a whole.

(b) If any of the disclosure activities identified in paragraph (a) of this section occurs after the purchaser or lessee has provided an offer to purchase or lease the housing, the seller or lessor shall complete the required disclosure activities prior to accepting the purchaser's or lessee's offer and allow the purchaser or lessee an opportunity to review the information and possibly amend the offer.

§ 745.110 Opportunity to conduct an evaluation.

(a) Before a purchaser is obligated under any contract to purchase target housing, the seller shall permit the purchaser a 10-day period (unless the parties mutually agree, in writing, upon a different period of time) to conduct a risk assessment or inspection for the presence of lead-based paint and/or lead-based paint hazards.

(b) Not withstanding paragraph (a) of this section, a purchaser may waive the opportunity to conduct the risk assessment or inspection by so indicating in writing.

§ 745.113 Certification and acknowledgment of disclosure.

(a) *Seller requirements.* Each contract to sell target housing shall include an attachment containing the following elements, in the language of the contract (e.g., English, Spanish):

(1) A Lead Warning Statement consisting of the following language:

> Every purchaser of any interest in residential real property on which a residential dwelling was built prior to 1978 is notified that such property may present exposure to lead from lead-based paint that may place young children at risk of developing lead poisoning. Lead poisoning in young children may produce permanent neurological damage, including learning disabilities, reduced intelligence quotient, behavioral problems, and impaired memory. Lead poisoning also poses a particular risk to pregnant women. The seller of any interest in residential real property is required to provide the buyer with any information on lead-based paint hazards from risk assessments or inspections in the seller's possession and notify the buyer of any known lead-based paint hazards. A risk assessment or inspection for possible lead-based paint hazards is recommended prior to purchase.

(2) A statement by the seller disclosing the presence of known lead-based paint and/or lead-based paint hazards in the target housing being sold or indicating no knowledge of the presence of lead-based paint and/or lead-based paint hazards. The seller shall also provide any additional information available concerning the known lead-based paint and/or lead-based paint hazards, such as the basis for the determination that lead-based paint and/or lead-based paint hazards exist, the location of the lead-based paint and/or lead-based paint hazards, and the condition of the painted surfaces.

(3) A list of any records or reports available to the seller pertaining to lead-based paint and/or lead-based paint hazards in the housing that have been provided to the purchaser. If no such records or reports are available, the seller shall so indicate.

(4) A statement by the purchaser affirming receipt of the information set out in paragraphs (a)(2) and (a)(3) of this section and the lead hazard information pamphlet required under 15 U.S.C. 2696.

(5) A statement by the purchaser that he/she has either:

(i) Received the opportunity to conduct the risk assessment or inspection required by § 745.110(a); or

(ii) Waived the opportunity.

(6) When one or more agents are involved in the transaction to sell target housing on behalf of the seller, a statement that:

(i) The agent has informed the seller of the seller's obligations under 42 U.S.C. 4852d; and

(ii) The agent is aware of his/her duty to ensure compliance with the requirements of this subpart.

(7) The signatures of the sellers, agents, and purchasers certifying to the accuracy of their statements to the best of their knowledge, along with the dates of signature.

(b) *Lessor requirements.* Each contract to lease target housing shall include, as an attachment or within the contract, the following elements, in the language of the contract (e.g., English, Spanish):

(1) A Lead Warning Statement with the following language:

Housing built before 1978 may contain lead-based paint. Lead from paint, paint chips, and dust can pose health hazards if not managed properly. Lead exposure is especially harmful to young children and pregnant women. Before renting pre-1978 housing, lessors must disclose the presence of lead-based paint and/or lead-based paint hazards in the dwelling. Lessees must also receive a federally approved pamphlet on lead poisoning prevention.

(2) A statement by the lessor disclosing the presence of known lead-based paint and/or lead-based paint hazards in the target housing being leased or indicating no knowledge of the presence of lead-based paint and/or lead-based paint hazards. The lessor shall also disclose any additional information available concerning the known lead-based paint and/or lead-based paint hazards, such as the basis for the determination that lead-based paint and/or lead-based paint hazards exist, the location of the lead-based paint and/or lead-based paint hazards, and the condition of the painted surfaces.

(3) A list of any records or reports available to the lessor pertaining to lead-based paint and/or lead-based paint hazards in the housing that have been provided to the lessee. If no such records or reports are available, the lessor shall so indicate.

(4) A statement by the lessee affirming receipt of the information set out in paragraphs (b)(2) and (b)(3) of this section and the lead hazard information pamphlet required under 15 U.S.C. 2696.

(5) When one or more agents are involved in the transaction to lease target housing on behalf of the lessor, a statement that:

(i) The agent has informed the lessor of the lessor as obligations under 42 U.S.C. 4852d; and

(ii) The agent is aware of his/her duty to ensure compliance with the requirements of this subpart.

(6) The signatures of the lessors, agents, and lessees, certifying to the accuracy of their statements, to the best of their knowledge, along with the dates of signature.

(c) *Retention of Certification and Acknowledgment Information.* (1) The seller, and any agent, shall retain a copy of the completed attachment required under paragraph (a) of this section for no less than 3 years from the completion date of the sale. The lessor, and any agent, shall retain a copy of the completed attachment or lease contract containing the information required under paragraph (b) of this section for no less than 3 years from the commencement of the leasing period.

(2) This recordkeeping requirement is not intended to place any limitations on civil suits under the Act, or to otherwise affect a lessee's or purchaser's rights under the civil penalty provisions of 42 U.S.C. 4852d(b)(3).

(d) The seller, lessor, or agent shall not be responsible for the failure of a purchaser's or lessee's legal representative (where such representative receives all compensation from the purchaser or lessee) to transmit disclosure materials to the purchaser or lessee, provided that all required parties have completed and signed the necessary certification and acknowledgment language required under paragraphs (a) and (b) of this section.

§ 745.115 Agent responsibilities.

(a) Each agent shall ensure compliance with all requirements of this subpart. To ensure compliance, the agent shall:

(1) Inform the seller or lessor of his/her obligations under §§ 745.107, 745.110, and 745.113.

(2) Ensure that the seller or lessor has performed all activities required under §§ 745.107, 745.110, and 745.113, or personally ensure compliance with the requirements of §§ 745.107, 745.110, and 745.113.

(b) If the agent has complied with paragraph (a)(1) of this section, the agent shall not be liable for the failure to disclose to a purchaser or lessee the presence of lead-based paint and/or lead-based paint hazards known by a seller or lessor but not disclosed to the agent.

§ 745.118 Enforcement.

(a) Any person who knowingly fails to comply with any provision of this subpart shall be subject to civil monetary penalties in accordance with the provisions of 42 U.S.C. 3545 and 24 CFR part 30.

(b) The Secretary is authorized to take such action as may be necessary to enjoin any violation of this subpart in the appropriate Federal district court.

(c) Any person who knowingly violates the provisions of this subpart shall be jointly and severally liable to the purchaser or lessee in an amount equal to 3 times the amount of damages incurred by such individual.

(d) In any civil action brought for damages pursuant to 42 U.S.C. 4852d(b)(3), the appropriate court may award court costs to the party commencing such action, together with reasonable attorney fees and any expert witness fees, if that party prevails.

(e) Failure or refusal to comply with § 745.107 (disclosure requirements for sellers and lessors), § 745.110 (opportunity to conduct an evaluation), § 745.113 (certification and acknowledgment of disclosure), or § 745.115 (agent responsibilities) is a violation of 42 U.S.C. 4852d(b)(5) and of TSCA section 409 (15 U.S.C. 2689).

(f) Violators may be subject to civil and criminal sanctions pursuant to TSCA section 16 (15 U.S.C. 2615) for each violation. For purposes of enforcing this subpart, the penalty for each violation applicable under 15 U.S.C. 2615 shall not be more than $11,000 for all violations occuring after July 28, 1997; all violations occuring on or prior to that date are subject to a penalty not more than $10,000.

[61 FR 9085, Mar. 6, 1996, as amended at 62 FR 35041, June 27, 1997]

§ 745.119 Impact on State and local requirements.

Nothing in this subpart shall relieve a seller, lessor, or agent from any responsibility for compliance with State or local laws, ordinances, codes, or regulations governing notice or disclosure of known lead-based paint or lead-based paint hazards. Neither HUD nor EPA assumes any responsibility for ensuring compliance with such State or local requirements.

Subparts G–K [Reserved]

Subpart L—Lead-Based Paint Activities

SOURCE: 61 FR 45813, Aug. 29, 1996, unless otherwise noted.

§ 745.220 Scope and applicability.

(a) This subpart contains procedures and requirements for the accreditation of training programs for lead-based paint activities and renovations, procedures and requirements for the certification of individuals and firms engaged in lead-based paint activities, and work practice standards for performing such activities. This subpart also requires that, except as discussed below, all lead-based paint activities, as defined in this subpart, be performed by certified individuals and firms.

(b) This subpart applies to all individuals and firms who are engaged in lead-based paint activities as defined in § 745.223, except persons who perform these activities within residential dwellings that they own, unless the residential dwelling is occupied by a person or persons other than the owner or the owner's immediate family while these activities are being performed, or a child residing in the building has been identified as having an elevated blood lead level. This subpart applies only in those States or Indian Country that do not have an authorized State or

Tribal program pursuant to § 745.324 of subpart Q.

(c) Each department, agency, and instrumentality of the executive, legislative, and judicial branches of the Federal Government having jurisdiction over any property or facility, or engaged in any activity resulting, or which may result, in a lead-based paint hazard, and each officer, agent, or employee thereof shall be subject to, and comply with, all Federal, State, interstate, and local requirements, both substantive and procedural, including the requirements of this subpart regarding lead-based paint, lead-based paint activities, and lead-based paint hazards.

(d) While this subpart establishes specific requirements for performing lead-based paint activities should they be undertaken, nothing in this subpart requires that the owner or occupant undertake any particular lead-based paint activity.

[61 FR 45813, Aug. 29, 1996, as amended at 73 FR 21766, Apr. 22, 2008]

§ 745.223 Definitions.

The definitions in subpart A apply to this subpart. In addition, the following definitions apply.

Abatement means any measure or set of measures designed to permanently eliminate lead-based paint hazards. Abatement includes, but is not limited to:

(1) The removal of paint and dust, the permanent enclosure or encapsulation of lead-based paint, the replacement of painted surfaces or fixtures, or the removal or permanent covering of soil, when lead-based paint hazards are present in such paint, dust or soil; and

(2) All preparation, cleanup, disposal, and post-abatement clearance testing activities associated with such measures.

(3) Specifically, abatement includes, but is not limited to:

(i) Projects for which there is a written contract or other documentation, which provides that an individual or firm will be conducting activities in or to a residential dwelling or child-occupied facility that:

(A) Shall result in the permanent elimination of lead-based paint hazards; or

(B) Are designed to permanently eliminate lead-based paint hazards and are described in paragraphs (1) and (2) of this definition.

(ii) Projects resulting in the permanent elimination of lead-based paint hazards, conducted by firms or individuals certified in accordance with § 745.226, unless such projects are covered by paragraph (4) of this definition;

(iii) Projects resulting in the permanent elimination of lead-based paint hazards, conducted by firms or individuals who, through their company name or promotional literature, represent, advertise, or hold themselves out to be in the business of performing lead-based paint activities as identified and defined by this section, unless such projects are covered by paragraph (4) of this definition; or

(iv) Projects resulting in the permanent elimination of lead-based paint hazards, that are conducted in response to State or local abatement orders.

(4) Abatement does not include renovation, remodeling, landscaping or other activities, when such activities are not designed to permanently eliminate lead-based paint hazards, but, instead, are designed to repair, restore, or remodel a given structure or dwelling, even though these activities may incidentally result in a reduction or elimination of lead-based paint hazards. Furthermore, abatement does not include interim controls, operations and maintenance activities, or other measures and activities designed to temporarily, but not permanently, reduce lead-based paint hazards.

Accredited training program means a training program that has been accredited by EPA pursuant to § 745.225 to provide training for individuals engaged in lead-based paint activities.

Adequate quality control means a plan or design which ensures the authenticity, integrity, and accuracy of samples, including dust, soil, and paint chip or paint film samples. Adequate quality control also includes provisions for representative sampling.

Business day means Monday through Friday with the exception of Federal holidays.

Certified firm means a company, partnership, corporation, sole proprietorship, association, or other business entity that performs lead-based paint activities to which EPA has issued a certificate of approval pursuant to §745.226(f).

Certified inspector means an individual who has been trained by an accredited training program, as defined by this section, and certified by EPA pursuant to §745.226 to conduct inspections. A certified inspector also samples for the presence of lead in dust and soil for the purposes of abatement clearance testing.

Certified abatement worker means an individual who has been trained by an accredited training program, as defined by this section, and certified by EPA pursuant to §745.226 to perform abatements.

Certified project designer means an individual who has been trained by an accredited training program, as defined by this section, and certified by EPA pursuant to §745.226 to prepare abatement project designs, occupant protection plans, and abatement reports.

Certified risk assessor means an individual who has been trained by an accredited training program, as defined by this section, and certified by EPA pursuant to §745.226 to conduct risk assessments. A risk assessor also samples for the presence of lead in dust and soil for the purposes of abatement clearance testing.

Certified supervisor means an individual who has been trained by an accredited training program, as defined by this section, and certified by EPA pursuant to §745.226 to supervise and conduct abatements, and to prepare occupant protection plans and abatement reports.

Child-occupied facility means a building, or portion of a building, constructed prior to 1978, visited regularly by the same child, 6 years of age or under, on at least two different days within any week (Sunday through Saturday period), provided that each day's visit lasts at least 3 hours and the combined weekly visit lasts at least 6 hours, and the combined annual visits last at least 60 hours. Child-occupied facilities may include, but are not limited to, day-care centers, preschools and kindergarten classrooms.

Clearance levels are values that indicate the maximum amount of lead permitted in dust on a surface following completion of an abatement activity.

Common area means a portion of a building that is generally accessible to all occupants. Such an area may include, but is not limited to, hallways, stairways, laundry and recreational rooms, playgrounds, community centers, garages, and boundary fences.

Component or building component means specific design or structural elements or fixtures of a building, residential dwelling, or child-occupied facility that are distinguished from each other by form, function, and location. These include, but are not limited to, interior components such as: ceilings, crown molding, walls, chair rails, doors, door trim, floors, fireplaces, radiators and other heating units, shelves, shelf supports, stair treads, stair risers, stair stringers, newel posts, railing caps, balustrades, windows and trim (including sashes, window heads, jambs, sills or stools and troughs), built in cabinets, columns, beams, bathroom vanities, counter tops, and air conditioners; and exterior components such as: painted roofing, chimneys, flashing, gutters and downspouts, ceilings, soffits, fascias, rake boards, cornerboards, bulkheads, doors and door trim, fences, floors, joists, lattice work, railings and railing caps, siding, handrails, stair risers and treads, stair stringers, columns, balustrades, window sills or stools and troughs, casings, sashes and wells, and air conditioners.

Containment means a process to protect workers and the environment by controlling exposures to the lead-contaminated dust and debris created during an abatement.

Course agenda means an outline of the key topics to be covered during a training course, including the time allotted to teach each topic.

Course test means an evaluation of the overall effectiveness of the training which shall test the trainees' knowledge and retention of the topics covered during the course.

Course test blue print means written documentation identifying the proportion of course test questions devoted to

each major topic in the course curriculum.

Deteriorated paint means paint that is cracking, flaking, chipping, peeling, or otherwise separating from the substrate of a building component.

Discipline means one of the specific types or categories of lead-based paint activities identified in this subpart for which individuals may receive training from accredited programs and become certified by EPA. For example, ''abatement worker'' is a discipline.

Distinct painting history means the application history, as indicated by its visual appearance or a record of application, over time, of paint or other surface coatings to a component or room.

Documented methodologies are methods or protocols used to sample for the presence of lead in paint, dust, and soil.

Elevated blood lead level (EBL) means an excessive absorption of lead that is a confirmed concentration of lead in whole blood of 20 µg/dl (micrograms of lead per deciliter of whole blood) for a single venous test or of 15–19 µg/dl in two consecutive tests taken 3 to 4 months apart.

Encapsulant means a substance that forms a barrier between lead-based paint and the environment using a liquid-applied coating (with or without reinforcement materials) or an adhesively bonded covering material.

Encapsulation means the application of an encapsulant.

Enclosure means the use of rigid, durable construction materials that are mechanically fastened to the substrate in order to act as a barrier between lead-based paint and the environment.

Guest instructor means an individual designated by the training program manager or principal instructor to provide instruction specific to the lecture, hands-on activities, or work practice components of a course.

Hands-on skills assessment means an evaluation which tests the trainees' ability to satisfactorily perform the work practices and procedures identified in § 745.225(d), as well as any other skill taught in a training course.

Hazardous waste means any waste as defined in 40 CFR 261.3.

Inspection means a surface-by-surface investigation to determine the presence of lead-based paint and the provision of a report explaining the results of the investigation.

Interim certification means the status of an individual who has successfully completed the appropriate training course in a discipline from an accredited training program, as defined by this section, but has not yet received formal certification in that discipline from EPA pursuant to § 745.226. Interim certifications expire 6 months after the completion of the training course, and is equivalent to a certificate for the 6-month period.

Interim controls means a set of measures designed to temporarily reduce human exposure or likely exposure to lead-based paint hazards, including specialized cleaning, repairs, maintenance, painting, temporary containment, ongoing monitoring of lead-based paint hazards or potential hazards, and the establishment and operation of management and resident education programs.

Lead-based paint means paint or other surface coatings that contain lead equal to or in excess of 1.0 milligrams per square centimeter or more than 0.5 percent by weight.

Lead-based paint activities means, in the case of target housing and child-occupied facilities, inspection, risk assessment, and abatement, as defined in this subpart.

Lead-based paint activities courses means initial and refresher training courses (worker, supervisor, inspector, risk assessor, project designer) provided by accredited training programs.

Lead-based paint hazard means any condition that causes exposure to lead from lead-contaminated dust, lead-contaminated soil, or lead-contaminated paint that is deteriorated or present in accessible surfaces, friction surfaces, or impact surfaces that would result in adverse human health effects as identified by the Administrator pursuant to TSCA section 403.

Lead-hazard screen is a limited risk assessment activity that involves limited paint and dust sampling as described in § 745.227(c).

Living area means any area of a residential dwelling used by one or more children age 6 and under, including, but not limited to, living rooms, kitchen

areas, dens, play rooms, and children's bedrooms.

Local government means a county, city, town, borough, parish, district, association, or other public body (including an agency comprised of two or more of the foregoing entities) created under State law.

Multi-family dwelling means a structure that contains more than one separate residential dwelling unit, which is used or occupied, or intended to be used or occupied, in whole or in part, as the home or residence of one or more persons.

Nonprofit means an entity which has demonstrated to any branch of the Federal Government or to a State, municipal, tribal or territorial government, that no part of its net earnings inure to the benefit of any private shareholder or individual.

Paint in poor condition means more than 10 square feet of deteriorated paint on exterior components with large surface areas; or more than 2 square feet of deteriorated paint on interior components with large surface areas (e.g., walls, ceilings, floors, doors); or more than 10 percent of the total surface area of the component is deteriorated on interior or exterior components with small surface areas (window sills, baseboards, soffits, trim).

Permanently covered soil means soil which has been separated from human contact by the placement of a barrier consisting of solid, relatively impermeable materials, such as pavement or concrete. Grass, mulch, and other landscaping materials are not considered permanent covering.

Person means any natural or judicial person including any individual, corporation, partnership, or association; any Indian Tribe, State, or political subdivision thereof; any interstate body; and any department, agency, or instrumentality of the Federal government.

Principal instructor means the individual who has the primary responsibility for organizing and teaching a particular course.

Recognized laboratory means an environmental laboratory recognized by EPA pursuant to TSCA section 405(b) as being capable of performing an analysis for lead compounds in paint, soil, and dust.

Reduction means measures designed to reduce or eliminate human exposure to lead-based paint hazards through methods including interim controls and abatement.

Residential dwelling means (1) a detached single family dwelling unit, including attached structures such as porches and stoops; or (2) a single family dwelling unit in a structure that contains more than one separate residential dwelling unit, which is used or occupied, or intended to be used or occupied, in whole or in part, as the home or residence of one or more persons.

Risk assessment means (1) an on-site investigation to determine the existence, nature, severity, and location of lead-based paint hazards, and (2) the provision of a report by the individual or the firm conducting the risk assessment, explaining the results of the investigation and options for reducing lead-based paint hazards.

Start date means the first day of any lead-based paint activities training course or lead-based paint abatement activity.

Start date provided to EPA means the start date included in the original notification or the most recent start date provided to EPA in an updated notification.

State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

Target housing means any housing constructed prior to 1978, except housing for the elderly or persons with disabilities (unless any one or more children age 6 years or under resides or is expected to reside in such housing for the elderly or persons with disabilities) or any 0-bedroom dwelling.

Training curriculum means an established set of course topics for instruction in an accredited training program for a particular discipline designed to provide specialized knowledge and skills.

Training hour means at least 50 minutes of actual learning, including, but not limited to, time devoted to lecture,

learning activities, small group activities, demonstrations, evaluations, and/or hands-on experience.

Training manager means the individual responsible for administering a training program and monitoring the performance of principal instructors and guest instructors.

Training provider means any organization or entity accredited under § 745.225 to offer lead-based paint activities courses.

Visual inspection for clearance testing means the visual examination of a residential dwelling or a child-occupied facility following an abatement to determine whether or not the abatement has been successfully completed.

Visual inspection for risk assessment means the visual examination of a residential dwelling or a child-occupied facility to determine the existence of deteriorated lead-based paint or other potential sources of lead-based paint hazards.

[61 FR 45813, Aug. 29, 1996, as amended at 64 FR 31097, June 9, 1999; 66 FR 1239, Jan. 5, 2001; 69 FR 18495, Apr. 8, 2004]

§ 745.225 Accreditation of training programs: target housing and child occupied facilities.

(a) *Scope.* (1) A training program may seek accreditation to offer courses in any of the following disciplines: Inspector, risk assessor, supervisor, project designer, abatement worker, renovator, and dust sampling technician. A training program may also seek accreditation to offer refresher courses for each of the above listed disciplines.

(2) Training programs may first apply to EPA for accreditation of their lead-based paint activities courses or refresher courses pursuant to this section on or after August 31, 1998. Training programs may first apply to EPA for accreditation of their renovator or dust sampling technician courses or refresher courses pursuant to this section on or after April 22, 2009.

(3) A training program must not provide, offer, or claim to provide EPA-accredited lead-based paint activities courses without applying for and receiving accreditation from EPA as required under paragraph (b) of this section on or after March 1, 1999. A training program must not provide, offer, or claim to provide EPA-accredited renovator or dust sampling technician courses without applying for and receiving accreditation from EPA as required under paragraph (b) of this section on or after June 23, 2008.

(4) Accredited training programs, training program managers, and principal instructors must comply with all of the requirements of this section including approved terms of the application and all of the requirements and limitations specified in any accreditation documents issued to training programs.

(b) *Application process.* The following are procedures a training program must follow to receive EPA accreditation to offer lead-based paint activities courses, renovator courses, or dust sampling technician courses:

(1) A training program seeking accreditation shall submit a written application to EPA containing the following information:

(i) The training program's name, address, and telephone number.

(ii) A list of courses for which it is applying for accreditation. For the purposes of this section, courses taught in different languages and electronic learning courses are considered different courses, and each must independently meet the accreditation requirements.

(iii) The name and documentation of the qualifications of the training program manager.

(iv) The name(s) and documentation of qualifications of any principal instructor(s).

(v) A statement signed by the training program manager certifying that the training program meets the requirements established in paragraph (c) of this section. If a training program uses EPA-recommended model training materials, or training materials approved by a State or Indian Tribe that has been authorized by EPA under subpart Q of this part, the training program manager shall include a statement certifying that, as well.

(vi) If a training program does not use EPA-recommended model training materials, its application for accreditation shall also include:

(A) A copy of the student and instructor manuals, or other materials to be used for each course.

(B) A copy of the course agenda for each course.

(C) When applying for accreditation of a course in a language other than English, a signed statement from a qualified, independent translator that they had compared the course to the English language version and found the translation to be accurate.

(vii) All training programs shall include in their application for accreditation the following:

(A) A description of the facilities and equipment to be used for lecture and hands-on training.

(B) A copy of the course test blueprint for each course.

(C) A description of the activities and procedures that will be used for conducting the assessment of hands-on skills for each course.

(D) A copy of the quality control plan as described in paragraph (c)(9) of this section.

(2) If a training program meets the requirements in paragraph (c) of this section, then EPA shall approve the application for accreditation no more than 180 days after receiving a complete application from the training program. In the case of approval, a certificate of accreditation shall be sent to the applicant. In the case of disapproval, a letter describing the reasons for disapproval shall be sent to the applicant. Prior to disapproval, EPA may, at its discretion, work with the applicant to address inadequacies in the application for accreditation. EPA may also request additional materials retained by the training program under paragraph (i) of this section. If a training program's application is disapproved, the program may reapply for accreditation at any time.

(3) A training program may apply for accreditation to offer courses or refresher courses in as many disciplines as it chooses. A training program may seek accreditation for additional courses at any time as long as the program can demonstrate that it meets the requirements of this section.

(4) A training program applying for accreditation must submit the appropriate fees in accordance with § 745.238.

(c) *Requirements for the accreditation of training programs.* A training program accredited by EPA to offer lead-based paint activities courses, renovator courses, or dust sampling technician courses must meet the following requirements:

(1) The training program shall employ a training manager who has:

(i) At least 2 years of experience, education, or training in teaching workers or adults; or

(ii) A bachelor's or graduate degree in building construction technology, engineering, industrial hygiene, safety, public health, education, business administration or program management or a related field; or

(iii) Two years of experience in managing a training program specializing in environmental hazards; and

(iv) Demonstrated experience, education, or training in the construction industry including: Lead or asbestos abatement, painting, carpentry, renovation, remodeling, occupational safety and health, or industrial hygiene.

(2) The training manager shall designate a qualified principal instructor for each course who has:

(i) Demonstrated experience, education, or training in teaching workers or adults; and

(ii) Successfully completed at least 16 hours of any EPA-accredited or EPA-authorized State or Tribal-accredited lead-specific training for instructors of lead-based paint activities courses or 8 hours of any EPA-accredited or EPA-authorized State or Tribal-accredited lead-specific training for instructors of renovator or dust sampling technician courses; and

(iii) Demonstrated experience, education, or training in lead or asbestos abatement, painting, carpentry, renovation, remodeling, occupational safety and health, or industrial hygiene.

(3) The principal instructor shall be responsible for the organization of the course, course delivery, and oversight of the teaching of all course material. The training manager may designate guest instructors as needed for a portion of the course to provide instruction specific to the lecture, hands-on

activities, or work practice components of a course. However, the principal instructor is primarily responsible for teaching the course materials and must be present to provide instruction (or oversight of portions of the course taught by guest instructors) for the course for which he has been designated the principal instructor.

(4) The following documents shall be recognized by EPA as evidence that training managers and principal instructors have the education, work experience, training requirements or demonstrated experience, specifically listed in paragraphs (c)(1) and (c)(2) of this section. This documentation must be submitted with the accreditation application and retained by the training program as required by the recordkeeping requirements contained in paragraph (i) of this section. Those documents include the following:

(i) Official academic transcripts or diploma as evidence of meeting the education requirements.

(ii) Resumes, letters of reference, or documentation of work experience, as evidence of meeting the work experience requirements.

(iii) Certificates from train-the-trainer courses and lead-specific training courses, as evidence of meeting the training requirements.

(5) The training program shall ensure the availability of, and provide adequate facilities for, the delivery of the lecture, course test, hands-on training, and assessment activities. This includes providing training equipment that reflects current work practices and maintaining or updating the equipment and facilities as needed.

(6) To become accredited in the following disciplines, the training program shall provide training courses that meet the following training requirements:

(i) The inspector course shall last a minimum of 24 training hours, with a minimum of 8 hours devoted to hands-on training activities. The minimum curriculum requirements for the inspector course are contained in paragraph (d)(1) of this section.

(ii) The risk assessor course shall last a minimum of 16 training hours, with a minimum of 4 hours devoted to hands-on training activities. The minimum curriculum requirements for the risk assessor course are contained in paragraph (d)(2) of this section.

(iii) The supervisor course shall last a minimum of 32 training hours, with a minimum of 8 hours devoted to hands-on activities. The minimum curriculum requirements for the supervisor course are contained in paragraph (d)(3) of this section.

(iv) The project designer course shall last a minimum of 8 training hours. The minimum curriculum requirements for the project designer course are contained in paragraph (d)(4) of this section.

(v) The abatement worker course shall last a minimum of 16 training hours, with a minimum of 8 hours devoted to hands-on training activities. The minimum curriculum requirements for the abatement worker course are contained in paragraph (d)(5) of this section.

(vi) The renovator course must last a minimum of 8 training hours, with a minimum of 2 hours devoted to hands-on training activities. The minimum curriculum requirements for the renovator course are contained in paragraph (d)(6) of this section.

(vii) The dust sampling technician course must last a minimum of 8 training hours, with a minimum of 2 hours devoted to hands-on training activities. The minimum curriculum requirements for the dust sampling technician course are contained in paragraph (d)(7) of this section.

(viii) Electronic learning and other alternative course delivery methods are permitted for the classroom portion of renovator, dust sampling technician, or lead-based paint activities courses but not the hands-on portion of these courses, or for final course tests or proficiency tests described in paragraph (c)(7) of this section. Electronic learning courses must comply with the following requirements:

(A) A unique identifier must be assigned to each student for them to use to launch and re-launch the course.

(B) The training provider must track each student's course log-ins, launches, progress, and completion, and maintain these records in accordance with paragraph (i) of this section.

(C) The course must include periodic knowledge checks equivalent to the number and content of the knowledge checks contained in EPA's model course, but at least 16 over the entire course. The knowledge checks must be successfully completed before the student can go on to the next module.

(D) There must be a test of at least 20 questions at the end of the electronic learning portion of the course, of which 80% must be answered correctly by the student for successful completion of the electronic learning portion of the course. The test must be designed so that students to do not receive feedback on their test answers until after they have completed and submitted the test.

(E) Each student must be able to save or print a copy of an electronic learning course completion certificate. The electronic certificate must not be susceptible to easy editing.

(7) For each course offered, the training program shall conduct either a course test at the completion of the course, and if applicable, a hands-on skills assessment, or in the alternative, a proficiency test for that discipline. Each student must successfully complete the hands-on skills assessment and receive a passing score on the course test to pass any course, or successfully complete a proficiency test.

(i) The training manager is responsible for maintaining the validity and integrity of the hands-on skills assessment or proficiency test to ensure that it accurately evaluates the trainees' performance of the work practices and procedures associated with the course topics contained in paragraph (d) of this section.

(ii) The training manager is responsible for maintaining the validity and integrity of the course test to ensure that it accurately evaluates the trainees' knowledge and retention of the course topics.

(iii) The course test shall be developed in accordance with the test blueprint submitted with the training accreditation application.

(8) The training program shall issue unique course completion certificates to each individual who passes the training course. The course completion certificate shall include:

(i) The name, a unique identification number, and address of the individual.

(ii) The name of the particular course that the individual completed.

(iii) Dates of course completion/test passage.

(iv) For initial inspector, risk assessor, project designer, supervisor, or abatement worker course completion certificates, the expiration date of interim certification, which is 6 months from the date of course completion.

(v) The name, address, and telephone number of the training program.

(vi) The language in which the course was taught.

(vii) For renovator and dust sampling technician course completion certificates, a photograph of the individual. The photograph must be an accurate and recognizable image of the individual. As reproduced on the certificate, the photograph must not be smaller than 1 square inch.

(viii) For renovator course completion certificates, the expiration date of certification.

(9) The training manager shall develop and implement a quality control plan. The plan shall be used to maintain and improve the quality of the training program over time. This plan shall contain at least the following elements:

(i) Procedures for periodic revision of training materials and the course test to reflect innovations in the field.

(ii) Procedures for the training manager's annual review of principal instructor competency.

(10) Courses offered by the training program must teach the work practice standards contained in §745.85 or §745.227, as applicable, in such a manner that trainees are provided with the knowledge needed to perform the renovations or lead-based paint activities they will be responsible for conducting.

(11) The training manager shall be responsible for ensuring that the training program complies at all times with all of the requirements in this section.

(12) The training manager shall allow EPA to audit the training program to verify the contents of the application for accreditation as described in paragraph (b) of this section.

(13) The training manager must provide notification of renovator, dust

sampling technician, or lead-based paint activities courses offered.

(i) The training manager must provide EPA with notification of all renovator, dust sampling technician, or lead-based paint activities courses offered except for any renovator course without hands-on training delivered via electronic learning. The original notification must be received by EPA at least 7 business days prior to the start date of any renovator, dust sampling technician, or lead-based paint activities course.

(ii) The training manager must provide EPA updated notification when renovator, dust sampling technician, or lead-based paint activities courses will begin on a date other than the start date specified in the original notification, as follows:

(A) For renovator, dust sampling technician, or lead-based paint activities courses beginning prior to the start date provided to EPA, an updated notification must be received by EPA at least 7 business days before the new start date.

(B) For renovator, dust sampling technician, or lead-based paint activities courses beginning after the start date provided to EPA, an updated notification must be received by EPA at least 2 business days before the start date provided to EPA.

(iii) The training manager must update EPA of any change in location of renovator, dust sampling technician, or lead-based paint activities courses at least 7 business days prior to the start date provided to EPA.

(iv) The training manager must update EPA regarding any course cancellations, or any other change to the original notification. Updated notifications must be received by EPA at least 2 business days prior to the start date provided to EPA.

(v) Each notification, including updates, must include the following:

(A) Notification type (original, update, cancellation).

(B) Training program name, EPA accreditation number, address, and telephone number.

(C) Course discipline, type (initial/refresher), and the language in which instruction will be given.

(D) Date(s) and time(s) of training.

(E) Training location(s) telephone number, and address.

(F) Principal instructor's name.

(G) Training manager's name and signature.

(vi) Notification must be accomplished using any of the following methods: Written notification, or electronically using the Agency's Central Data Exchange (CDX). Written notification of lead-based paint activities course schedules can be accomplished by using either the sample form titled ''Lead-Based Paint Training Notification'' or a similar form containing the information required in paragraph (c)(13)(v) of this section. All written notifications must be delivered to EPA by U.S. Postal Service, fax, commercial delivery service, or hand delivery (persons submitting notification by U.S. Postal Service are reminded that they should allow 3 additional business days for delivery in order to ensure that EPA receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD(5323), or on the Internet at *http://www.epa.gov/lead*. Hearing- or speech-impaired persons may reach the above telephone number through TTY by calling the toll-free Federal Relay Service at 1–800–877–8339.

(vii) Renovator, dust sampling technician, or lead-based paint activities courses must not begin on a date, or at a location other than that specified in the original notification unless an updated notification identifying a new start date or location is submitted, in which case the course must begin on the new start date and/or location specified in the updated notification.

(viii) No training program shall provide renovator, dust sampling technician, or lead-based paint activities courses without first notifying EPA of such activities in accordance with the requirements of this paragraph.

(14) The training manager must provide notification following completion of renovator, dust sampling technician, or lead-based paint activities courses.

(i) The training manager must provide EPA notification after the completion of any renovator, dust sampling, or lead-based paint activities

course. This notification must be received by EPA no later than 10 business days following course completion. Notifications for any e-learning renovator refresher course that does not include hands-on training must be submitted via the Central Data Exchange no later than the 10th day of the month and include all students trained in the previous month.

(ii) The notification must include the following:

(A) Training program name, EPA accreditation number, address, and telephone number.

(B) Course discipline and type (initial/refresher).

(C) Date(s) of training.

(D) The following information for each student who took the course:

(*1*) Name.

(*2*) Address.

(*3*) Date of birth.

(*4*) Course completion certificate number.

(*5*) Course test score.

(*6*) For renovator or dust sampling technician courses, a digital photograph of the student.

(*7*) For renovator refresher courses, the expiration date of certification.

(E) Training manager's name and signature.

(iii) Notification must be accomplished using any of the following methods: Written notification, or electronically using the Agency's Central Data Exchange (CDX). Written notification following renovator, dust sampling technician, or lead-based paint activities training courses can be accomplished by using either the sample form titled ''Lead-Based Paint Training Course Follow-up'' or a similar form containing the information required in paragraph (c)(14)(ii) of this section. All written notifications must be delivered to EPA by U.S. Postal Service, fax, commercial delivery service, or hand delivery (persons submitting notification by U.S. Postal Service are reminded that they should allow 3 additional business days for delivery in order to ensure that EPA receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD (5323), or on the Internet at *http://www.epa.gov/lead*.

(d) *Minimum training curriculum requirements.* A training program accredited by EPA to offer lead-based paint courses in the specific disciplines listed in this paragraph (d) must ensure that its courses of study include, at a minimum, the following course topics.

(1) *Inspector.* Instruction in the topics described in paragraphs (d)(1)(iv), (v), (vi), and (vii) of this section must be included in the hands-on portion of the course.

(i) Role and responsibilities of an inspector.

(ii) Background information on lead and its adverse health effects.

(iii) Background information on Federal, State, and local regulations and guidance that pertains to lead-based paint and lead- based paint activities.

(iv) Lead-based paint inspection methods, including selection of rooms and components for sampling or testing.

(v) Paint, dust, and soil sampling methodologies.

(vi) Clearance standards and testing, including random sampling.

(vii) Preparation of the final inspection report.

(viii) Recordkeeping.

(2) *Risk assessor.* Instruction in the topics described in paragraphs (d)(2)(iv), (vi), and (vii) of this section must be included in the hands-on portion of the course.

(i) Role and responsibilities of a risk assessor.

(ii) Collection of background information to perform a risk assessment.

(iii) Sources of environmental lead contamination such as paint, surface dust and soil, water, air, packaging, and food.

(iv) Visual inspection for the purposes of identifying potential sources of lead-based paint hazards.

(v) Lead hazard screen protocol.

(vi) Sampling for other sources of lead exposure.

(vii) Interpretation of lead-based paint and other lead sampling results, including all applicable Federal or State guidance or regulations pertaining to lead-based paint hazards.

(viii) Development of hazard control options, the role of interim controls, and operations and maintenance activities to reduce lead-based paint hazards.

(ix) Preparation of a final risk assessment report.

(3) *Supervisor*. Instruction in the topics described in paragraphs (d)(3)(v), (vii), (viii), (ix), and (x) of this section must be included in the hands-on portion of the course.

(i) Role and responsibilities of a supervisor.

(ii) Background information on lead and its adverse health effects.

(iii) Background information on Federal, State, and local regulations and guidance that pertain to lead-based paint abatement.

(iv) Liability and insurance issues relating to lead-based paint abatement.

(v) Risk assessment and inspection report interpretation.

(vi) Development and implementation of an occupant protection plan and abatement report.

(vii) Lead-based paint hazard recognition and control.

(viii) Lead-based paint abatement and lead-based paint hazard reduction methods, including restricted practices.

(ix) Interior dust abatement/cleanup or lead-based paint hazard control and reduction methods.

(x) Soil and exterior dust abatement or lead-based paint hazard control and reduction methods.

(xi) Clearance standards and testing.

(xii) Cleanup and waste disposal.

(xiii) Recordkeeping.

(4) *Project designer*. (i) Role and responsibilities of a project designer.

(ii) Development and implementation of an occupant protection plan for large-scale abatement projects.

(iii) Lead-based paint abatement and lead-based paint hazard reduction methods, including restricted practices for large-scale abatement projects.

(iv) Interior dust abatement/cleanup or lead hazard control and reduction methods for large-scale abatement projects.

(v) Clearance standards and testing for large scale abatement projects.

(vi) Integration of lead-based paint abatement methods with modernization and rehabilitation projects for large scale abatement projects.

(5) *Abatement worker*. Instruction in the topics described in paragraphs (d)(5)(iv), (v), (vi), and (vii) of this section must be included in the hands-on portion of the course.

(i) Role and responsibilities of an abatement worker.

(ii) Background information on lead and its adverse health effects.

(iii) Background information on Federal, State and local regulations and guidance that pertain to lead-based paint abatement.

(iv) Lead-based paint hazard recognition and control.

(v) Lead-based paint abatement and lead-based paint hazard reduction methods, including restricted practices.

(vi) Interior dust abatement methods/cleanup or lead-based paint hazard reduction.

(vii) Soil and exterior dust abatement methods or lead-based paint hazard reduction.

(6) *Renovator*. Instruction in the topics described in paragraphs (d)(6)(iv), (vi), (vii), and (viii) of this section must be included in the hands-on portion of the course.

(i) Role and responsibility of a renovator.

(ii) Background information on lead and its adverse health effects.

(iii) Background information on EPA, HUD, OSHA, and other Federal, State, and local regulations and guidance that pertains to lead-based paint and renovation activities.

(iv) Procedures for using acceptable test kits to determine whether paint is lead-based paint.

(v) Procedures for collecting a paint chip sample and sending it to a laboratory recognized by EPA under section 405(b) of TSCA.

(vi) Renovation methods to minimize the creation of dust and lead-based paint hazards.

(vii) Interior and exterior containment and cleanup methods.

(viii) Methods to ensure that the renovation has been properly completed, including cleaning verification and clearance testing.

(ix) Waste handling and disposal.

(x) Providing on-the-job training to other workers.

(xi) Record preparation.

(7) *Dust sampling technician*. Instruction in the topics described in paragraphs (d)(6)(iv) and (vi) of this section

must be included in the hands-on portion of the course.

(i) Role and responsibility of a dust sampling technician.

(ii) Background information on lead and its adverse health effects.

(iii) Background information on Federal, State, and local regulations and guidance that pertains to lead-based paint and renovation activities.

(iv) Dust sampling methodologies.

(v) Clearance standards and testing.

(vi) Report preparation.

(e) *Requirements for the accreditation of refresher training programs.* A training program may seek accreditation to offer refresher training courses in any of the following disciplines: Inspector, risk assessor, supervisor, project designer, abatement worker, renovator, and dust sampling technician. A training program accredited by EPA to offer refresher training must meet the following minimum requirements:

(1) Each refresher course shall review the curriculum topics of the full-length courses listed under paragraph (d) of this section, as appropriate. In addition, to become accredited to offer refresher training courses, training programs shall ensure that their courses of study include, at a minimum, the following:

(i) An overview of current safety practices relating to lead-based paint in general, as well as specific information pertaining to the appropriate discipline.

(ii) Current laws and regulations relating to lead-based paint in general, as well as specific information pertaining to the appropriate discipline.

(iii) Current technologies relating to lead-based paint in general, as well as specific information pertaining to the appropriate discipline.

(2) Refresher courses for inspector, risk assessor, supervisor, and abatement worker must last a minimum of 8 training hours. Refresher courses for project designer, renovator, and dust sampling technician must last a minimum of 4 training hours. Refresher courses for all disciplines except renovator and project designer must include a hands-on component. Renovators must take a refresher course that includes hands-on training at least every other recertification.

(3) Except for renovator and project designer courses, for all other courses offered, the training program shall conduct a hands-on assessment. With the exception of project designer courses, the training program shall conduct a course test at the completion of the course. Renovators must take a refresher course that includes hands-on training at least every other recertification.

(4) A training program may apply for accreditation of a refresher course concurrently with its application for accreditation of the corresponding training course as described in paragraph (b) of this section. If so, EPA shall use the approval procedure described in paragraph (b) of this section. In addition, the minimum requirements contained in paragraphs (c)(1) through (5), (c)(6)(viii) and (c)(7) through (14), and (e)(1) through (3) of this section shall also apply.

(5) A training program seeking accreditation to offer refresher training courses only shall submit a written application to EPA containing the following information:

(i) The refresher training program's name, address, and telephone number.

(ii) A list of courses for which it is applying for accreditation.

(iii) The name and documentation of the qualifications of the training program manager.

(iv) The name(s) and documentation of the qualifications of the principal instructor(s).

(v) A statement signed by the training program manager certifying that the refresher training program meets the minimum requirements established in paragraph (c) of this section, except for the requirements in paragraph (c)(6) of this section. If a training program uses EPA-developed model training materials, or training materials approved by a State or Indian Tribe that has been authorized by EPA under §745.324 to develop its refresher training course materials, the training manager shall include a statement certifying that, as well.

(vi) If the refresher training course materials are not based on EPA-developed model training materials, the training program's application for accreditation shall include:

(A) A copy of the student and instructor manuals to be used for each course.

(B) A copy of the course agenda for each course.

(vii) All refresher training programs shall include in their application for accreditation the following:

(A) A description of the facilities and equipment to be used for lecture and hands-on training.

(B) A copy of the course test blueprint for each course.

(C) A description of the activities and procedures that will be used for conducting the assessment of hands-on skills for each course (if applicable).

(D) A copy of the quality control plan as described in paragraph (c)(9) of this section.

(viii) The requirements in paragraphs (c)(1) through (5), (c)(6)(viii) and (c)(7) through (14) of this section apply to refresher training providers.

(ix) If a refresher training program meets the requirements listed in this paragraph, then EPA shall approve the application for accreditation no more than 180 days after receiving a complete application from the refresher training program. In the case of approval, a certificate of accreditation shall be sent to the applicant. In the case of disapproval, a letter describing the reasons for disapproval shall be sent to the applicant. Prior to disapproval, EPA may, at its discretion, work with the applicant to address inadequacies in the application for accreditation. EPA may also request additional materials retained by the refresher training program under paragraph (i) of this section. If a refresher training program's application is disapproved, the program may reapply for accreditation at any time.

(f) *Re-accreditation of training programs.* (1) Unless re-accredited, a training program's accreditation, including refresher training accreditation, shall expire 4 years after the date of issuance. If a training program meets the requirements of this section, the training program shall be reaccredited.

(2) A training program seeking re-accreditation shall submit an application to EPA no later than 180 days before its accreditation expires. If a training program does not submit its application for re-accreditation by that date, EPA cannot guarantee that the program will be re-accredited before the end of the accreditation period.

(3) The training program's application for re-accreditation shall contain:

(i) The training program's name, address, and telephone number.

(ii) A list of courses for which it is applying for re-accreditation.

(iii) The name and qualifications of the training program manager.

(iv) The name(s) and qualifications of the principal instructor(s).

(v) A description of any changes to the training facility, equipment or course materials since its last application was approved that adversely affects the students' ability to learn.

(vi) A statement signed by the program manager stating:

(A) That the training program complies at all times with all requirements in paragraphs (c) and (e) of this section, as applicable; and

(B) The recordkeeping and reporting requirements of paragraph (i) of this section shall be followed.

(vii) A payment of appropriate fees in accordance with § 745.238.

(4) Upon request, the training program shall allow EPA to audit the training program to verify the contents of the application for re-accreditation as described in paragraph (f)(3) of this section.

(g) *Suspension, revocation, and modification of accredited training programs.* (1) EPA may, after notice and an opportunity for hearing, suspend, revoke, or modify training program accreditation, including refresher training accreditation, if a training program, training manager, or other person with supervisory authority over the training program has:

(i) Misrepresented the contents of a training course to EPA and/or the student population.

(ii) Failed to submit required information or notifications in a timely manner.

(iii) Failed to maintain required records.

(iv) Falsified accreditation records, instructor qualifications, or other accreditation-related information or documentation.

(v) Failed to comply with the training standards and requirements in this section.

(vi) Failed to comply with Federal, State, or local lead-based paint statutes or regulations.

(vii) Made false or misleading statements to EPA in its application for accreditation or re-accreditation which EPA relied upon in approving the application.

(2) In addition to an administrative or judicial finding of violation, execution of a consent agreement in settlement of an enforcement action constitutes, for purposes of this section, evidence of a failure to comply with relevant statutes or regulations.

(h) *Procedures for suspension, revocation or modification of training program accreditation.* (1) Prior to taking action to suspend, revoke, or modify the accreditation of a training program, EPA shall notify the affected entity in writing of the following:

(i) The legal and factual basis for the suspension, revocation, or modification.

(ii) The anticipated commencement date and duration of the suspension, revocation, or modification.

(iii) Actions, if any, which the affected entity may take to avoid suspension, revocation, or modification, or to receive accreditation in the future.

(iv) The opportunity and method for requesting a hearing prior to final EPA action to suspend, revoke or modify accreditation.

(v) Any additional information, as appropriate, which EPA may provide.

(2) If a hearing is requested by the accredited training program, EPA shall:

(i) Provide the affected entity an opportunity to offer written statements in response to EPA's assertions of the legal and factual basis for its proposed action, and any other explanations, comments, and arguments it deems relevant to the proposed action.

(ii) Provide the affected entity such other procedural opportunities as EPA may deem appropriate to ensure a fair and impartial hearing.

(iii) Appoint an official of EPA as Presiding Officer to conduct the hearing. No person shall serve as Presiding Officer if he or she has had any prior connection with the specific matter.

(3) The Presiding Officer appointed pursuant to paragraph (h)(2) of this section shall:

(i) Conduct a fair, orderly, and impartial hearing within 90 days of the request for a hearing.

(ii) Consider all relevant evidence, explanation, comment, and argument submitted.

(iii) Notify the affected entity in writing within 90 days of completion of the hearing of his or her decision and order. Such an order is a final agency action which may be subject to judicial review.

(4) If EPA determines that the public health, interest, or welfare warrants immediate action to suspend the accreditation of any training program prior to the opportunity for a hearing, it shall:

(i) Notify the affected entity of its intent to immediately suspend training program accreditation for the reasons listed in paragraph (g)(1) of this section. If a suspension, revocation, or modification notice has not previously been issued pursuant to paragraph (g)(1) of this section, it shall be issued at the same time the emergency suspension notice is issued.

(ii) Notify the affected entity in writing of the grounds for the immediate suspension and why it is necessary to suspend the entity's accreditation before an opportunity for a suspension, revocation or modification hearing.

(iii) Notify the affected entity of the anticipated commencement date and duration of the immediate suspension.

(iv) Notify the affected entity of its right to request a hearing on the immediate suspension within 15 days of the suspension taking place and the procedures for the conduct of such a hearing.

(5) Any notice, decision, or order issued by EPA under this section, any transcripts or other verbatim record of oral testimony, and any documents filed by an accredited training program in a hearing under this section shall be available to the public, except as otherwise provided by section 14 of TSCA or by 40 CFR part 2. Any such hearing at which oral testimony is presented shall be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow

presentation of information which may be entitled to confidential treatment under section 14 of TSCA or 40 CFR part 2.

(6) The public shall be notified of the suspension, revocation, modification or reinstatement of a training program's accreditation through appropriate mechanisms.

(7) EPA shall maintain a list of parties whose accreditation has been suspended, revoked, modified or reinstated.

(i) *Training program recordkeeping requirements.* (1) Accredited training programs shall maintain, and make available to EPA, upon request, the following records:

(i) All documents specified in paragraph (c)(4) of this section that demonstrate the qualifications listed in paragraphs (c)(1) and (c)(2) of this section of the training manager and principal instructors.

(ii) Current curriculum/course materials and documents reflecting any changes made to these materials.

(iii) The course test blueprint.

(iv) Information regarding how the hands-on assessment is conducted including, but not limited to:

(A) Who conducts the assessment.

(B) How the skills are graded.

(C) What facilities are used.

(D) The pass/fail rate.

(v) The quality control plan as described in paragraph (c)(9) of this section.

(vi) Results of the students' hands-on skills assessments and course tests, and a record of each student's course completion certificate.

(vii) Any other material not listed in paragraphs (i)(1)(i) through (i)(1)(vi) of this section that was submitted to EPA as part of the program's application for accreditation.

(viii) For renovator refresher and dust sampling technician refresher courses, a copy of each trainee's prior course completion certificate showing that each trainee was eligible to take the refresher course.

(ix) For course modules delivered in an electronic format, a record of each student's log-ins, launches, progress, and completion, and a copy of the electronic learning completion certificate for each student.

(2) The training program must retain records pertaining to renovator, dust sampling technician and lead-based paint activities courses at the address specified on the training program accreditation application (or as modified in accordance with paragraph (i)(3) of this section) for the following minimum periods:

(i) Records pertaining to lead-based paint activities courses must be retained for a minimum of 3 years and 6 months.

(ii) Records pertaining to renovator or dust sampling technician courses offered before April 22, 2010 must be retained until July 1, 2015.

(iii) Records pertaining to renovator or dust sampling technician courses offered on or after April 22, 2010 must be retained for a minimum of 5 years.

(3) The training program shall notify EPA in writing within 30 days of changing the address specified on its training program accreditation application or transferring the records from that address.

(j) *Amendment of accreditation.* (1) A training program must amend its accreditation within 90 days of the date a change occurs to information included in the program's most recent application. If the training program fails to amend its accreditation within 90 days of the date the change occurs, the program may not provide renovator, dust sampling technician, or lead-based paint activities training until its accreditation is amended.

(2) To amend an accreditation, a training program must submit a completed ''Accreditation Application for Training Providers,'' signed by an authorized agent of the training provider, noting on the form that it is submitted as an amendment and indicating the information that has changed.

(3) *Training managers, principal instructors, permanent training locations.* If the amendment includes a new training program manager, any new or additional principal instructor(s), or any new permanent training location(s), the training provider is not permitted to provide training under the new training manager or offer courses taught by any new principal instructor(s) or at the new training location(s)

until EPA either approves the amendment or 30 days have elapsed, whichever occurs earlier. Except:

(i) If the amendment includes a new training program manager or new or additional principal instructor that was identified in a training provider accreditation application that EPA has already approved under this section, the training provider may begin to provide training under the new training manager or offer courses taught by the new principal instructor on an interim basis as soon as the provider submits the amendment to EPA. The training provider may continue to provide training under the new training manager or offer courses taught by the new principal instructor if EPA approves the amendment or if EPA does not disapprove the amendment within 30 days.

(ii) If the amendment includes a new permanent training location, the training provider may begin to provide training at the new permanent training location on an interim basis as soon as the provider submits the amendment to EPA. The training provider may continue to provide training at the new permanent training location if EPA approves the amendment or if EPA does not disapprove the amendment within 30 days.

[76 FR 47939, Aug. 5, 2011, as amended at 81 FR 7995, Feb. 17, 2016]

§ 745.226 Certification of individuals and firms engaged in lead-based paint activities: target housing and child-occupied facilities.

(a) *Certification of individuals.* (1) Individuals seeking certification by EPA to engage in lead-based paint activities must either:

(i) Submit to EPA an application demonstrating that they meet the requirements established in paragraphs (b) or (c) of this section for the particular discipline for which certification is sought; or

(ii) Submit to EPA an application with a copy of a valid lead-based paint activities certification (or equivalent) from a State or Tribal program that has been authorized by EPA pursuant to subpart Q of this part.

(2) Individuals may first apply to EPA for certification to engage in lead-based paint activities pursuant to this section on or after March 1, 1999.

(3) Following the submission of an application demonstrating that all the requirements of this section have been meet, EPA shall certify an applicant as an inspector, risk assessor, supervisor, project designer, or abatement worker, as appropriate.

(4) Upon receiving EPA certification, individuals conducting lead-based paint activities shall comply with the work practice standards for performing the appropriate lead-based paint activities as established in § 745.227.

(5) It shall be a violation of TSCA for an individual to conduct any of the lead-based paint activities described in § 745.227 after March 1, 2000, if that individual has not been certified by EPA pursuant to this section to do so.

(6) Individuals applying for certification must submit the appropriate fees in accordance with § 745.238.

(b) *Inspector, risk assessor or supervisor.* (1) To become certified by EPA as an inspector, risk assessor, or supervisor, pursuant to paragraph (a)(1)(i) of this section, an individual must:

(i) Successfully complete an accredited course in the appropriate discipline and receive a course completion certificate from an accredited training program.

(ii) Pass the certification exam in the appropriate discipline offered by EPA; and,

(iii) Meet or exceed the following experience and/or education requirements:

(A) Inspectors. (*1*) No additional experience and/or education requirements.

(*2*) [Reserved]

(B) Risk assessors. (*1*) Successful completion of an accredited training course for inspectors; and

(*2*) Bachelor's degree and 1 year of experience in a related field (e.g., lead, asbestos, environmental remediation work, or construction), or an Associates degree and 2 years experience in a related field (e.g., lead, asbestos, environmental remediation work, or construction); or

(*3*) Certification as an industrial hygienist, professional engineer, registered architect and/or certification in

a related engineering/health/environmental field (e.g., safety professional, environmental scientist); or

(*4*) A high school diploma (or equivalent), and at least 3 years of experience in a related field (e.g., lead, asbestos, environmental remediation work or construction).

(C) Supervisor: (*1*) One year of experience as a certified lead-based paint abatement worker; or

(*2*) At least 2 years of experience in a related field (e.g., lead, asbestos, or environmental remediation work) or in the building trades.

(2) The following documents shall be recognized by EPA as evidence of meeting the requirements listed in (b)(2)(iii) of this paragraph:

(i) Official academic transcripts or diploma, as evidence of meeting the education requirements.

(ii) Resumes, letters of reference, or documentation of work experience, as evidence of meeting the work experience requirements.

(iii) Course completion certificates from lead-specific or other related training courses, issued by accredited training programs, as evidence of meeting the training requirements.

(3) In order to take the certification examination for a particular discipline an individual must:

(i) Successfully complete an accredited course in the appropriate discipline and receive a course completion certificate from an accredited training program.

(ii) Meet or exceed the education and/or experience requirements in paragraph (b)(1)(iii) of this section.

(4) The course completion certificate shall serve as interim certification for an individual until the next available opportunity to take the certification exam. Such interim certification shall expire 6 months after issuance.

(5) After passing the appropriate certification exam and submitting an application demonstrating that he/she meets the appropriate training, education, and/or experience prerequisites described in paragraph (b)(1) of this section, an individual shall be issued a certificate by EPA. To maintain certification, an individual must be recertified as described in paragraph (e) of this section.

(6) An individual may take the certification exam no more than three times within 6 months of receiving a course completion certificate.

(7) If an individual does not pass the certification exam and receive a certificate within 6 months of receiving his/her course completion certificate, the individual must retake the appropriate course from an accredited training program before reapplying for certification from EPA.

(c) *Abatement worker and project designer.* (1) To become certified by EPA as an abatement worker or project designer, pursuant to paragraph (a)(1)(i) of this section, an individual must:

(i) Successfully complete an accredited course in the appropriate discipline and receive a course completion certificate from an accredited training program.

(ii) Meet or exceed the following additional experience and/or education requirements:

(A) Abatement workers. (*1*) No additional experience and/or education requirements.

(*2*) [Reserved]

(B) Project designers. (*1*) Successful completion of an accredited training course for supervisors.

(*2*) Bachelor's degree in engineering, architecture, or a related profession, and 1 year of experience in building construction and design or a related field; or

(*3*) Four years of experience in building construction and design or a related field.

(2) The following documents shall be recognized by EPA as evidence of meeting the requirements listed in this paragraph:

(i) Official academic transcripts or diploma, as evidence of meeting the education requirements.

(ii) Resumes, letters of reference, or documentation of work experience, as evidence of meeting the work experience requirements.

(iii) Course completion certificates from lead-specific or other related training courses, issued by accredited training programs, as evidence of meeting the training requirements.

(3) The course completion certificate shall serve as an interim certification

until certification from EPA is received, but shall be valid for no more than 6 months from the date of completion.

(4) After successfully completing the appropriate training courses and meeting any other qualifications described in paragraph (c)(1) of this section, an individual shall be issued a certificate from EPA. To maintain certification, an individual must be re-certified as described in paragraph (e) of this section.

(d) *Certification based on prior training.* (1) Any individual who received training in a lead-based paint activity between October 1, 1990, and March 1, 1999 shall be eligible for certification by EPA under the alternative procedures contained in this paragraph. Individuals who have received lead-based paint activities training at an EPA-authorized State or Tribal accredited training program shall also be eligible for certification by EPA under the following alternative procedures:

(i) Applicants for certification as an inspector, risk assessor, or supervisor shall:

(A) Demonstrate that the applicant has successfully completed training or on-the-job training in the conduct of a lead-based paint activity.

(B) Demonstrate that the applicant meets or exceeds the education and/or experience requirements in paragraph (b)(1)(iii) of this section.

(C) Successfully complete an accredited refresher training course for the appropriate discipline.

(D) Pass a certification exam administered by EPA for the appropriate discipline.

(ii) Applicants for certification as an abatement worker or project designer shall:

(A) Demonstrate that the applicant has successfully completed training or on-the-job training in the conduct of a lead-based paint activity.

(B) Demonstrate that the applicant meets the education and/or experience requirements in paragraphs (c)(1) of this section; and

(C) Successfully complete an accredited refresher training course for the appropriate discipline.

(2) Individuals shall have until March 1, 2000, to apply to EPA for certification under the above procedures. After that date, all individuals wishing to obtain certification must do so through the procedures described in paragraph (a), and paragraph (b) or (c) of this section, according to the discipline for which certification is being sought.

(e) *Re-certification.* (1) To maintain certification in a particular discipline, a certified individual shall apply to and be re-certified by EPA in that discipline by EPA either:

(i) Every 3 years if the individual completed a training course with a course test and hands-on assessment; or

(ii) Every 5 years if the individual completed a training course with a proficiency test.

(2) An individual shall be re-certified if the individual successfully completes the appropriate accredited refresher training course and submits a valid copy of the appropriate refresher course completion certificate.

(3) Individuals applying for re-certification must submit the appropriate fees in accordance with §745.238.

(f) *Certification of firms.* (1) All firms which perform or offer to perform any of the lead-based paint activities described in §745.227 after March 1, 2000, shall be certified by EPA.

(2) A firm seeking certification shall submit to EPA a letter attesting that the firm shall only employ appropriately certified employees to conduct lead-based paint activities, and that the firm and its employees shall follow the work practice standards in §745.227 for conducting lead-based paint activities.

(3) From the date of receiving the firm's letter requesting certification, EPA shall have 90 days to approve or disapprove the firm's request for certification. Within that time, EPA shall respond with either a certificate of approval or a letter describing the reasons for a disapproval.

(4) The firm shall maintain all records pursuant to the requirements in §745.227.

(5) Firms may first apply to EPA for certification to engage in lead-based paint activities pursuant to this section on or after March 1, 1999.

(6) Firms applying for certification must submit the appropriate fees in accordance with § 745.238.

(7) To maintain certification a firm shall submit appropriate fees in accordance with § 745.238 every 3 years.

(g) *Suspension, revocation, and modification of certifications of individuals engaged in lead-based paint activities.* (1) EPA may, after notice and opportunity for hearing, suspend, revoke, or modify an individual's certification if an individual has:

(i) Obtained training documentation through fraudulent means.

(ii) Gained admission to and completed an accredited training program through misrepresentation of admission requirements.

(iii) Obtained certification through misrepresentation of certification requirements or related documents dealing with education, training, professional registration, or experience.

(iv) Performed work requiring certification at a job site without having proof of certification.

(v) Permitted the duplication or use of the individual's own certificate by another.

(vi) Performed work for which certification is required, but for which appropriate certification has not been received.

(vii) Failed to comply with the appropriate work practice standards for lead-based paint activities at § 745.227.

(viii) Failed to comply with Federal, State, or local lead-based paint statutes or regulations.

(2) In addition to an administrative or judicial finding of violation, for purposes of this section only, execution of a consent agreement in settlement of an enforcement action constitutes evidence of a failure to comply with relevant statutes or regulations.

(h) *Suspension, revocation, and modification of certifications of firms engaged in lead-based paint activities.* (1) EPA may, after notice and opportunity for hearing, suspend, revoke, or modify a firm's certification if a firm has:

(i) Performed work requiring certification at a job site with individuals who are not certified.

(ii) Failed to comply with the work practice standards established in § 745.227.

(iii) Misrepresented facts in its letter of application for certification to EPA.

(iv) Failed to maintain required records.

(v) Failed to comply with Federal, State, or local lead-based paint statutes or regulations.

(2) In addition to an administrative or judicial finding of violation, for purposes of this section only, execution of a consent agreement in settlement of an enforcement action constitutes evidence of a failure to comply with relevant statutes or regulations.

(i) *Procedures for suspension, revocation, or modification of the certification of individuals or firms.* (1) If EPA decides to suspend, revoke, or modify the certification of any individual or firm, it shall notify the affected entity in writing of the following:

(i) The legal and factual basis for the suspension, revocation, or modification.

(ii) The commencement date and duration of the suspension, revocation, or modification.

(iii) Actions, if any, which the affected entity may take to avoid suspension, revocation, or modification or to receive certification in the future.

(iv) The opportunity and method for requesting a hearing prior to final EPA action to suspend, revoke, or modify certification.

(v) Any additional information, as appropriate, which EPA may provide.

(2) If a hearing is requested by the certified individual or firm, EPA shall:

(i) Provide the affected entity an opportunity to offer written statements in response to EPA's assertion of the legal and factual basis and any other explanations, comments, and arguments it deems relevant to the proposed action.

(ii) Provide the affected entity such other procedural opportunities as EPA may deem appropriate to ensure a fair and impartial hearing.

(iii) Appoint an official of EPA as Presiding Officer to conduct the hearing. No person shall serve as Presiding Officer if he or she has had any prior connection with the specific matter.

(3) The Presiding Officer shall:

(i) Conduct a fair, orderly, and impartial hearing within 90 days of the request for a hearing;

(ii) Consider all relevant evidence, explanation, comment, and argument submitted; and

(iii) Notify the affected entity in writing within 90 days of completion of the hearing of his or her decision and order. Such an order is a final EPA action subject to judicial review.

(4) If EPA determines that the public health, interest, or welfare warrants immediate action to suspend the certification of any individual or firm prior to the opportunity for a hearing, it shall:

(i) Notify the affected entity of its intent to immediately suspend certification for the reasons listed in paragraph (h)(1) of this section. If a suspension, revocation, or modification notice has not previously been issued, it shall be issued at the same time the immediate suspension notice is issued.

(ii) Notify the affected entity in writing of the grounds upon which the immediate suspension is based and why it is necessary to suspend the entity's accreditation before an opportunity for a hearing to suspend, revoke, or modify the individual's or firm's certification.

(iii) Notify the affected entity of the commencement date and duration of the immediate suspension.

(iv) Notify the affected entity of its right to request a hearing on the immediate suspension within 15 days of the suspension taking place and the procedures for the conduct of such a hearing.

(5) Any notice, decision, or order issued by EPA under this section, transcript or other verbatim record of oral testimony, and any documents filed by a certified individual or firm in a hearing under this section shall be available to the public, except as otherwise provided by section 14 of TSCA or by part 2 of this title. Any such hearing at which oral testimony is presented shall be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow presentation of information which may be entitled to confidential treatment under section 14 of TSCA or part 2 of this title.

[61 FR 45813, Aug. 29, 1996, as amended at 64 FR 31098, June 9, 1999; 64 FR 42851, Aug. 6, 1999]

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

(a) *Effective date, applicability, and terms.* (1) Beginning on March 1, 2000, all lead-based paint activities shall be performed pursuant to the work practice standards contained in this section.

(2) When performing any lead-based paint activity described by the certified individual as an inspection, lead-hazard screen, risk assessment or abatement, a certified individual must perform that activity in compliance with the appropriate requirements below.

(3) Documented methodologies that are appropriate for this section are found in the following: The U.S. Department of Housing and Urban Development (HUD) Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing; the EPA Guidance on Residential Lead-Based Paint, Lead-Contaminated Dust, and Lead-Contaminated Soil; the EPA Residential Sampling for Lead: Protocols for Dust and Soil Sampling (EPA report number 7474–R–95–001); Regulations, guidance, methods or protocols issued by States and Indian Tribes that have been authorized by EPA; and other equivalent methods and quidelines.

(4) Clearance levels are appropriate for the purposes of this section may be found in the EPA Guidance on Residential Lead-Based Paint, Lead-Contaminated Dust, and Lead Contaminiated Soil or other equivalent guidelines.

(b) *Inspection.* (1) An inspection shall be conducted only by a person certified by EPA as an inspector or risk assessor and, if conducted, must be conducted according to the procedures in this paragraph.

(2) When conducting an inspection, the following locations shall be selected according to documented methodologies and tested for the presence of lead-based paint:

(i) In a residential dwelling and child-occupied facility, each component with a distinct painting history and each exterior component with a distinct painting history shall be tested for lead-based paint, except those

components that the inspector or risk assessor determines to have been replaced after 1978, or to not contain lead-based paint; and

(ii) In a multi-family dwelling or child-occupied facility, each component with a distinct painting history in every common area, except those components that the inspector or risk assessor determines to have been replaced after 1978, or to not contain lead-based paint.

(3) Paint shall be sampled in the following manner:

(i) The analysis of paint to determine the presence of lead shall be conducted using documented methodologies which incorporate adequate quality control procedures; and/or

(ii) All collected paint chip samples shall be analyzed according to paragraph (f) of this section to determine if they contain detectable levels of lead that can be quantified numerically.

(4) The certified inspector or risk assessor shall prepare an inspection report which shall include the following information:

(i) Date of each inspection.

(ii) Address of building.

(iii) Date of construction.

(iv) Apartment numbers (if applicable).

(v) Name, address, and telephone number of the owner or owners of each residential dwelling or child-occupied facility.

(vi) Name, signature, and certification number of each certified inspector and/or risk assessor conducting testing.

(vii) Name, address, and telephone number of the certified firm employing each inspector and/or risk assessor, if applicable.

(viii) Each testing method and device and/or sampling procedure employed for paint analysis, including quality control data and, if used, the serial number of any x-ray fluorescence (XRF) device.

(ix) Specific locations of each painted component tested for the presence of lead-based paint.

(x) The results of the inspection expressed in terms appropriate to the sampling method used.

(c) *Lead hazard screen.* (1) A lead hazard screen shall be conducted only by a person certified by EPA as a risk assessor.

(2) If conducted, a lead hazard screen shall be conducted as follows:

(i) Background information regarding the physical characteristics of the residential dwelling or child-occupied facility and occupant use patterns that may cause lead-based paint exposure to one or more children age 6 years and under shall be collected.

(ii) A visual inspection of the residential dwelling or child-occupied facility shall be conducted to:

(A) Determine if any deteriorated paint is present, and

(B) Locate at least two dust sampling locations.

(iii) If deteriorated paint is present, each surface with deteriorated paint, which is determined, using documented methodologies, to be in poor condition and to have a distinct painting history, shall be tested for the presence of lead.

(iv) In residential dwellings, two composite dust samples shall be collected, one from the floors and the other from the windows, in rooms, hallways or stairwells where one or more children, age 6 and under, are most likely to come in contact with dust.

(v) In multi-family dwellings and child-occupied facilities, in addition to the floor and window samples required in paragraph (c)(1)(iii) of this section, the risk assessor shall also collect composite dust samples from common areas where one or more children, age 6 and under, are most likely to come into contact with dust.

(3) Dust samples shall be collected and analyzed in the following manner:

(i) All dust samples shall be taken using documented methodologies that incorporate adequate quality control procedures.

(ii) All collected dust samples shall be analyzed according to paragraph (f) of this section to determine if they contain detectable levels of lead that can be quantified numerically.

(4) Paint shall be sampled in the following manner:

(i) The analysis of paint to determine the presence of lead shall be conducted using documented methodologies which incorporate adequate quality control procedures; and/or

(ii) All collected paint chip samples shall be analyzed according to paragraph (f) of this section to determine if they contain detectable levels of lead that can be quantified numerically.

(5) The risk assessor shall prepare a lead hazard screen report, which shall include the following information:

(i) The information required in a risk assessment report as specified in paragraph (d) of this section, including paragraphs (d)(11)(i) through (d)(11)(xiv), and excluding paragraphs (d)(11)(xv) through (d)(11)(xviii) of this section. Additionally, any background information collected pursuant to paragraph (c)(2)(i) of this section shall be included in the risk assessment report; and

(ii) Recommendations, if warranted, for a follow-up risk assessment, and as appropriate, any further actions.

(d) *Risk assessment.* (1) A risk assessment shall be conducted only by a person certified by EPA as a risk assessor and, if conducted, must be conducted according to the procedures in this paragraph.

(2) A visual inspection for risk assessment of the residential dwelling or child-occupied facility shall be undertaken to locate the existence of deteriorated paint, assess the extent and causes of the deterioration, and other potential lead-based paint hazards.

(3) Background information regarding the physical characteristics of the residential dwelling or child-occupied facility and occupant use patterns that may cause lead-based paint exposure to one or more children age 6 years and under shall be collected.

(4) The following surfaces which are determined, using documented methodologies, to have a distinct painting history, shall be tested for the presence of lead:

(i) Each friction surface or impact surface with visibly deteriorated paint; and

(ii) All other surfaces with visibly deteriorated paint.

(5) In residential dwellings, dust samples (either composite or single-surface samples) from the interior window sill(s) and floor shall be collected and analyzed for lead concentration in all living areas where one or more children, age 6 and under, are most likely to come into contact with dust.

(6) For multi-family dwellings and child-occupied facilities, the samples required in paragraph (d)(4) of this section shall be taken. In addition, interior window sill and floor dust samples (either composite or single-surface samples) shall be collected and analyzed for lead concentration in the following locations:

(i) Common areas adjacent to the sampled residential dwelling or child-occupied facility; and

(ii) Other common areas in the building where the risk assessor determines that one or more children, age 6 and under, are likely to come into contact with dust.

(7) For child-occupied facilities, interior window sill and floor dust samples (either composite or single-surface samples) shall be collected and analyzed for lead concentration in each room, hallway or stairwell utilized by one or more children, age 6 and under, and in other common areas in the child-occupied facility where one or more children, age 6 and under, are likely to come into contact with dust.

(8) Soil samples shall be collected and analyzed for lead concentrations in the following locations:

(i) Exterior play areas where bare soil is present; and

(ii) The rest of the yard (i.e., non-play areas) where bare soil is present.

(iii) Dripline/foundation areas where bare soil is present.

(9) Any paint, dust, or soil sampling or testing shall be conducted using documented methodologies that incorporate adequate quality control procedures.

(10) Any collected paint chip, dust, or soil samples shall be analyzed according to paragraph (f) of this section to determine if they contain detectable levels of lead that can be quantified numerically.

(11) The certified risk assessor shall prepare a risk assessment report which shall include the following information:

(i) Date of assessment.

(ii) Address of each building.

(iii) Date of construction of buildings.

(iv) Apartment number (if applicable).

(v) Name, address, and telephone number of each owner of each building.

(vi) Name, signature, and certification of the certified risk assessor conducting the assessment.

(vii) Name, address, and telephone number of the certified firm employing each certified risk assessor if applicable.

(viii) Name, address, and telephone number of each recognized laboratory conducting analysis of collected samples.

(ix) Results of the visual inspection.

(x) Testing method and sampling procedure for paint analysis employed.

(xi) Specific locations of each painted component tested for the presence of lead.

(xii) All data collected from on-site testing, including quality control data and, if used, the serial number of any XRF device.

(xiii) All results of laboratory analysis on collected paint, soil, and dust samples.

(xiv) Any other sampling results.

(xv) Any background information collected pursuant to paragraph (d)(3) of this section.

(xvi) To the extent that they are used as part of the lead-based paint hazard determination, the results of any previous inspections or analyses for the presence of lead-based paint, or other assessments of lead-based paint-related hazards.

(xvii) A description of the location, type, and severity of identified lead-based paint hazards and any other potential lead hazards.

(xviii) A description of interim controls and/or abatement options for each identified lead-based paint hazard and a suggested prioritization for addressing each hazard. If the use of an encapsulant or enclosure is recommended, the report shall recommend a maintenance and monitoring schedule for the encapsulant or enclosure.

(e) *Abatement.* (1) An abatement shall be conducted only by an individual certified by EPA, and if conducted, shall be conducted according to the procedures in this paragraph.

(2) A certified supervisor is required for each abatement project and shall be onsite during all work site preparation and during the post-abatement cleanup of work areas. At all other times when abatement activities are being conducted, the certified supervisor shall be onsite or available by telephone, pager or answering service, and able to be present at the work site in no more than 2 hours.

(3) The certified supervisor and the certified firm employing that supervisor shall ensure that all abatement activities are conducted according to the requirements of this section and all other Federal, State and local requirements.

(4) A certified firm must notify EPA of lead-based paint abatement activities as follows:

(i) Except as provided in paragraph (e)(4)(ii) of this section, EPA must be notified prior to conducting lead-based paint abatement activities. The original notification must be received by EPA at least 5 business days before the start date of any lead-based paint abatement activities.

(ii) Notification for lead-based paint abatement activities required in response to an elevated blood lead level (EBL) determination, or Federal, State, Tribal, or local emergency abatement order should be received by EPA as early as possible before, but must be received no later than the start date of the lead-based paint abatement activities. Should the start date and/or location provided to EPA change, an updated notification must be received by EPA on or before the start date provided to EPA. Documentation showing evidence of an EBL determination or a copy of the Federal/State/Tribal/local emergency abatement order must be included in the written notification to take advantage of this abbreviated notification period.

(iii) Except as provided in paragraph (e)(4)(ii) of this section, updated notification must be provided to EPA for lead-based paint abatement activities that will begin on a date other than the start date specified in the original notification, as follows:

(A) For lead-based paint abatement activities beginning prior to the start

date provided to EPA an updated notification must be received by EPA at least 5 business days before the new start date included in the notification.

(B) For lead-based paint abatement activities beginning after the start date provided to EPA an updated notification must be received by EPA on or before the start date provided to EPA.

(iv) Except as provided in paragraph (e)(4)(ii) of this section, updated notification must be provided to EPA for any change in location of lead-based paint abatement activities at least 5 business days prior to the start date provided to EPA.

(v) Updated notification must be provided to EPA when lead-based paint abatement activities are canceled, or when there are other significant changes including, but not limited to, when the square footage or acreage to be abated changes by more than 20%. This updated notification must be received by EPA on or before the start date provided to EPA, or if work has already begun, within 24 hours of the change.

(vi) The following must be included in each notification:

(A) Notification type (original, updated, cancellation).

(B) Date when lead-based paint abatement activities will start.

(C) Date when lead-based paint abatement activities will end (approximation using best professional judgement).

(D) Firm's name, EPA certification number, address, telephone number.

(E) Type of building (e.g., single family dwelling, multi-family dwelling, child-occupied facilities) on/in which abatement work will be performed.

(F) Property name (if applicable).

(G) Property address including apartment or unit number(s) (if applicable) for abatement work.

(H) Documentation showing evidence of an EBL determination or a copy of the Federal/State/Tribal/local emergency abatement order, if using the abbreviated time period as described in paragraph (e)(4)(ii) of this section.

(I) Name and EPA certification number of the project supervisor.

(J) Approximate square footage/acreage to be abated.

(K) Brief description of abatement activities to be performed.

(L) Name, title, and signature of the representative of the certified firm who prepared the notification.

(vii) Notification must be accomplished using any of the following methods: Written notification, or electronically using the Agency's Central Data Exchange (CDX). Written notification can be accomplished using either the sample form titled ''Notification of Lead-Based Paint Abatement Activities'' or similar form containing the information required in paragraph (e)(4)(vi) of this section. All written notifications must be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery (persons submitting notification by U.S. Postal Service are reminded that they should allow 3 additional business days for delivery in order to ensure that EPA receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD(5323), or on the Internet at *http://www.epa.gov/lead*.

(viii) Lead-based paint abatement activities shall not begin on a date, or at a location other than that specified in either an original or updated notification, in the event of changes to the original notification.

(ix) No firm or individual shall engage in lead-based paint abatement activities, as defined in §745.223, prior to notifying EPA of such activities according to the requirements of this paragraph.

(5) A written occupant protection plan shall be developed for all abatement projects and shall be prepared according to the following procedures:

(i) The occupant protection plan shall be unique to each residential dwelling or child-occupied facility and be developed prior to the abatement. The occupant protection plan shall describe the measures and management procedures that will be taken during the abatement to protect the building occupants from exposure to any lead-based paint hazards.

(ii) A certified supervisor or project designer shall prepare the occupant protection plan.

(6) The work practices listed below shall be restricted during an abatement as follows:

(i) Open-flame burning or torching of lead-based paint is prohibited;

(ii) Machine sanding or grinding or abrasive blasting or sandblasting of lead-based paint is prohibited unless used with High Efficiency Particulate Air (HEPA) exhaust control which removes particles of 0.3 microns or larger from the air at 99.97 percent or greater efficiency;

(iii) Dry scraping of lead-based paint is permitted only in conjunction with heat guns or around electrical outlets or when treating defective paint spots totaling no more than 2 square feet in any one room, hallway or stairwell or totaling no more than 20 square feet on exterior surfaces; and

(iv) Operating a heat gun on lead-based paint is permitted only at temperatures below 1100 degrees Fahrenheit.

(7) If conducted, soil abatement shall be conducted in one of the following ways:

(i) If the soil is removed:

(A) The soil shall be replaced by soil with a lead concentration as close to local background as practicable, but no greater than 400 ppm.

(B) The soil that is removed shall not be used as top soil at another residential property or child-occupied facility.

(ii) If soil is not removed, the soil shall be permanently covered, as defined in § 745.223.

(8) The following post-abatement clearance procedures shall be performed only by a certified inspector or risk assessor:

(i) Following an abatement, a visual inspection shall be performed to determine if deteriorated painted surfaces and/or visible amounts of dust, debris or residue are still present. If deteriorated painted surfaces or visible amounts of dust, debris or residue are present, these conditions must be eliminated prior to the continuation of the clearance procedures.

(ii) Following the visual inspection and any post-abatement cleanup required by paragraph (e)(8)(i) of this section, clearance sampling for lead in dust shall be conducted. Clearance sampling may be conducted by employing single-surface sampling or composite sampling techniques.

(iii) Dust samples for clearance purposes shall be taken using documented methodologies that incorporate adequate quality control procedures.

(iv) Dust samples for clearance purposes shall be taken a minimum of 1 hour after completion of final post-abatement cleanup activities.

(v) The following post-abatement clearance activities shall be conducted as appropriate based upon the extent or manner of abatement activities conducted in or to the residential dwelling or child-occupied facility:

(A) After conducting an abatement with containment between abated and unabated areas, one dust sample shall be taken from one interior window sill and from one window trough (if present) and one dust sample shall be taken from the floors of each of no less than four rooms, hallways or stairwells within the containment area. In addition, one dust sample shall be taken from the floor outside the containment area. If there are less than four rooms, hallways or stairwells within the containment area, then all rooms, hallways or stairwells shall be sampled.

(B) After conducting an abatement with no containment, two dust samples shall be taken from each of no less than four rooms, hallways or stairwells in the residential dwelling or child-occupied facility. One dust sample shall be taken from one interior window sill and window trough (if present) and one dust sample shall be taken from the floor of each room, hallway or stairwell selected. If there are less than four rooms, hallways or stairwells within the residential dwelling or child-occupied facility then all rooms, hallways or stairwells shall be sampled.

(C) Following an exterior paint abatement, a visible inspection shall be conducted. All horizontal surfaces in the outdoor living area closest to the abated surface shall be found to be cleaned of visible dust and debris. In addition, a visual inspection shall be conducted to determine the presence of paint chips on the dripline or next to the foundation below any exterior surface abated. If paint chips are present, they must be removed from the site and properly disposed of, according to

all applicable Federal, State and local requirements.

(vi) The rooms, hallways or stairwells selected for sampling shall be selected according to documented methodologies.

(vii) The certified inspector or risk assessor shall compare the residual lead level (as determined by the laboratory analysis) from each single surface dust sample with clearance levels in paragraph (e)(8)(viii) of this section for lead in dust on floors, interior window sills, and window troughs or from each composite dust sample with the applicable clearance levels for lead in dust on floors, interior window sills, and window troughs divided by half the number of subsamples in the composite sample. If the residual lead level in a single surface dust sample equals or exceeds the applicable clearance level or if the residual lead level in a composite dust sample equals or exceeds the applicable clearance level divided by half the number of subsamples in the composite sample, the components represented by the failed sample shall be recleaned and retested.

(viii) The clearance levels for lead in dust are 40 μg/ft^2 for floors, 250 μg/ft^2 for interior window sills, and 400 μg/ft^2 for window troughs.

(9) In a multi-family dwelling with similarly constructed and maintained residential dwellings, random sampling for the purposes of clearance may be conducted provided:

(i) The certified individuals who abate or clean the residential dwellings do not know which residential dwelling will be selected for the random sample.

(ii) A sufficient number of residential dwellings are selected for dust sampling to provide a 95 percent level of confidence that no more than 5 percent or 50 of the residential dwellings (whichever is smaller) in the randomly sampled population exceed the appropriate clearance levels.

(iii) The randomly selected residential dwellings shall be sampled and evaluated for clearance according to the procedures found in paragraph (e)(8) of this section.

(10) An abatement report shall be prepared by a certified supervisor or project designer. The abatement report shall include the following information:

(i) Start and completion dates of abatement.

(ii) The name and address of each certified firm conducting the abatement and the name of each supervisor assigned to the abatement project.

(iii) The occupant protection plan prepared pursuant to paragraph (e)(5) of this section.

(iv) The name, address, and signature of each certified risk assessor or inspector conducting clearance sampling and the date of clearance testing.

(v) The results of clearance testing and all soil analyses (if applicable) and the name of each recognized laboratory that conducted the analyses.

(vi) A detailed written description of the abatement, including abatement methods used, locations of rooms and/or components where abatement occurred, reason for selecting particular abatement methods for each component, and any suggested monitoring of encapsulants or enclosures.

(f) *Collection and laboratory analysis of samples.* Any paint chip, dust, or soil samples collected pursuant to the work practice standards contained in this section shall be:

(1) Collected by persons certified by EPA as an inspector or risk assessor; and

(2) Analyzed by a laboratory recognized by EPA pursuant to section 405(b) of TSCA as being capable of performing analyses for lead compounds in paint chip, dust, and soil samples.

(g) *Composite dust sampling.* Composite dust sampling may only be conducted in the situations specified in paragraphs (c) through (e) of this section. If such sampling is conducted, the following conditions shall apply:

(1) Composite dust samples shall consist of at least two subsamples;

(2) Every component that is being tested shall be included in the sampling; and

(3) Composite dust samples shall not consist of subsamples from more than one type of component.

(h) *Determinations.* (1) Lead-based paint is present:

(i) On any surface that is tested and found to contain lead equal to or in excess of 1.0 milligrams per square centimeter or equal to or in excess of 0.5% by weight; and

(ii) On any surface like a surface tested in the same room equivalent that has a similar painting history and that is found to be lead-based paint.

(2) A paint-lead hazard is present:

(i) On any friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (e.g., the window sill or floor) are equal to or greater than the dust hazard levels identified in § 745.227(b);

(ii) On any chewable lead-based paint surface on which there is evidence of teeth marks;

(iii) Where there is any damaged or otherwise deteriorated lead-based paint on an impact surface that is cause by impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against its door frame; and

(iv) If there is any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(3) A dust-lead hazard is present in a residential dwelling or child occupied facility:

(i) In a residential dwelling on floors and interior window sills when the weighted arithmetic mean lead loading for all single surface or composite samples of floors and interior window sills are equal to or greater than 40 μg/ft^2 for floors and 250 μg/ft^2 for interior window sills, respectively;

(ii) On floors or interior window sills in an unsampled residential dwelling in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window sills, respectively, in at least one sampled residential unit on the property; and

(iii) On floors or interior window sills in an unsampled common area in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window sills, respectively, in at least one sampled common area in the same common area group on the property.

(4) A soil-lead hazard is present:

(i) In a play area when the soil-lead concentration from a composite play area sample of bare soil is equal to or greater than 400 parts per million; or

(ii) In the rest of the yard when the arithmetic mean lead concentration from a composite sample (or arithmetic mean of composite samples) of bare soil from the rest of the yard (i.e., non-play areas) for each residential building on a property is equal to or greater than 1,200 parts per million.

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

[61 FR 45813, Aug. 29, 1996, as amended at 64 FR 42852, Aug. 6, 1999; 66 FR 1239, Jan. 5, 2001; 69 FR 18496, Apr. 8, 2004]

§ 745.228 Accreditation of training programs: public and commercial buildings, bridges and superstructures. [Reserved]

§ 745.229 Certification of individuals and firms engaged in lead-based paint activities: public and commercial buildings, bridges and superstructures. [Reserved]

§ 745.230 Work practice standards for conducting lead-based paint activities: public and commercial buildings, bridges and superstructures. [Reserved]

§ 745.233 Lead-based paint activities requirements.

Lead-based paint activities, as defined in this part, shall only be conducted according to the procedures and work practice standards contained in § 745.227 of this subpart. No individual or firm may offer to perform or perform any lead-based paint activity as defined in this part, unless certified to perform that activity according to the procedures in § 745.226.

§ 745.235 Enforcement.

(a) Failure or refusal to comply with any requirement of § 745.225, § 745.226, § 745.227, or § 745.233 is a prohibited act under sections 15 and 409 of TSCA (15 U.S.C. 2614, 2689).

(b) Failure or refusal to establish, maintain, provide, copy, or permit access to records or reports as required by § 745.225, § 745.226, or § 745.227 is a prohibited act under sections 15 and 409 of TSCA (15 U.S.C. 2614, 2689).

(c) Failure or refusal to permit entry or inspection as required by § 745.237 and section 11 of TSCA (15 U.S.C. 2610) is a prohibited act under sections 15 and 409 of TSCA (15 U.S.C. 2614, 2689).

(d) In addition to the above, any individual or firm that performs any of the following acts shall be deemed to have committed a prohibited act under sections 15 and 409 of TSCA (15 U.S.C. 2614, 2689). These include the following:

(i) Obtaining certification through fraudulent representation;

(ii) Failing to obtain certification from EPA and performing work requiring certification at a job site; or

(iii) Fraudulently obtaining certification and engaging in any lead-based paint activities requiring certification.

(e) Violators are subject to civil and criminal sanctions pursuant to section 16 of TSCA (15 U.S.C. 2615) for each violation.

§ 745.237 Inspections.

EPA may conduct reasonable inspections pursuant to the provisions of section 11 of TSCA (15 U.S.C. 2610) to ensure compliance with this subpart.

§ 745.238 Fees for accreditation and certification of lead-based paint activities.

(a) *Purpose.* To establish and impose fees for certified individuals and firms engaged in lead-based paint activities and persons operating accredited training programs under section 402(a) of the Toxic Substances Control Act (TSCA).

(b) *Persons who must pay fees.* Fees in accordance with paragraph (c) of this section must be paid by:

(1) *Training programs.* (i) All non-exempt training programs applying to EPA for the accreditation and re-accreditation of training programs in one or more of the following disciplines: inspector, risk assessor, supervisor, project designer, abatement worker.

(ii) *Exemptions.* No fee shall be imposed on any training program operated by a State, federally recognized Indian Tribe, local government, or nonprofit organization. This exemption does not apply to the certification of firms or individuals.

(2) *Firms and individuals.* All firms and individuals seeking certification and re-certification from EPA to engage in lead-based paint activities in one or more of the following disciplines: inspector, risk assessor, supervisor, project designer, abatement worker.

(c) *Fee amounts*—(1) *Certification and accreditation fees.* Initial and renewal certification and accreditation fees are specified in the following table:

Training Program	Accreditation	Re-accreditation (every 4 years, see 40 CFR 745.225(f)(1) for details)
Initial Course		
Inspector	$870	$620
Risk assessor	$870	$620
Supervisor	$870	$620
Worker	$870	$620
Project Designer	$870	$620
Refresher Course		
Inspector	$690	$580
Risk assessor	$690	$580
Supervisor	$690	$580
Worker	$690	$580
Project Designer	$690	$580
Lead-based Paint Activities—Individual	Certification	Re-certification (every 3 years, see 40 CFR 745.226(e)(1) for details)

Training Program	Accreditation	Re-accreditation (every 4 years, see 40 CFR 745.225(f)(1) for details)
Inspector	$410	$410
Risk assessor	$410	$410
Supervisor	$410	$410
Worker	$310	$310
Project designer	$410	$410
Tribal certification (each discipline)	$10	$10
Lead-based Paint Activities—Firm	Certification	Re-certification (every 3 years, see 40 CFR 745.226(f)(7) for details)
Firm	$550	$550
Combined Renovation and Lead-based Paint Activities Firm Application	$550	$550
Combined Renovation and Lead-based Paint Activities Tribal Firm Application	$20	$20
Tribal Firm	$20	$20

(2) *Certification examination fee.* Individuals required to take a certification exam in accordance with § 745.226 will be assessed a fee of $70 for each exam attempt.

(3) *Lost identification card or certificate.* A $15 fee shall be charged for replacement of an identification card or certificate. (See replacement procedure in paragraph (e) of this section.)

(4) *Accreditation amendment fees.* No fee will be charged for accreditation amendments.

(d) *Application/payment procedure*—(1) *Certification and re-certification*—(i) *Individuals.* Submit a completed application (titled ''Application for Individuals to Conduct Lead-based Paint Activities''), the materials described at § 745.226, and the application fee(s) described in paragraph (c) of this section.

(ii) *Firms.* Submit a completed application (titled ''Application for Firms ''), the materials described at § 745.226, and the application fee(s) described in paragraph (c) of this section.

(2) *Accreditation and re-accreditation.* Submit a completed application (titled ''Accreditation Application for Training Programs''), the materials described at § 745.225, and the application fee described in paragraph (c) of this section.

(3) *Application forms.* Application forms and instructions can be obtained from the National Lead Information Center at: 1–800–424–LEAD.

(e) *Identification card replacement and certificate replacement.* (1) Parties seeking identification card or certificate replacement shall complete the applicable portions of the appropriate application in accordance with the instructions provided. The appropriate applications are:

(i) *Individuals.* ''Application for Individuals to Conduct Lead-based Paint Activities.''

(ii) *Firms.* ''Application for Firms.''

(iii) *Training programs.* ''Accreditation Application for Training Programs.''

(2) Submit application and payment in the amount specified in paragraph (c)(3) of this section in accordance with the instructions provided with the application package.

(f) *Adjustment of fees.* (1) EPA will collect fees reflecting the costs associated with the administration and enforcement of subpart L of this part with the exception of costs associated with the accreditation of training programs operated by a State, federally recognized Indian Tribe, local government, and nonprofit organization. In order to do this, EPA will periodically adjust the fees to reflect changed economic conditions.

(2) The fees will be evaluated based on the cost to administer and enforce the program, and the number of applicants. New fee schedules will be published in the FEDERAL REGISTER.

(g) *Failure to remit a fee.* (1) EPA will not provide certification, re-certification, accreditation, or re-accreditation for any individual, firm, or training program which does not remit fees described in paragraph (c) of this section in accordance with the procedures

specified in paragraph (d) of this section.

(2) EPA will not replace identification cards or certificates for any individual, firm, or training program which does not remit fees described in paragraph (c) of this section in accordance with the procedures specified in paragraph (e) of this section.

[64 FR 31098, June 9, 1999, as amended at 74 FR 11870, Mar. 20, 2009; 76 FR 47945, Aug. 5, 2011; 81 FR 7996, Feb. 17, 2016]

§ 745.239 Effective dates.

This subpart L shall apply in any State or Indian Country that does not have an authorized program under subpart Q, effective August 31, 1998. In such States or Indian Country:

(a) Training programs shall not provide, offer or claim to provide training or refresher training for certification without accreditation from EPA pursuant to § 745.225 on or after March 1, 1999.

(b) No individual or firm shall perform, offer, or claim to perform lead-based paint activities, as defined in this subpart, without certification from EPA to conduct such activities pursuant to § 745.226 on or after March 1, 2000.

(c) All lead-based paint activities shall be performed pursuant to the work practice standards contained in § 745.227 on or after March 1, 2000.

[61 FR 45813, Aug. 29, 1996, as amended at 64 FR 42852, Aug. 6, 1999]

Subparts M–P [Reserved]

Subpart Q—State and Indian Tribal Programs

SOURCE: 61 FR 45825, Aug. 29, 1996, unless otherwise noted.

§ 745.320 Scope and purpose.

(a) This subpart establishes the requirements that State or Tribal programs must meet for authorization by the Administrator to administer and enforce the standards, regulations, or other requirements established under TSCA section 402 and/or section 406 and establishes the procedures EPA will follow in approving, revising, and withdrawing approval of State or Tribal programs.

(b) For State or Tribal lead-based paint training and certification programs, a State or Indian Tribe may seek authorization to administer and enforce §§ 745.225, 745.226, and 745.227. The provisions of §§ 745.220, 745.223, 745.233, 745.235, 745.237, and 745.239 shall be applicable for the purposes of such program authorization.

(c) A State or Indian Tribe may seek authorization to administer and enforce all of the provisions of subpart E of this part, just the pre-renovation education provisions of subpart E of this part, or just the training, certification, accreditation, and work practice provisions of subpart E of this part. The provisions of §§ 745.324 and 745.326 apply for the purposes of such program authorizations.

(d) A State or Indian Tribe applying for program authorization may seek either interim approval or final approval of the compliance and enforcement portion of the State or Tribal lead-based paint program pursuant to the procedures at § 745.327(a).

(e) State or Tribal submissions for program authorization shall comply with the procedures set out in this subpart.

(f) Any State or Tribal program approved by the Administrator under this subpart shall at all times comply with the requirements of this subpart.

(g) In many cases States will lack authority to regulate activities in Indian Country. This lack of authority does not impair a State's ability to obtain full program authorization in accordance with this subpart. EPA will administer the program in Indian Country if neither the State nor Indian Tribe has been granted program authorization by EPA.

[61 FR 45825, Aug. 29, 1996, as amended at 73 FR 21767, Apr. 22, 2008]

§ 745.323 Definitions.

The definitions in subpart A apply to this subpart. In addition, the definitions in § 745.223 and the following definitions apply:

Indian Country means (1) all land within the limits of any American Indian reservation under the jurisdiction of the U.S. government, notwithstanding the issuance of any patent, and including rights-of-way running

throughout the reservation; (2) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or outside the limits of a State; and (3) all Indian allotments, the Indian titles which have not been extinguished, including rights-of-way running through the same.

Indian Tribe means any Indian Tribe, band, nation, or community recognized by the Secretary of the Interior and exercising substantial governmental duties and powers.

§ 745.324 Authorization of State or Tribal programs.

(a) *Application content and procedures.* (1) Any State or Indian Tribe that seeks authorization from EPA to administer and enforce the provisions of subpart E or subpart L of this part must submit an application to the Administrator in accordance with this paragraph.

(2) Before developing an application for authorization, a State or Indian Tribe shall disseminate a public notice of intent to seek such authorization and provide an opportunity for a public hearing.

(3) A State or Tribal application shall include:

(i) A transmittal letter from the State Governor or Tribal Chairperson (or equivalent official) requesting program approval.

(ii) A summary of the State or Tribal program. This summary will be used to provide notice to residents of the State or Tribe.

(iii) A description of the State or Tribal program in accordance with paragraph (b) of this section.

(iv) An Attorney General's or Tribal Counsel's (or equivalent) statement in accordance with paragraph (c) of this section.

(v) Copies of all applicable State or Tribal statutes, regulations, standards, and other materials that provide the State or Indian Tribe with the authority to administer and enforce a lead-based paint program.

(4) After submitting an application, the Agency will publish a FEDERAL REGISTER notice that contains an announcement of the receipt of the State or Tribal application, the summary of the program as provided by the State or Tribe, and a request for public comments to be mailed to the appropriate EPA Regional Office. This comment period shall last for no less than 45 days. EPA will consider these comments during its review of the State or Tribal application.

(5) Within 60 days of submission of a State or Tribal application, EPA will, if requested, conduct a public hearing in each State or Indian Country seeking program authorization and will consider all comments submitted at that hearing during the review of the State or Tribal application.

(b) *Program description.* A State or Indian Tribe seeking to administer and enforce a program under this subpart must submit a description of the program. The description of the State or Tribal program must include:

(1)(i) The name of the State or Tribal agency that is or will be responsible for administering and enforcing the program, the name of the official in that agency designated as the point of contact with EPA, and addresses and phone numbers where this official can be contacted.

(ii) Where more than one agency is or will be responsible for administering and enforcing the program, the State or Indian Tribe must designate a primary agency to oversee and coordinate administration and enforcement of the program and serve as the primary contact with EPA.

(iii) In the event that more than one agency is or will be responsible for administering and enforcing the program, the application must also include a description of the functions to be performed by each agency. The desciption shall explain and how the program will be coordinated by the primary agency to ensure consistency and effective administration of the within the State or Indian Tribe.

(2) To demonstrate that the State or Tribal program is at least as protective as the Federal program, fulfilling the criteria in paragraph (e)(2)(i) of this section, the State or Tribal application must include:

(i) A description of the program that demonstrates that the program contains all of the elements specified in § 745.325, § 745.326, or both; and

(ii) An analysis of the State or Tribal program that compares the program to the Federal program in subpart E or subpart L of this part, or both. This analysis must demonstrate how the program is, in the State's or Indian Tribe's assessment, at least as protective as the elements in the Federal program at subpart E or subpart L of this part, or both. EPA will use this analysis to evaluate the protectiveness of the State or Tribal program in making its determination pursuant to paragraph (e)(2)(i) of this section.

(3) To demonstrate that the State or Tribal program provides adequate enforcement, fulfilling the criteria in paragraph (e)(2)(ii) of this section, the State or Tribal application must include a description of the State or Tribal lead-based paint compliance and enforcement program that demonstrates that the program contains all of the elements specified at § 745.327. This description shall include copies of all policies, certifications, plans, reports, and other materials that demonstrate that the State or Tribal program contains all of the elements specified at § 745.327.

(4)(i) The program description for an Indian Tribe shall also include a map, legal description, or other information sufficient to identify the geographical extent of the territory over which the Indian Tribe exercises jurisdiction.

(ii) The program description for an Indian Tribe shall also include a demonstration that the Indian Tribe:

(A) Is recognized by the Secretary of the Interior.

(B) has an existing government exercising substantial governmental duties and powers.

(C) has adequate civil regulatory jurisdiction (as shown in the Tribal legal certification in paragraph (c)(2) of this section) over the subject matter and entities regulated.

(D) is reasonably expected to be capable of administering the Federal program for which it is seeking authorization.

(iii) If the Administrator has previously determined that an Indian Tribe has met the prerequisites in paragraphs (b)(4)(ii)(A) and (B) of this section for another EPA program, the Indian Tribe need provide only that information unique to the lead-based paint program required by paragraphs (b)(4)(ii)(C) and (D) of this section.

(c) *Attorney General's statement.* (1) A State or Indian Tribe must submit a written statement signed by the Attorney General or Tribal Counsel (or equivalent) certifying that the laws and regulations of the State or Indian Tribe provide adequate legal authority to administer and enforce the State or Tribal program. This statement shall include citations to the specific statutes and regulations providing that legal authority.

(2) The Tribal legal certification (the equivalent to the Attorney General's statement) may also be submitted and signed by an independent attorney retained by the Indian Tribe for representation in matters before EPA or the courts pertaining to the Indian Tribe's program. The certification shall include an assertion that the attorney has the authority to represent the Indian Tribe with respect to the Indian Tribe's authorization application.

(3) If a State application seeks approval of its program to operate in Indian Country, the required legal certification shall include an analysis of the applicant's authority to implement its provisions in Indian Country. The applicant shall include a map delineating the area over which it seeks to operate the program.

(d) *Program certification.* (1) At the time of submitting an application, a State may also certify to the Administrator that the State program meets the requirements contained in paragraphs (e)(2)(i) and (e)(2)(ii) of this section.

(2) If this certification is contained in a State's application, the program shall be deemed to be authorized by EPA until such time as the Administrator disapproves the program application or withdraws the program authorization. A program shall not be deemed authorized pursuant to this subpart to the extent that jurisdiction is asserted over Indian Country, including non-member fee lands within an Indian reservation.

(3) If the application does not contain such certification, the State program will be authorized only after the Administrator authorizes the program in accordance with paragraph (e) of this section.

(4) This certification shall take the form of a letter from the Governor or the Attorney General to the Administrator. The certification shall reference the program analysis in paragraph (b)(3) of this section as the basis for concluding that the State program is at least as protective as the Federal program, and provides adequate enforcement.

(e) *EPA approval.* (1) EPA will fully review and consider all portions of a State or Tribal application.

(2) Within 180 days of receipt of a complete State or Tribal application, the Administrator shall either authorize the program or disapprove the application. The Administrator shall authorize the program, after notice and the opportunity for public comment and a public hearing, only if the Administrator finds that:

(i) The State or Tribal program is at least as protective of human health and the environment as the corresponding Federal program under subpart E or subpart L of this part, or both; and

(ii) The State or Tribal program provides adequate enforcement.

(3) EPA shall notify in writing the State or Indian Tribe of the Administrator's decision to authorize the State or Tribal program or disapprove the State's or Indian Tribe's application.

(4) If the State or Indian Tribe applies for authorization of State or Tribal programs under both subpart E and subpart L, EPA may, as appropriate, authorize one program and disapprove the other.

(f) *EPA administration and enforcement.* (1) If a State or Indian Tribe does not have an authorized program to administer and enforce subpart L of this part in effect by August 31, 1998, the Administrator shall, by such date, establish and enforce the provisions of subpart L of this part as the Federal program for that State or Indian Country.

(2) If a State or Indian Tribe does not have an authorized program to administer and enforce the pre-renovation education requirements of subpart E of this part by August 31, 1998, the Administrator will, by such date, enforce those provisions of subpart E of this part as the Federal program for that State or Indian Country. If a State or Indian Tribe does not have an authorized program to administer and enforce the training, certification and accreditation requirements and work practice standards of subpart E of this part by April 22, 2009, the Administrator will, by such date, enforce those provisions of subpart E of this part as the Federal program for that State or Indian Country.

(3) Upon authorization of a State or Tribal program, pursuant to paragraph (d) or (e) of this section, it shall be an unlawful act under sections 15 and 409 of TSCA for any person to fail or refuse to comply with any requirements of such program.

(g) *Oversight.* EPA shall periodically evaluate the adequacy of a State's or Indian Tribe's implementation and enforcement of its authorized programs.

(h) *Reports.* Beginning 12 months after the date of program authorization, the primary agency for each State or Indian Tribe that has an authorized program shall submit a written report to the EPA Regional Administrator for the Region in which the State or Indian Tribe is located. This report shall be submitted at least once every 12 months for the first 3 years after program authorization. If these reports demonstrate successful program implementation, the Agency will automatically extend the reporting interval to every 2 years. If the subsequent reports demonstrate problems with implementation, EPA will require a return to annual reporting until the reports demonstrate successful program implementation, at which time the Agency will extend the reporting interval to every 2 years. The report shall include the following information:

(1) Any significant changes in the content or administration of the State or Tribal program implemented since the previous reporting period; and

(2) All information regarding the lead-based paint enforcement and compliance activities listed at § 745.327(d)

''Summary on Progress and Performance.''

(i) *Withdrawal of authorization.* (1) If EPA concludes that a State or Indian Tribe is not administering and enforcing an authorized program in compliance with the standards, regulations, and other requirements of sections 401 through 412 of TSCA and this subpart, the Administrator shall notify the primary agency for the State or Indian Tribe in writing and indicate EPA's intent to withdraw authorization of the program.

(2) The Notice of Intent to Withdraw shall:

(i) Identify the program aspects that EPA believes are inadequate and provide a factual basis for such findings.

(ii) Include copies of relevant documents.

(iii) Provide an opportunity for the State or Indian Tribe to respond either in writing or at a meeting with appropriate EPA officials.

(3) EPA may request that an informal conference be held between representatives of the State or Indian Tribe and EPA officials.

(4) Prior to issuance of a withdrawal, a State or Indian Tribe may request that EPA hold a public hearing. At this hearing, EPA, the State or Indian Tribe, and the public may present facts bearing on whether the State's or Indian Tribe's authorization should be withdrawn.

(5) If EPA finds that deficiencies warranting withdrawal did not exist or were corrected by the State or Indian Tribe, EPA may rescind its Notice of Intent to Withdraw authorization.

(6) Where EPA finds that deficiencies in the State or Tribal program exist that warrant withdrawal, an agreement to correct the deficiencies shall be jointly prepared by the State or Indian Tribe and EPA. The agreement shall describe the deficiencies found in the program, specify the steps the State or Indian Tribe has taken or will take to remedy the deficiencies, and establish a schedule, no longer than 180 days, for each remedial action to be initiated.

(7) If the State or Indian Tribe does not respond within 60 days of issuance of the Notice of Intent to Withdraw or an agreement is not reached within 180 days after EPA determines that a State or Indian Tribe is not in compliance with the Federal program, the Agency shall issue an order withdrawing the State's or Indian Tribe's authorization.

(8) By the date of such order, the Administrator will establish and enforce the provisions of subpart E or subpart L of this part, or both, as the Federal program for that State or Indian Country.

[61 FR 45825, Aug. 29, 1996, as amended at 73 FR 21767, Apr. 22, 2008]

§ 745.325 Lead-based paint activities: State and Tribal program requirements.

(a) *Program elements.* To receive authorization from EPA, a State or Tribal program must contain at least the following program elements for lead-based paint activities:

(1) Procedures and requirements for the accreditation of lead-based paint activities training programs.

(2) Procedures and requirements for the certification of individuals engaged in lead-based paint activities.

(3) Work practice standards for the conduct of lead-based paint activities.

(4) Requirements that all lead-based paint activities be conducted by appropriately certified contractors.

(5) Development of the appropriate infrastructure or government capacity to effectively carry out a State or Tribal program.

(b) *Accreditation of training programs.* The State or Indian Tribe must have either:

(1) Procedures and requirements for the accreditation of training programs that establish:

(i) Requirements for the accreditation of training programs, including but not limited to:

(A) Training curriculum requirements.

(B) Training hour requirements.

(C) Hands-on training requirements.

(D) Trainee competency and proficiency requirements.

(E) Requirements for training program quality control.

(ii) Procedures for the re-accreditation of training programs.

(iii) Procedures for the oversight of training programs.

(iv) Procedures for the suspension, revocation, or modification of training program accreditations; or

(2) Procedures or regulations, for the purposes of certification, for the acceptance of training offered by an accredited training provider in a State or Tribe authorized by EPA.

(c) *Certification of individuals.* The State or Indian Tribe must have requirements for the certification of individuals that:

(1) Ensure that certified individuals:

(i) Are trained by an accredited training program; and

(ii) Possess appropriate education or experience qualifications for certification.

(2) Establish procedures for re-certification.

(3) Require the conduct of lead-based paint activities in accordance with work practice standards established by the State or Indian Tribe.

(4) Establish procedures for the suspension, revocation, or modification of certifications.

(5) Establish requirements and procedures for the administration of a third-party certification exam.

(d) *Work practice standards for the conduct of lead-based paint activities.* The State or Indian Tribe must have requirements or standards that ensure that lead-based paint activities are conducted reliably, effectively, and safely. At a minimum the State's or Indian Tribe's work practice standards for conducting inspections, risk assessments, and abatements must contain the requirements specified in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

(1) The work practice standards for the inspection for the presence of lead-based paint must require that:

(i) Inspections are conducted only by individuals certified by the appropriate State or Tribal authority to conduct inspections.

(ii) Inspections are conducted in a way that identifies the presence of lead-based paint on painted surfaces within the interior or on the exterior of a residential dwelling or child-occupied facility.

(iii) Inspections are conducted in a way that uses documented methodologies that incorporate adequate quality control procedures.

(iv) A report is developed that clearly documents the results of the inspection.

(v) Records are retained by the certified inspector or the firm.

(2) The work practice standards for risk assessment must require that:

(i) Risk assessments are conducted only by individuals certified by the appropriate State or Tribal authority to conduct risk assessments.

(ii) Risk assessments are conducted in a way that identifies and reports the presence of lead-based paint hazards.

(iii) Risk assessments consist of, at least:

(A) An assessment, including a visual inspection, of the physical characteristics of the residential dwelling or child-occupied facility;

(B) Environmental sampling for lead in paint, dust, and soil;

(C) Environmental sampling requirements for lead in paint, dust, and soil that allow for comparison to the standards for lead-based paint hazards established or revised by the State or Indian Tribe pursuant to paragraph (e) of this section; and

(D) A determination of the presence of lead-based paint hazards made by comparing the results of visual inspection and environmental sampling to the standards for lead-based paint hazards established or revised by the State or Indian Tribe pursuant to paragraph (e) of this section.

(iv) The program elements required in paragraph (d)(2)(iii)(C) and (d)(2)(iii)(D) of this section shall be adopted in accordance with the schedule for the demonstration required in paragraph (e) of this section.

(v) The risk assessor develops a report that clearly presents the results of the assessment and recommendations for the control or elimination of all identified hazards.

(vi) The certified risk assessor or the firm retains the appropriate records.

(3) The work practice standards for abatement must require that:

(i) Abatements are conducted only by individuals certified by the appropriate State or Tribal authority to conduct or supervise abatements.

(ii) Abatements permanently eliminate lead-based paint hazards and are conducted in a way that does not increase the hazards of lead-based paint to the occupants of the dwelling or child-occupied facility.

(iii) Abatements include post-abatement lead in dust clearance sampling and conformance with clearance levels established or adopted by the State or Indian Tribe.

(iv) The abatement contractor develops a report that describes areas of the residential dwelling or child-occupied facility abated and the techniques employed.

(v) The certified abatement contractor or the firm retains appropriate records.

(e) The State or Indian Tribe must demonstrate that it has standards for identifying lead-based paint hazards and clearance standards for dust, that are at least as protective as the standards in §745.227 as amended on February 5, 2001. A State or Indian Tribe with such a section 402 program approved before February 5, 2003 shall make this demonstration no later than the first report submitted pursuant to §745.324(h) on or after February 5, 2003. A State or Indian Tribe with such a program submitted but not approved before February 5, 2003 may make this demonstration by amending its application or in its first report submitted pursuant to §745.324(h). A State or Indian Tribe submitting its program on or after February 5, 2003 shall make this demonstration in its application.

[61 FR 45825, Aug. 29, 1996, as amended at 66 FR 1240, Jan. 5, 2001]

§745.326 Renovation: State and Tribal program requirements.

(a) *Program elements.* To receive authorization from EPA, a State or Tribal program must contain the following program elements:

(1) For pre-renovation education programs, procedures and requirements for the distribution of lead hazard information to owners and occupants of target housing and child-occupied facilities before renovations for compensation.

(2) For renovation training, certification, accreditation, and work practice standards programs:

(i) Procedures and requirements for the accreditation of renovation and dust sampling technician training programs. A State and Tribal program is not required to include procedures and requirements for the dust sampling technician training discipline if the State or Tribal program requires dust sampling to be performed by a certified lead-based paint inspector or risk assessor.

(ii) Procedures and requirements for accredited initial and refresher training for renovators and dust sampling technicians and on-the-job training for other individuals who perform renovations.

(iii) Procedures and requirements for the certification of individuals and/or firms.

(iv) Requirements that all renovations be conducted by appropriately certified individuals and/or firms.

(v) Work practice standards for the conduct of renovations.

(3) For all renovation programs, development of the appropriate infrastructure or government capacity to effectively carry out a State or Tribal program.

(b) *Pre-renovation education.* To be considered at least as protective as the Federal program, the State or Tribal program must:

(1) Establish clear standards for identifying renovation activities that trigger the information distribution requirements.

(2) Establish procedures for distributing the lead hazard information to owners and occupants of housing and child-occupied facilities prior to renovation activities.

(3) Require that the information to be distributed include either the pamphlet titled *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools*, developed by EPA under section 406(a) of TSCA, or an alternate pamphlet or package of lead hazard information that has been submitted by the State or Tribe, reviewed by EPA, and approved by EPA for that State or Tribe. Such information must contain renovation-specific information similar to that in *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools*, must meet

the content requirements prescribed by section 406(a) of TSCA, and must be in a format that is readable to the diverse audience of housing and child-occupied facility owners and occupants in that State or Tribe.

(i) A State or Tribe with a pre-renovation education program approved before June 23, 2008, must demonstrate that it meets the requirements of this section no later than the first report that it submits pursuant to § 745.324(h) on or after April 22, 2009.

(ii) A State or Tribe with an application for approval of a pre-renovation education program submitted but not approved before June 23, 2008, must demonstrate that it meets the requirements of this section either by amending its application or in the first report that it submits pursuant to § 745.324(h) of this part on or after April 22, 2009.

(iii) A State or Indian Tribe submitting its application for approval of a pre-renovation education program on or after June 23, 2008, must demonstrate in its application that it meets the requirements of this section.

(c) *Accreditation of training programs.* To be considered at least as protective as the Federal program, the State or Tribal program must meet the requirements of either paragraph (c)(1) or (c)(2) of this section:

(1) The State or Tribal program must establish accreditation procedures and requirements, including:

(i) Procedures and requirements for the accreditation of training programs, including, but not limited to:

(A) Training curriculum requirements.

(B) Training hour requirements.

(C) Hands-on training requirements.

(D) Trainee competency and proficiency requirements.

(E) Requirements for training program quality control.

(ii) Procedures and requirements for the re-accreditation of training programs.

(iii) Procedures for the oversight of training programs.

(iv) Procedures and standards for the suspension, revocation, or modification of training program accreditations; or

(2) The State or Tribal program must establish procedures and requirements for the acceptance of renovation training offered by training providers accredited by EPA or a State or Tribal program authorized by EPA under this subpart.

(d) *Certification of individuals and/or renovation firms.* To be considered at least as protective as the Federal program, the State or Tribal program must:

(1) Establish procedures and requirements that ensure that individuals who perform or direct renovations are properly trained. These procedures and requirements must include:

(i) A requirement that renovations be performed and directed by at least one individual who has been trained by an accredited training program.

(ii) Procedures and requirements for accredited refresher training for these individuals.

(iii) Procedures and requirements for individuals who have received accredited training to provide on-the-job training for those individuals who perform renovations but do not receive accredited training. A State and Tribal program is not required to include procedures and requirements for on-the-job training for renovation workers if the State or Tribal program requires accredited initial and refresher training for all persons who perform renovations.

(2) Establish procedures and requirements for the formal certification and re-certification of renovation firms.

(3) Establish procedures for the suspension, revocation, or modification of certifications.

(e) *Work practice standards for renovations.* To be considered at least as protective as the Federal program, the State or Tribal program must establish standards that ensure that renovations are conducted reliably, effectively, and safely. At a minimum, the State or Tribal program must contain the following requirements:

(1) Renovations must be conducted only by certified renovation firms, using trained individuals.

(2) Renovations are conducted using lead-safe work practices that are at least as protective to occupants as the requirements in § 745.85.

(3) Certified individuals and/or renovation firms must retain appropriate records.

(f) *Revisions to renovation program requirements.* When EPA publishes in the FEDERAL REGISTER revisions to the renovation program requirements contained in subparts E and L of this part:

(1) A State or Tribe with a renovation program approved before the effective date of the revisions to the renovation program requirements in subparts E and L of this part must demonstrate that it meets the requirements of this section no later than the first report that it submits pursuant to §745.324(h) but no later than 2 years after the effective date of the revisions.

(2) A State or Tribe with an application for approval of a renovation program submitted but not approved before the effective date of the revisions to the renovation program requirements in subparts E and L of this part must demonstrate that it meets the requirements of this section either by amending its application or in the first report that it submits pursuant to §745.324(h) of this part but no later than 2 years after the effective date of the revisions.

(3) A State or Tribe submitting its application for approval of a renovation program on or after the effective date of the revisions must demonstrate in its application that it meets the requirements of the new renovation program requirements in subparts E and L of this part.

[73 FR 21768, Apr. 22, 2008, as amended at 75 FR 24819, May 6, 2010; 76 FR 47945, Aug. 5, 2011]

§745.327 State or Indian Tribal lead-based paint compliance and enforcement programs.

(a) *Approval of compliance and enforcement programs.* A State or Indian Tribe seeking authorization of a lead-based paint program can apply for and receive either interim or final approval of the compliance and enforcement program portion of its lead-based paint program. Indian Tribes are not required to exercise criminal enforcement jurisdiction as a condition for program authorization.

(1) *Interim approval.* Interim approval of the compliance and enforcement program portion of the State or Tribal lead-based paint program may be granted by EPA only once, and subject to a specific expiration date.

(i) To be considered adequate for purposes of obtaining interim approval for the compliance and enforcement program portion of a State or Tribal lead-based paint program, a State or Indian Tribe must, in its application described at §745.324(a):

(A) Demonstrate it has the legal authority and ability to immediately implement the elements in paragraph (b) of this section. This demonstration shall include a statement that the State or Indian Tribe, during the interim approval period, shall carry out a level of compliance monitoring and enforcement necessary to ensure that the State or Indian Tribe addresses any significant risks posed by noncompliance with lead-based paint activity requirements.

(B) Present a plan with time frames identified for implementing in the field each element in paragraph (c) of this section. All elements of paragraph (c) of this section must be fully implemented no later than 3 years from the date of EPA's interim approval of the compliance and enforcement program portion of a State or Tribal lead-based paint program. A statement of resources must be included in the State or Tribal plan which identifies what resources the State or Indian Tribe intends to devote to the administration of its lead-based paint compliance and enforcement program.

(C) Agree to submit to EPA the Summary on Progress and Performance of lead-based paint compliance and enforcement activities as described at paragraph (d) of this section.

(ii) Any interim approval granted by EPA for the compliance and enforcement program portion of a State or Tribal lead-based paint program will expire no later than 3 years from the date of EPA's interim approval. One hundred and eighty days prior to this expiration date, a State or Indian Tribe shall apply to EPA for final approval of the compliance and enforcement program portion of a State or Tribal lead-based paint program. Final approval shall be given to any State or Indian Tribe which has in place all of the elements of paragraphs (b), (c), and (d) of this section. If a State or Indian Tribe

does not receive final approval for the compliance and enforcement program portion of a State or Tribal lead-based paint program by the date 3 years after the date of EPA's interim approval, the Administrator shall, by such date, initiate the process to withdraw the State or Indian Tribe's authorization pursuant to § 745.324(i).

(2) *Final approval.* Final approval of the compliance and enforcement program portion of a State or Tribal lead-based paint program can be granted by EPA either through the application process described at § 745.324(a), or, for States or Indian Tribes which previously received interim approval as described in paragraph (a)(1) of this section, through a separate application addressing only the compliance and enforcement program portion of a State or Tribal lead-based paint program.

(i) For the compliance and enforcement program to be considered adequate for final approval through the application described at § 745.324(a), a State or Indian Tribe must, in its application:

(A) Demonstrate it has the legal authority and ability to immediately implement the elements in paragraphs (b) and (c) of this section.

(B) Submit a statement of resources which identifies what resources the State or Indian Tribe intends to devote to the administration of its lead-based paint compliance and enforcement program.

(C) Agree to submit to EPA the Summary on Progress and Performance of lead-based paint compliance and enforcement activities as described at paragraph (d) of this section.

(ii) For States or Indian Tribes which previously received interim approval as described in paragraph (a)(1) of this section, in order for the State or Tribal compliance and enforcement program to be considered adequate for final approval through a separate application addressing only the compliance and enforcement program portion of a State or Tribal lead-based paint program, a State or Indian Tribe must, in its application:

(A) Demonstrate that it has the legal authority and ability to immediately implement the elements in paragraphs (b) and (c) of this section.

(B) Submit a statement which identifies the resources the State or Indian Tribe intends to devote to the administration of its lead-based paint compliance and enforcement program.

(C) Agree to submit to EPA the Summary on Progress and Performance of lead-based paint compliance and enforcement activities as described at paragraph (d) of this section.

(D) To the extent not previously submitted through the application described at § 745.324(a), submit copies of all applicable State or Tribal statutes, regulations, standards, and other material that provide the State or Indian Tribe with authority to administer and enforce the lead-based paint compliance and enforcement program, and copies of the policies, certifications, plans, reports, and any other documents that demonstrate that the program meets the requirements established in paragraphs (b) and (c) of this section.

(b) *Standards, regulations, and authority.* The standards, regulations, and authority described in paragraphs (b)(1) through (b)(4) of this section are part of the required elements for the compliance and enforcement portion of a State or Tribal lead-based paint program.

(1) *Lead-based paint activities or renovation requirements.* State or Tribal lead-based paint compliance and enforcement programs will be considered adequate if the State or Indian Tribe demonstrates, in its application at § 745.324(b)(2), that it has established a lead-based paint program that contains all of the elements specified in § 745.325 or § 745.326, or both, as applicable.

(2) *Authority to enter.* State or Tribal officials must be able to enter, through consent, warrant, or other authority, premises or facilities where lead-based paint violations may occur for purposes of conducting inspections.

(i) State or Tribal officials must be able to enter premises or facilities where those engaged in training for lead-based paint activities or renovations conduct business.

(ii) For the purposes of enforcing a renovation program, State or Tribal officials must be able to enter a firm's place of business or work site.

(iii) State or Tribal officials must have authority to take samples and review records as part of the lead-based paint inspection process.

(3) *Flexible remedies.* A State or Tribal lead-based paint compliance and enforcement program must provide for a diverse and flexible array of enforcement statutory and regulatory authorities and remedies. At a minimum, these authorities and remedies, which must also be reflected in an enforcement response policy, must include the following:

(i) The authority to issue warning letters, Notices of Noncompliance, Notices of Violation, or the equivalent;

(ii) The authority to assess administrative or civil fines, including a maximum penalty authority for any violation in an amount no less than $5,000 per violation per day;

(iii) The authority to assess the maximum penalties or fines for each instance of violation and, if the violation is continuous, the authority to assess penalties or fines up to the maximum amount for each day of violation, with all penalties assessed or collected being appropriate for the violation after consideration of factors as the State or Tribe determine to be relevant, including the size or viability of the business, enforcement history, risks to human health or the environment posed by the violation, and other similar factors;

(iv) The authority to commence an administrative proceeding or to sue in courts of competent jurisdiction to recover penalties;

(v) The authority to suspend, revoke, or modify the accreditation of any training provider or the certification of any individual or firm;

(vi) The authority to commence an administrative proceeding or to sue in courts of competent jurisdiction to enjoin any threatened or continuing violation of any program requirement, without the necessity of a prior suspension or revocation of a trainer's accreditation or a firm's or individual's certification;

(vii) The authority to apply criminal sanctions, including recovering fines; and

(viii) The authority to enforce its authorized program using a burden of proof standard, including the degree of knowledge or intent of the respondent that is no greater than it is for EPA under TSCA.

(4) *Adequate resources.* An application must include a statement that identifies the resources that will be devoted by the State or Indian Tribe to the administration of the State or Tribal lead-based paint compliance and enforcement program. This statement must address fiscal and personnel resources that will be devoted to the program.

(c) *Performance elements.* The performance elements described in paragraphs (c)(1) through (c)(7) of this section are part of the required elements for the compliance and enforcement program portion of a State or Tribal lead-based paint program.

(1) *Training.* A State or Tribal lead-based paint compliance and enforcement program must implement a process for training enforcement and inspection personnel and ensure that enforcement personnel and inspectors are well trained. Enforcement personnel must understand case development procedures and the maintenance of proper case files. Inspectors must successfully demonstrate knowledge of the requirements of the particular discipline (e.g., abatement supervisor, and/or abatement worker, and/or lead-based paint inspector, and/or risk assessor, and/or project designer) for which they have compliance monitoring and enforcement responsibilities. Inspectors must also be trained in violation discovery, methods of obtaining consent, evidence gathering, preservation of evidence and chain-of-custody, and sampling procedures. A State or Tribal lead-based paint compliance and enforcement program must also implement a process for the continuing education of enforcement and inspection personnel.

(2) *Compliance assistance.* A State or Tribal lead-based paint compliance and enforcement program must provide compliance assistance to the public and the regulated community to facilitate awareness and understanding of and compliance with State or Tribal requirements governing the conduct of lead-based paint activities or renovations. The type and nature of this assistance can be defined by the State or Indian Tribe to achieve this goal.

(3) *Sampling techniques.* A State or Tribal lead-based paint compliance and enforcement program must have the technological capability to ensure compliance with the lead-based paint program requirements. A State or Tribal application for approval of a lead-based paint program must show that the State or Indian Tribe is technologically capable of conducting a lead-based paint compliance and enforcement program. The State or Tribal program must have access to the facilities and equipment necessary to perform sampling and laboratory analysis as needed. This laboratory facility must be a recognized laboratory as defined at § 745.223, or the State or Tribal program must implement a quality assurance program that ensures appropriate quality of laboratory personnel and protects the integrity of analytical data.

(4) *Tracking tips and complaints.* A State or Tribal lead-based paint compliance and enforcement program must demonstrate the ability to process and react to tips and complaints or other information indicating a violation.

(5) *Targeting inspections.* A State or Tribal lead-based paint compliance and enforcement program must demonstrate the ability to target inspections to ensure compliance with the lead-based paint program requirements. Such targeting must include a method for obtaining and using notifications of commencement of abatement activities.

(6) *Follow up to inspection reports.* A State or Tribal lead-based paint compliance and enforcement program must demonstrate the ability to reasonably, and in a timely manner, process and follow-up on inspection reports and other information generated through enforcement-related activities associated with a lead-based paint program. The State or Tribal program must be in a position to ensure correction of violations and, as appropriate, effectively develop and issue enforcement remedies/responses to follow up on the identification of violations.

(7) *Compliance monitoring and enforcement.* A State or Tribal lead-based paint compliance and enforcement program must demonstrate, in its application for approval, that it is in a position to implement a compliance monitoring and enforcement program. Such a compliance monitoring and enforcement program must ensure correction of violations, and encompass either planned and/or responsive lead-based paint compliance inspections and development/issuance of State or Tribal enforcement responses which are appropriate to the violations.

(d) *Summary on Progress and Performance.* The Summary on Progress and Performance described below is part of the required elements for the compliance and enforcement program portion of a State or Tribal lead-based paint program. A State or Tribal lead-based paint compliance and enforcement program must submit to the appropriate EPA Regional Administrator a report which summarizes the results of implementing the State or Tribal lead-based paint compliance and enforcement program, including a summary of the scope of the regulated community within the State or Indian Tribe (which would include the number of individuals and firms certified in lead-based paint activities and the number of training programs accredited), the inspections conducted, enforcement actions taken, compliance assistance provided, and the level of resources committed by the State or Indian Tribe to these activities. The report shall be submitted according to the requirements at § 745.324(h).

(e) *Memorandum of Agreement.* An Indian Tribe that obtains program approval must establish a Memorandum of Agreement with the Regional Administrator. The Memorandum of Agreement shall be executed by the Indian Tribe's counterpart to the State Director (e.g., the Director of Tribal Environmental Office, Program or Agency). The Memorandum of Agreement must include provisions for the timely and appropriate referral to the Regional Administrator for those criminal enforcement matters where that Indian Tribe does not have the authority (e.g., those addressing criminal violations by non-Indians or violations meriting penalties over $5,000). The Agreement must also identify any enforcement agreements that may exist between the Indian Tribe and any State.

(f) *Electronic reporting under State or Indian Tribe programs.* States and tribes that choose to receive electronic documents under the authorized state or Indian tribe lead-based paint program, must ensure that the requirements of 40 CFR part 3—(Electronic reporting) are satisfied in their lead-based paint program.

[61 FR 45825, Aug. 29, 1996, as amended at 70 FR 59889, Oct. 13, 2005; 73 FR 21769, Apr. 22, 2008; 76 FR 47946, Aug. 5, 2011]

§ 745.339 Effective date.

States and Indian Tribes may seek authorization to administer and enforce subpart L of this part pursuant to this subpart at any time. States and Indian Tribes may seek authorization to administer and enforce the pre-renovation education provisions of subpart E of this part pursuant to this subpart at any time. States and Indian Tribes may seek authorization to administer and enforce all of subpart E of this part pursuant to this subpart effective June 23, 2008.

[73 FR 21769, Apr. 22, 2008]

PART 747—METALWORKING FLUIDS

Subpart A [Reserved]

Subpart B—Specific Use Requirements for Certain Chemical Substances

Sec.

747.115 Mixed mono and diamides of an organic acid.
747.195 Triethanolamine salt of a substituted organic acid.
747.200 Triethanolamine salt of tricarboxylic acid.

AUTHORITY: 15 U.S.C. 2604 and 2605.

Subpart A [Reserved]

Subpart B—Specific Use Requirements for Certain Chemical Substances

§ 747.115 Mixed mono and diamides of an organic acid.

This section identifies activities with respect to a chemical substance which are prohibited and requires that warnings and instructions accompany the substance when distributed in commerce.

(a) *Chemical substance subject to this section.* The following chemical substance, referred to by its premanufacture notice number and generic chemical name, is subject to this section: P-84–529, mixed mono and diamides of an organic acid.

(b) *Definitions.* Definitions in section 3 of the Act, 15 U.S.C. 2602, apply to this section unless otherwise specified in this paragraph. In addition, the following definitions apply:

(1) The terms *Act*, *article*, *chemical substance*, *commerce*, *importer*, *impurity*, *Inventory*, *manufacturer*, *person*, *process*, *processor*, and *small quantities solely for research and development* have the same meaning as in § 720.3 of this chapter.

(2) *Metalworking fluid* means a liquid of any viscosity or color containing intentionally added water used in metal machining operations for the purpose of cooling, lubricating, or rust inhibition.

(3) *Nitrosating agent* means any substance that has the potential to transfer a nitrosyl group (–NO) to a primary, secondary, or tertiary amine to form the corresponding nitrosamine.

(4) *Process or distribute in commerce solely for export* means to process or distribute in commerce solely for export from the United States under the following restrictions on domestic activity:

(i) Processing must be performed at sites under the control of the processor.

(ii) Distribution in commerce is limited to purposes of export.

(iii) The processor or distributor may not use the substance except in small quantities solely for research and development.

(c) *Use limitations.* (1) Any person producing a metalworking fluid, or a product which could be used in or as a metalworking fluid, which includes as one of its components P-84–529, is prohibited from adding any nitrosating agent to the metalworking fluid or product.

(2) Any person using as a metalworking fluid a product containing P-84–529 is prohibited from adding any nitrosating agent to the product.

(d) *Warnings and instructions.* (1) Any person who distributes in commerce P-84–529 in a metalworking fluid, or in any form in which it could be used as

a component of a metalworking fluid, must send to each recipient of P-84–529 and confirm receipt in writing prior to the first shipment to that person:

(i) A letter that includes the following statements:

A substance, identified generically as mixed mono and diamides of an organic acid, contained in the product (*insert distributor's other identifier for product containing P-84–529*) has been regulated by the Environmental Protection Agency, at 40 CFR 747.115, as published in the FEDERAL REGISTER of September 20, 1984. A copy of the regulation is enclosed. The regulation prohibits the addition of any nitrosating agent, including nitrites, to the mixed mono and diamides of an organic acid, when the substance is or could be used in metalworking fluids. The addition of nitrites or other nitrosating agents to this substance leads to formation of a substance known to cause cancer in laboratory animals. The mixed mono and diamides of an organic acid has been specifically designed to be used without nitrites. Consult the enclosed regulation for further information.

(ii) A copy of this § 747.115.

(2)(i) Any person who distributes in commerce a metalworking fluid containing P-84–529 must affix a label to each container containing the fluid.

(ii) The label shall contain a warning statement which shall consist only of the following language:

WARNING! Do Not Add Nitrites to This Metalworking Fluid under Penalty of Federal Law. Addition of nitrites leads to formation of a substance known to cause cancer. This product is designed to be used without nitrites.

(iii) The first work of the warning statement shall be capitalized, and the type size for the first word shall be no smaller than six point type for a label five square inches or less in area, ten point type for a label above five but below ten square inches in area, twelve point type for a label above ten but below fifteen square inches in area, fourteen point type for a label above fifteen but below thirty square inches in area, or eighteen point type for a label over thirty square inches in area. The type size of the remainder of the warning statement shall be no smaller than six point type. All required label text shall be of sufficient prominence, and shall be placed with such conspicuousness relative to other label text and graphic material, to insure that the warning statement is read and understood by the ordinary individual under customary conditions of purchase and use.

(e) *Liability and determining whether a chemical substance is subject to this section.* (1) If a manufacturer or importer of a chemical substance which is described by the generic chemical name in paragraph (a) of this section makes an inquiry under § 710.7(g) of this chapter or § 720.25(b) of this chapter as to whether the specific substance is on the Inventory and EPA informs the manufacturer or importer that the substance is on the Inventory, EPA will also inform the manufacturer or importer whether the substance is subject to this section.

(2) Except for manufacturers and importers of P-84–529, no processor, distributor, or user of P-84–529 will be in violation of this section unless that person has received a letter specified in paragraph (d)(1) of this section or a container with the label specified in paragraph (d)(2) of this section.

(f) *Exemptions.* A person identified in paragraphs (c) and (d) of this section is not subject to the requirements of those paragraphs if:

(1) The person manufactures, imports, processes, distributes in commerce, or uses the substance only in small quantities solely for research and development and in accordance with section 5(h)(3) of the Act.

(2) The person manufactures, imports, processes, distributes in commerce, or uses the substance only as an impurity.

(3) The person imports, processes, distributes in commerce, or uses the substance only as part of an article.

(4) The person processes or distributes the substance in commerce solely for export and, when distributing in commerce, lables the substance in accordance with section 12(a)(1)(B) of the Act.

(g) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act [15 U.S.C. 2614].

(2) Failure or refusal to permit access to or copying of records, as required

under section 11 of the Act, is a violation of section 15 of the Act [15 U.S.C. 2614].

(3) Failure or refusal to permit entry or inspection, as required under section 11 of the Act, is a violation of section 15 of the Act [15 U.S.C. 2614].

(4) Violators may be subject to the civil and criminal penalties in section 16 of the Act [15 U.S.C. 2615] for each violation.

(5) EPA may seek to enjoin the processing, distribution in commerce, or use of a chemical substance in violation of this section; act to seize any chemical substance processed, distributed in commerce, or used in violation of this section; or take other actions under the authority of sections 7 and 17 of the Act [15 U.S.C. 2605 and 2616].

[49 FR 36855, Sept. 20, 1984]

§ 747.195 Triethanolamine salt of a substituted organic acid.

This section identifies activities with respect to a chemical substance which are prohibited and requires that warnings and instructions accompany the substance when distributed in commerce.

(a) *Chemical substance subject to this section.* The following chemical substance, referred to by its premanufacture notice number and generic chemical name, is subject to this section: P-84–310, triethanolamine salt of a substituted organic acid.

(b) *Definitions.* Definitions in section 3 of the Act, 15 U.S.C. 2602, apply to this section unless otherwise specified in this paragraph. In addition, the following definitions apply:

(1) The terms *Act*, *article*, *chemical substance*, *commerce*, *importer*, *impurity*, *Inventory*, *manufacturer*, *person*, *process*, *processor*, and *small quantities solely for research and development*, have the same meaning as in § 720.3 of this chapter.

(2) *Metalworking fluid* means a liquid of any viscosity or color containing intentionally added water used in metal machining operations for the purpose of cooling, lubricating, or rust inhibition.

(3) *Nitrosating agent* means any substance that has the potential to transfer a nitrosyl group (—NO) to a primary, secondary, or tertiary amine to form the corresponding nitrosamine.

(4) *Process or distribute in commerce solely for export* means to process or distribute in commerce solely for export from the United States under the following restrictions on domestic activity:

(i) Processing must be performed at sites under the control of the processor.

(ii) Distribution in commerce is limited to purposes of export.

(iii) The processor or distributor may not use the substance except in small quantities solely for research and development.

(c) *Use limitations.* (1) Any person producing a metalworking fluid, or a product which could be used in or as a metalworking fluid, which includes as one of its components P-84–310, is prohibited from adding any nitrosating agent to the metalworking fluid or product.

(2) A person using as a metalworking fluid a product containing P-84–310 is prohibited from adding any nitrosating agent to the product.

(d) *Warnings and instructions.* (1) Any person who distributes in commerce P-84–310 in a metalworking fluid, or in any form in which it could be used as a component of a metalworking fluid, must send to each recipient of P-84–310 and confirm receipt in writing prior to the first shipment to that person:

(i) A letter that includes the following statements: A substance, identified generically as a triethanolamine salt of a substituted organic acid, contained in the product (*insert distributor's trade name or other identifier for product containing P-84–310*) has been regulated by the Environmental Protection Agency, at 40 CFR 747.195, as published in the FEDERAL REGISTER of June 14, 1984. A copy of the regulation is enclosed. The regulation prohibits the addition of any nitrosating agent, including nitrites, to the triethanolamine salt of a substituted organic acid, when the substance is or could be used in metalworking fluids. The addition of nitrites or other nitrosating agents to this substance leads to formation of a substance known to cause

cancer in laboratory animals. The triethanolamine salt of a substituted organic acid has been specifically designed to be used without nitrites. Consult the enclosed regulation for further information.

(ii) A copy of this § 747.195.

(2)(i) Any person who distributes in commerce a metalworking fluid containing P-84–310 must affix a label to each container containing the fluid.

(ii) The label shall contain a warning statement which shall consist only of the following language:

WARNING! Do Not Add Nitrites to This Metalworking Fluid under Penalty of Federal Law. Addition of nitrites leads to formation of a substance known to cause cancer. This product is designed to be used without nitrites.

(iii) The first word of the warning statement shall be capitalized, and the type size for the first word shall be no smaller than six point type for a label five square inches or less in area, ten point type for a label above five but below ten square inches in area, twelve point type for a label above ten but below fifteen square inches in area, fourteen point type for a label above fifteen but below thirty square inches in area, or eighteen point type for a label over thirty square inches in area. The type size of the remainder of the warning statement shall be no smaller than six point type. All required label text shall be of sufficient prominence, and shall be placed with such conspicuousness relative to other label text and graphic material, to insure that the warning statement is read and understood by the ordinary individual under customary conditions of purchase and use.

(e) *Liability and determining whether a chemical substance is subject to this section.* (1) If a manufacturer or importer of a chemical substance which is described by the generic chemical name in paragraph (a) of this section makes an inquiry under § 710.7(g) of this chapter or § 720.25(b) of this chapter as to whether the specific substance is on the Inventory and EPA informs the manufacturer or importer that the substance is on the Inventory, EPA will also inform the manufacturer or importer whether the substance is subject to this section.

(2) Except for manufacturers and importers of P-84–310, no processor, distributor, or user of P-84–310 will be in violation of this section unless that person has received a letter specified in paragraph (d)(1) of this section or a container with the label specified in paragraph (d)(2) of this section.

(f) *Exemptions.* A person identified in paragraphs (c) and (d) of this section is not subject to the requirements of those paragraphs if:

(1) The person manufactures, imports, processes, distributes in commerce, or uses the substance only in small quantities solely for research and development and in accordance with section 5(h)(3) of the Act.

(2) The person manufactures, imports, processes, distributes in commerce, or uses the substance only as an impurity.

(3) The person imports, processes, distributes in commerce, or uses the substance only as part of an article.

(4) The person processes or distributes the substance in commerce solely for export, and when distributing in commerce, labels the substance in accordance with section 12(a)(1)(B) of the Act.

(g) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Failure or refusal to permit access to or copying of records, as required under section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit entry or inspection, as required under section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

[49 FR 24668, June 14, 1984]

§ 747.200 Triethanolamine salt of tricarboxylic acid.

This section identifies activities with respect to two chemical substances which are prohibited and requires that warnings and instructions accompany the substances when distributed in commerce.

(a) *Chemical substances subject to this section.* The following chemical substances, referred to by their premanufacture notice numbers and

generic chemical names, are subject to this section:

P-83–1005, triethanolamine salt of tricarboxylic acid; and
P-83–1062, tricarboxylic acid.

(b) *Definitions.* Definitions in section 3 of the Act, 15 U.S.C. 2602, apply to this section unless otherwise specified in this paragraph. In addition, the following definitions apply:

(1) The terms *Act*, *article*, *byproducts*, *chemical substance*, *commerce*, *imported*, *impurity*, *Inventory*, *manufacture or import for commercial purposes*, *manufacture solely for export*, *manufacturer*, *new chemical substance*, *person*, *process*, *processor*, and *small quantities solely for research and development* have the same meaning as in § 720.3 of this chapter.

(2) *Metalworking fluid* means a liquid of any viscosity or color containing intentionally added water used in metal machining operations for the purpose of cooling or lubricating.

(3) *Nitrosating agent* means any substance that has the potential to transfer a nitrosyl group (—NO) to a secondary or tertiary amine to form the corresponding nitrosamine.

(c) *Use limitations.* (1) Any person producing a metalworking fluid, or a product which could be used in or as a metalworking fluid, which includes as one of its components P-83–1005 is prohibited from adding any nitrosating agent to the metalworking fluid or product.

(2) Any person using as metalworking fluid a product containing P-83–1005 is prohibited from adding any nitrosating agent to the product.

(d) *Warnings and instructions.* (1) Any person who distributes in commerce P-83–1005 in a metalworking fluid, or in any form in which it could be used as a component of a metalworking fluid, must sent to each recipient of P-83–1005 and confirm receipt prior to the first shipment to that person:

(i) A letter that includes the following statements:

A substance, identified generically as triethanolamine salt, of tricarboxylic acid, contained in the product (*insert distributor's trade name or other identifier for product containing P–83–1005*) has been regulated by the Environmental Protection Agency, at 40 CFR 747.200, as published in the FEDERAL REGISTER of January 23, 1984. A copy of the regulation is enclosed. The regulation prohibits the addition of any nitrosating agent, including nitrites, to the triethanolamine salt of tricarboxylic acid, when the substance is or could be used in metalworking fluids. The addition of nitrites or other nitrosating agents to this substance leads to formation of a substance known to cause cancer in laboratory animals. The triethanolamine salt of the tricarboxylic acid, has been specifically designed to be used without nitrites. Consult the enclosed regulation for further information.

(ii) A copy of this rule.

(2) Any person who distributes in commerce a metalworking fluid containing P-83–1005 must affix to each container containing the fluid a label that includes, in letters no smaller than ten point type, the following statement:

WARNING! Do Not Add Nitrites to This Metalworking Fluid under Penalty of Federal Law. Addition of nitrite leads to formation of a substance known to cause cancer. This product is designed to be used without nitrites.

(3) Any person who distributes in commerce P-83–1062 in any form in which it could be combined with water and triethanolamine to produce P-83–1005 must send to each recipient of P-83–1062, and confirm receipt prior to the first shipment to that person:

(i) A letter that includes the following statements:

A substance, identified generically as tricarboxylic acid, contained in the product (*insert distributor's trade name or other identifier for product containing P–83–1062*) has been regulated by the Environmental Protection Agency (40 CFR 747.200 published in the FEDERAL REGISTER of January 23, 1984. A copy of the regulation is enclosed. Combining tricarboxylic acid with water and the triethanolamine produces a substance, identified generically as the triethanolamine salt of the tricarboxylic acid. The regulation prohibits the addition of nitrosating agents, including nitrites, to the triethanolamine salt of tricarboxylic acid, when that substance is or could be used in metalworking fluids. The addition of nitrites or other nitrosating agents to that substance leads to formation of a substance known to cause cancer in laboratory animals. Consult the enclosed regulation for further information.

(ii) A copy of this rule.

(e) *Liability and determining whether a chemical substance is subject to this section.* (1) If a manufacturer or importer

of a chemical substance which is described by one of the generic names in paragraph (a) of this section makes an inquiry under §710.7(g) of this chapter or §720.25(b) of this chapter as to whether the specific substance is on the Inventory and EPA informs the manufacturer or importer that the substance is on the Inventory, EPA will also inform the manufacturer or importer whether the substance is subject to this section.

(2) Except for manufacturers and importers of P-83–1005 and P-83–1062, no processor, distributor, or user of P-83–1005 or P-83–1062 will be in violation of this section unless that person has received a letter specified in paragraph (d)(1) or (3) of this section or a container with the label specified in paragraph (d)(2) of this section.

(f) *Exemptions and exclusions.* The chemical substances identified in paragraph (a) of this section are not subject to the requirements of paragraphs (c) and (d) of this section, if:

(1) The substance is manufactured, imported, processed, distributed in commerce, and used only in small quantities solely for research and development, and if the substance is manufactured, imported, processed, distributed in commerce, and used in accordance with section 5(h)(3) of the Act.

(2) The substance is manufactured, imported, processed, distributed in commerce, or used only as an impurity.

(3) The substance is imported, processed, distributed in commerce, or used only as part of an article.

(4) The substance is manufactured solely for export.

(g) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Failure or refusal to permit access to or copying of records, as required under section 11 of the Act, is a violation of a section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit entry or inspection, as required under section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C 2615) for each violation.

(5) EPA may seek to enjoin the processing, distribution in commerce, or use of a chemical substance in violation of this section, act to seize any chemical substance, processed, distributed in commerce, or used in violation of this section or take other actions under the authority of section 7 or 17 of the Act (15 U.S.C. 2605 or 2616).

[49 FR 2772, Jan. 23, 1984]

PART 749—WATER TREATMENT CHEMICALS

Subparts A–C [Reserved]

Subpart D—Air Conditioning and Cooling Systems

Sec.

749.68 Hexavalent chromium-based water treatment chemicals in cooling systems.

AUTHORITY: 15 U.S.C. 2605 and 2607.

Subparts A–C [Reserved]

Subpart D—Air Conditioning and Cooling Systems

§ 749.68 Hexavalent chromium-based water treatment chemicals in cooling systems.

(a) *Chemicals subject to this section.* Hexavalent chromium-based water treatment chemicals that contain hexavalent chromium, usually in the form of sodium dichromate (CAS No. 10588–01–9), are subject to this section. Other examples of hexavalent chromium compounds that can be used to treat water are: Chromic acid (CAS No. 7738–94–5), chromium trioxide (CAS No. 1333–83–0), dichromic acid (CAS No.13530–68–2), potassium chromate (CAS No. 7789–00–6), potassium dichromate (CAS No. 7778–50–9), sodium chromate (CAS No. 7775–11–3), zinc chromate (CAS No. 13530–65–9), zinc chromate hydroxide (CAS No. 153936–94–6), zinc dichromate (CAS No. 14018–95–2), and zinc potassium chromate (CAS No. 11103–86–9).

(b) *Purpose.* The purpose of this section is to impose certain requirements on activities involving hexavalent chromium-based water treatment chemicals to prevent unreasonable

risks associated with human exposure to air emissions of hexavalent chromium from comfort cooling towers.

(c) *Applicability.* This section is applicable to use of hexavalent chromium-based water treatment chemicals in comfort cooling towers and to distribution in commerce of hexavalent chromium-based water treatment chemicals for use in cooling systems.

(d) *Definitions.* Definitions in section 3 of the Toxic Substances Control Act, 15 U.S.C. 2602, apply to this section unless otherwise specified in this paragraph. In addition, the following definitions apply:

(1) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(2) *Chilled water loop* means any closed cooling water system that transfers heat from air handling units or refrigeration equipment to a refrigeration machine, or chiller.

(3) *Closed cooling water system* means any configuration of equipment in which heat is transferred by circulating water that is contained within the equipment and not discharged to the air; chilled water loops are included.

(4) *Comfort cooling towers* means cooling towers that are dedicated exlusively to and are an integral part of heating, ventilation, and air conditioning or refrigeration systems.

(5) *Container* means any bag, barrel, bottle, box, can, cylinder, drum, or the like that holds hexavalent chromium-based water treatment chemicals for use in cooling systems.

(6) *Cooling tower* means an open water recirculating device that uses fans or natural draft to draw or force ambient air through the device to cool warm water by direct contact.

(7) *Cooling system* means any cooling tower or closed cooling water system.

(8) *Distributor* means any person who distributes in commerce water treatment chemicals for use in cooling systems.

(9) *EPA* means the Environmental Protection Agency.

(10) *Hexavalent chromium* means the oxidation state of chromium with an oxidation number of + 6; a coordination number of 4 and tetrahedral geometry.

(11) *Hexavalent chromium-based water treatment chemicals* means any chemical containing hexavalent chromium which can be used to treat water, either alone or in combination with other chemicals, where the mixture can be used to treat water.

(12) *Industrial cooling tower* means any cooling tower used to remove heat from industrial processes, chemical reactions, or plants producing electrical power.

(13) *Label* means any written, printed, or graphic material displayed on or affixed to containers of hexavalent chromium-based water treatment chemicals that are to be used in cooling systems.

(14) *Person* means any natural person, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.

(15) *Shipment* means the act or process of shipping goods by any form of conveyance.

(16) *Water treatment chemicals* means any combination of chemical substances used to treat water in cooling systems and can include corrosion inhibitors, antiscalants, dispersants, and any other chemical substances except biocides.

(e) *Prohibition of distribution in commerce and commercial use.* (1) All persons are prohibited from distributing in commerce hexavalent chromium-based water treatment chemicals for use in comfort cooling towers.

(2) All persons are prohibited from commercial use of hexavalent chromium-based water treatment chemicals in comfort cooling towers.

(3) Distribution in commerce of hexavalent chromium-based water treatment chemicals for use in, and commercial use of hexavalent chromium-based water treatment chemicals in, industrial cooling towers and closed cooling water systems are not prohibited.

(f) *Effective dates.* (1) The prohibition described in paragraph (e)(1) of this section against distributing in commerce hexavalent chromium-based water treatment chemicals for use in

comfort cooling towers is effective February 20, 1990.

(2) The prohibition described in paragraph (e)(2) of this section against using hexavalent chromium-based water treatment chemicals in comfort cooling towers is effective May 18, 1990.

(g) *Labeling.* (1) Each person who distributes in commerce hexavalent chromium-based water treatment chemicals for use in cooling systems after February 20, 1990, shall affix a label or keep affixed an existing label in accordance with this paragraph, to each container of the chemicals. The label shall consist of the following language:

WARNING: This product contains hexavalent chromium. Inhalation of hexavalent chromium air emissions increases the risk of lung cancer. Federal Law prohibits use of this substance in comfort cooling towers, which are towers that are open water recirculation devices and that are dedicated exclusively to, and are an integral part of, heating, ventilation, and air conditioning or refrigeration systems.

(2) The first word of the warning statement shall be capitalized, and the type size for the first word shall be no smaller than 10-point type for a label less than or equal to 10 square inches in area, 12-point type for a label above 10 but less than or equal to 15 square inches in area, 14-point type for a label above 15 but less than or equal to 30 square inches in area, or 18-point type for a label above 30 square inches in area. The type size of the remainder of the warning statement shall be no smaller than 6-point type. All required label text shall be in English and of sufficient prominence and shall be placed with such conspicuousness, relative to other label text and graphic material, to ensure that the warning statement is read and understood by the ordinary individual under customary conditions of purchase and use.

(h) *Recordkeeping.* (1) Each person who distributes in commerce any hexavalent chromium-based water treatment chemicals for use in cooling systems after February 20, 1990, shall retain in one location at the headquarters of the distributor documentation showing:

(i) The name, address, contact, and telephone number of the cooling system owners/operators to whom the chemicals were shipped.

(ii) The chemicals included in the shipment, the amount of each chemical shipped, and the location(s) at which the chemicals will be used.

(2) The information described in paragraph (h)(1) of this section shall be retained for 2 years from the date of shipment.

(i) *Reporting.* (1) Each person who distributes in commerce any hexavalent chromium-based water treatment chemicals for use in cooling systems shall report to the Regional Administrator of the EPA Region in which the distibutor headquarters is located. The report shall be postmarked not later than February 20, 1990, or 30 days after the person first begins the distribution in commerce of hexavalent chromium-based water treatment chemicals, whichever is later, and shall include:

(i) For the headquarters, the distributor name, address, telephone number, and the name of a contact.

(ii) For the shipment offices through which hexavalent chromium-based water treatment chemicals are sold for use in cooling systems, the distributor name, address, telephone number, and the name of a contact.

(2) The report identified in paragraph (i)(1) of this section shall be updated as changes occur in the distributor headquarters or shipment office information. The updated report shall be submitted to the Regional Administrator and postmarked no later than 10 calendar days after the change occurs.

(3) A person may assert a claim of confidentiality for any information submitted to EPA in connection with this rule. Any claim of confidentiality must accompany the information when submitted to EPA. Persons claiming information as confidential should do so by circling, bracketing, or underlining it and marking it with ''CONFIDENTIAL.'' EPA will disclose information subject to a claim of confidentiality only to the extent permitted by section 14 of TSCA and 40 CFR part 2, subpart B. If a person does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public without further notice to that person.

(j) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit entry or inspection as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(k) *Inspections.* EPA will conduct inspections under section 11 of the Act (15 U.S.C. 2610) to ensure compliance with this section.

[55 FR 240, Jan. 3, 1990, as amended at 59 FR 42773, Aug. 19, 1994]

PART 750—PROCEDURES FOR RULEMAKING UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

Subpart A [Reserved]

Subpart B—Interim Procedural Rules for Manufacturing Exemptions

Sec.

750.10 Applicability.
750.11 Filing of petitions for exemption.
750.12 Consolidation of rulemakings.
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750.14 Confidentiality.
750.15 Final rule.

Subpart C—Interim Procedural Rules for Processing and Distribution in Commerce Exemptions

750.30 Applicability.
750.31 Filing of petitions for exemption.
750.32 Consolidation of rulemaking.
750.33 Notice of proposed rulemaking.
750.34 Confidentiality.
750.35 Final rule.

AUTHORITY: 15 U.S.C. 2605.

Subpart A [Reserved]

Subpart B—Interim Procedural Rules for Manufacturing Exemptions

SOURCE: 43 FR 50905, Nov. 1, 1978, unless otherwise noted.

§ 750.10 Applicability.

Sections 750.10–750.15 apply to all rulemakings under authority of section 6(e)(3)(B) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e)(3)(B) with respect to petitions filed pursuant to § 750.11(a).

[81 FR 93636, Dec. 21, 2016]

§ 750.11 Filing of petitions for exemption.

(a) *Who may file.* Any person seeking an exemption from the PCB manufacturing ban imposed by section 6(e)(3)(A) of TSCA may file a petition for exemption. Petitions must be submitted on an individual basis for each manufacturer or individual affected by the 1979 manufacturing ban.

(b) *Where to file.* All petitions pertaining to:

(1) PCB use, which includes storage for use or reuse, manufacture, processing related to manufacture and use, and distribution in commerce related to use or processing for use, must be submitted to: OPPT Document Control Officer (7407T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(2) PCB disposal, which includes cleanup, storage for disposal, processing related to disposal, distribution in commerce related to disposal or processing for disposal, and decontamination, must be submitted to: Document Control Officer, Office of Resource Conservation and Recovery (5305P), Environmental Protection Agency, 1200 Pennsylvania, NW., Washington, DC 20460–0001.

(c) *Content of petition.* Each petition shall contain the following:

(1) Name, address and telephone number of petitioner.

(2) Description of PCB ban exemption requested, including items to be manufactured and nature of manufacturing process—such as smelting.

(3) Location(s) of manufacturing sites requiring exemption.

(4) Length of time requested for exemption (maximum length of exemption is 1 year).

(5) Amount of PCB chemical substance or PCB mixture (by pounds and/or volume) to be manufactured or used during requested exemption period and the manner of release of PCB's into the environment associated with such manufacture or use.

(6) The basis for the petitioner's contention that under section 6(e)(3)(B)(i) of TSCA ''an unreasonable risk of injury to health or environment would not result'' from the granting of his petition for exemption.

(7) The basis for the petitioner's contention that he meets the criterion of section 6(e)(3)(B)(ii) of TSCA concerning substitutes for PCB's.

(8) Quantification of the reasonably ascertainable economic consequences of denial of the petition for exemption from the 1979 manufacturing ban and an explanation of the manner of computation.

(d) *Request for further information.* The Agency reserves the right to request further information as to each petition prior to or after publication of the notice of proposed rulemaking required by § 750.13.

(e) *Renewal requests.* (1) Any petitioner who has been granted an exemption under section 6(e)(3)(B) of TSCA, on or after May 25, 1994, and who seeks to renew that exemption without changing its terms, must submit a letter by certified mail to EPA requesting that the exemption be granted for the following year.

(i) This letter must contain a certification by the petitioner that the type of activities, the procedures for handling the PCBs, the amount of PCBs handled, and any other aspect of the exemption have not changed from the original exemption petition request.

(ii) This letter must be received by EPA at least 6 months prior to the expiration of the existing exemption.

(iii) If a petitioner fails to make a submission or the submission is not timely under this section, the exemption will expire 1 year from the effective date of granting that exemption.

(iv) EPA will address a timely submission of a renewal request by rulemaking and either grant or deny the request.

(2) Any petitioner who has been granted an exemption on or after May 25, 1994, and who seeks to increase the amount of PCBs handled or to change the type of activities, the procedures for handling the PCBs, and any other aspect of their existing exemption must submit a new exemption petition to EPA. The existing exemption activity may continue until the new submission is addressed by rulemaking, provided the activity conforms to the terms of the current exemption approved by EPA, and the petitioner complies with the conditions of paragraph (e)(1) of this section.

(3) Any petitioner who has been granted a TSCA section 6(e)(3)(B) exemption in a rule prior to May 25, 1994, and who seeks to increase the amount of PCBs handled or to change the type of activities, the procedures for handling the PCBs, and any other aspect of their existing exemption must submit a new exemption petition to EPA. The existing exemption activity may continue until the new submission is addressed by rulemaking, provided the activity conforms to the terms of the original exemption approved by EPA.

[43 FR 50905, Nov. 1, 1978, as amended at 53 FR 12524, Apr. 15, 1988; 59 FR 16998, Apr. 11, 1994; 72 FR 57238, Oct. 9, 2007; 74 FR 30232, June 25, 2009]

§ 750.12 Consolidation of rulemakings.

All petitions received pursuant to § 750.11(a) will be consolidated into one rulemaking with one informal hearing held on all petitions.

§ 750.13 Notice of proposed rulemaking.

Rulemaking for PCB exemptions filed pursuant to § 750.11(a) shall begin with the publication of a notice of proposed rulemaking in the FEDERAL REGISTER. The notice shall state in summary form the required information described in § 750.11(c). Due to time constraints, the notice need not indicate what action EPA proposes to take on the exemption petitions.

[81 FR 93636, Dec. 21, 2016]

§ 750.14 Confidentiality.

The Agency encourages the submission of nonconfidential information by petitioners and commenters. The Agency does not wish to have unnecessary restrictions on access to the rulemaking record. However, if a petitioner or commenter believes that he can only state his position through the use of information claimed to be confidential, he may submit it. Such information must be separately submitted for the rulemaking record and marked ''confidential'' by the submitter. For the information claimed to be confidential, the Agency will list only the date and the name and address of the petitioner or commenter in the public file, noting that the petitioner or commenter has requested confidential treatment. The information claimed to be confidential will be placed in a confidential file. A petitioner must also file a nonconfidential petition with a nonconfidential summary of the confidential information to be placed in the public file. Similarly, a commenter must supply a nonconfidential summary of the information claimed to be confidential to be placed in the public file. Any information not marked as confidential will be placed in the public file. Information marked confidential will be treated in accordance with the procedures in part 2, subpart B of this title.

[43 FR 50905, Nov. 1, 1978. Redesignated at 81 FR 93636, Dec. 21, 2016]

§ 750.15 Final rule.

(a) [Reserved]

(b) EPA will grant or deny petitions under TSCA section 6(e)(3)(B) submitted pursuant to § 750.11.

(c) In determining whether to grant an exemption to the PCB ban, the Agency shall apply the two standards enunciated in TSCA section 6(e)(3)(B).

[81 FR 93636, Dec. 21, 2016]

Subpart C—Interim Procedural Rules for Processing and Distribution in Commerce Exemptions

SOURCE: 44 FR 31560, Mar. 31, 1979, unless otherwise noted.

§ 750.30 Applicability.

Sections 750.30 through 750.35 apply to all rulemakings under authority of section 6(e)(3)(B) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e)(3)(B) with respect to petitions for PCB processing and distribution in commerce exemptions filed pursuant to § 750.31(a).

[81 FR 93636, Dec. 21, 2016]

§ 750.31 Filing of petitions for exemption.

(a) *Who may file.* Any person seeking an exemption from the PCB processing and distribution in commerce prohibitions imposed by section 6(e)(3)(A)(ii) of TSCA may file a petition for exemption. Petitions must be submitted on an individual basis for each processor, distributor, seller or individual affected by the 1979 processing and distribution in commerce prohibitions, except as described in paragraphs (a)(1) through (9) of this section.

(1) *Processing and distribution in commerce of PCB-contaminated transformer dielectric fluid.* Persons who process or distribute in commerce dielectric fluid containing 50 ppm or greater PCB (but less than 500 ppm PCB) for use in PCB-Contaminated Transformers may submit a single consolidated petition on behalf of any number of petitioners. The name and address of each petitioner must be stated in the petition.

(2) *Contaminated substances and mixtures—processing.* Persons who process the same chemical substance or the same mixture containing 50 ppm or greater PCB as an impurity or contaminant may submit a consolidated petition if the chemical substance or mixture is processed for the same use by each person represented by the petition. For example, persons who process a PCB-contaminated pigment into printing inks may combine their petitions into one petition. The name and address of each petitioner must be stated in the petition.

(3) *Contaminated substances and mixtures—distribution in commerce.* Persons who distribute in commerce the same chemical substance or the same mixture containing 50 ppm or greater PCB as an impurity or contaminant may submit a consolidated petition if the

chemical substance or mixture is distributed in commerce for a common use. Such a petition is not required to name each person who distributes in commerce the chemical substance or mixture.

(4) *PCB capacitor distribution for purposes of repair*. Persons who distribute in commerce PCB capacitors for servicing (repair) of PCB Equipment may submit a single consolidated petition on behalf of any number of petitioners engaged in such distribution in commerce for purposes of repair. The name of each petitioner need not be stated in the petition.

(5) *Small quantities for research and development*. Persons who process or distribute in commerce small quantities of PCBs for research and development may submit a single consolidated petition. The name and address of each petitioner must be stated in the petition.

(6) *Microscopy*. Persons who process or distribute in commerce PCBs for use as a mounting medium in microscopy may submit a single consolidated petition on behalf of any number of petitioners. The name and address of each petitioner must be stated in the petition.

(7) *Processing of PCB Articles into PCB Equipment*. A person who processes (incorporates) PCB Articles (such as small PCB Capacitors) into PCB Equipment may submit a petition on behalf of himself and all persons who further process or distribute in commerce PCB Equipment built by the petitioner. For example, a builder of motors who places small PCB Capacitors in the motors may submit a petition on behalf of all persons who process or incorporate motors built by the petitioner into other pieces of PCB Equipment and all those who sell the equipment. Such a petition is not required to identify the persons who distribute in commerce or further process the PCB Equipment. A separate petition must be filed, however, by each processor of PCB Articles into PCB Equipment.

(8) *Processing of PCB Equipment into other PCB Equipment*. A person who processes (incorporates) PCB Equipment into other PCB Equipment may submit a petition on behalf of himself and all persons who further process or distribute in commerce PCB Equipment built by the petitioner. Such a petition is not required to identify the persons who distribute in commerce or further process the PCB Equipment. If a petition has been filed under paragraph (a)(7) of this section by the builder of the original PCB Equipment, no other petition is required.

(9) *Distribution of PCB Equipment*. Distributors in commerce of PCB Equipment may submit a consolidated petition on behalf of persons who distribute in commerce PCB Equipment of one type (such as air conditioners). The petition is not required to name the persons who distribute in commerce the affected PCB Equipment.

(b) *Where to file*. All petitions pertaining to:

(1) PCB use, which includes storage for use or reuse, manufacture, processing related to manufacture and use, and distribution in commerce related to use or processing for use, must be submitted to: OPPT Document Control Officer (7407T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(2) PCB disposal, which includes cleanup, storage for disposal, processing related to disposal, distribution in commerce related to disposal or processing for disposal, and decontamination, must be submitted to: Document Control Officer, Office of Resource Conservation and Recovery (5305P), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001.

(c) *Content of petition*. Each petition must contain the following:

(1) Name, address and telephone number of petitioner. See also paragraphs (a) (1) through (9) of this section for additional identification requirements applicable to certain consolidated petitions.

(2) Description of PCB processing or distribution in commerce exemption requested, including a description of the chemical substances, mixtures or items to be processed or distributed in commerce and, if processing is involved, the nature of the processing.

(3) For processing petitions, location(s) of sites requiring exemption.

(4) Length of time requested for exemption (maximum length of exemption is one year).

(5) Estimated amount of PCBs (by pound and/or volume) to be processed, distributed in commerce, or used during requested exemption period and the manner of release of PCBs into the environment associated with such processing, distribution in commerce, or use. Where the PCB concentration is less than 500 ppm, both the total liquid volume and the total PCB volume must be provided.

(6) The basis for the petitioner's contention that under section 6(e)(3)(B)(i) of TSCA ''an unreasonable risk of injury to health or environment would not result'' from the granting of the petition for exemption.

(7) The basis for the petitioner's contention that under section 6(e)(3)(B)(ii) ''good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for'' the PCB.

(8) Quantification of the reasonably ascertainable economic consequences of denying the petition for exemption and an explanation of the manner of computation.

(9) In addition to the information in paragraphs (c)(1) through (c)(8) of this section, certain petitions must contain additional information as follows:

(i) Persons who process or distribute in commerce dielectric fluids containing 50 ppm or greater PCB for use in PCB Transformers, railroad transformers, or PCB electromagnets must also state the expected number of PCB Transformers, railroad transformers, or PCB electromagnets to be serviced under the exemption. In addition, a person must identify all the facilities which he owns or operates where he services PCB transformers, railroad transformers, or PCB electromagnets.

(ii) Persons filing petitions under paragraph (a)(1) of this section (Processing and Distribution in Commerce of PCB-Contaminated Transformer Dielectric Fluid) must also provide the expected number of PCB-Contaminated Transformers to be serviced under the requested exemption and the expected method of disposal of waste dielectric fluid. In addition, a person must identify all the facilities which he owns or operates where he services PCB-Contaminated Transformers. This information, as well as the information required by paragraphs (c)(1), (c)(3), and (c)(5) of this section, must be provided for each person represented by the petition. All other information may be provided on a group basis.

(iii) Persons filing petitions under paragraphs (a)(2) (Contaminated Substances and Mixtures-Processing) and (a)(3) (Contaminated Substances and Mixtures-Distribution in Commerce) must also provide a justification for the class grouping selected and a description of the uses and the human and environmental exposure associated with each use of the PCB-contaminated chemical substance or mixture for which an exemption is sought. Information may be provided on a group basis, except that the information required by paragraphs (c)(1), (c)(3) and (c)(5) of this section, must be provided for each person represented by a petition under paragraph (a)(2) of this section.

(iv) Persons filing petitions under paragraph (a)(4) of this section (PCB Capacitor Distribution for Purposes of Repair) must also provide an estimate of the expected total number of PCB Capacitors to be distributed in commerce under the requested exemption. All information may be provided on a group basis.

(v) Persons filing petitions under paragraphs (a) (7) and (8) of this section (Processing of PCB Articles into PCB Equipment and Processing of PCB Equipment into Other PCB Equipment) must provide a description of each type of PCB Equipment (including the amount of PCBs by poundage and/or volume in the PCB Equipment) to be processed and/or distributed in commerce under the exemption, the number of each type of equipment expected to be processed and/or distributed in commerce, and the approximate number of distributors or further processors covered by the petition. All information may be provided on a group basis. However, in the case of a petition under paragraph (a)(7) of this section, the processor of PCB Articles into PCB Equipment must be identified in the petition. In the case of a petition under paragraph (a)(8) of this section,

the processor of PCB Equipment who files the petition must be identified.

(vi) Persons filing petitions under paragraph (a)(9) of this section (Distribution of PCB Equipment) must provide a description of each type of PCB Equipment (including the amount of PCBs by poundage and/or volume in the PCB Equipment) to be distributed in commerce under the exemption, the number of each type of equipment to be distributed in commerce, and the approximate number of distributors covered by the petition. All information may be provided on a group basis.

(vii) Persons filing petitions under paragraphs (a) (5) and (6) of this section must provide the information required by paragraphs (c) (1) through (8) of this section for each petitioner named in the petition.

(d) EPA reserves the right to request further information as to each petition where necessary to determine whether the petition meets the statutory tests of section 6(e)(3)(B) of TSCA prior to or after publication of the notice of proposed rulemaking required by § 750.33 of these rules.

(e) *Renewal requests.* (1) Any petitioner who has been granted an exemption under 40 CFR 761.80, except paragraph (g) of 40 CFR 761.80, on or after May 25, 1994, and who seeks to renew that exemption without changing its terms, must submit a letter by certified mail to EPA requesting that the exemption be granted for the following year.

(i) This letter must contain a certification by the petitioner that the type of activities, the procedures for handling the PCBs, the amount of PCBs handled, and any other aspect of the exemption have not changed from the original exemption petition request.

(ii) This letter must be received by EPA at least 6 months prior to the expiration of the existing exemption.

(iii) If a petitioner fails to make a submission or the submission is not timely under this section, the exemption will expire 1 year from the effective date of granting that exemption.

(iv) EPA will address a timely submission of a renewal request by rulemaking and either grant or deny the request.

(2) Any petitioner who has been granted an exemption on or after May 25, 1994, and who seeks to increase the amount of PCBs handled or to change the type of activities, the procedures for handling the PCBs, and any other aspect of their existing exemption must submit a new exemption petition to EPA. The existing exemption activity may continue until the new submission is addressed by rulemaking, provided the activity conforms to the terms of the current exemption approved by EPA, and the petitioner complies with the conditions of paragraph (e)(1) of this section.

(3) Any petitioner who has been granted a TSCA section 6(e)(3)(B) exemption in a rule prior to May 25, 1994, and who seeks to increase the amount of PCBs handled or to change the type of activities, the procedures for handling the PCBs, and any other aspect of their existing exemption must submit a new exemption petition to EPA. The existing exemption activity may continue until the new submission is addressed by rulemaking, provided the activity conforms to the terms of the original exemption approved by EPA.

[44 FR 31560, Mar. 31, 1979, as amended at 53 FR 12524, Apr. 15, 1988; 59 FR 16998, Apr. 11, 1994; 63 FR 35436, June 29, 1998; 72 FR 57238, Oct. 9, 2007; 74 FR 30232, June 25, 2009]

§ 750.32 Consolidation of rulemaking.

All petitions received pursuant to § 750.31(a) will be consolidated into one rulemaking with one informal hearing held on all petitions.

§ 750.33 Notice of proposed rulemaking.

Rulemaking for PCB exemptions filed pursuant to § 750.31(a) shall begin with the publication of a notice of proposed rulemaking in the FEDERAL REGISTER. The notice shall state in summary form the required information described in § 750.31(c).

[81 FR 93636, Dec. 21, 2016]

§ 750.34 Confidentiality.

EPA encourages the submission of non-confidential information by petitioners and commentors. EPA does not wish to have unnecessary restrictions on access to the rulemaking record.

However, if a petitioner or commentor believes that he can only state his position through the use of information claimed to be confidential, he may submit it. Such information must be separately submitted for the rulemaking record and marked ''confidential'' by the submitter. For the information claimed to be confidential, EPA will list only the date and the name and address of the petitioner or commentor in the public file, noting that the petitioner or commentor has requested confidential treatment. The information claimed to be confidential will be placed in a confidential file. A petitioner must also file a non-confidential petition with a non-confidential summary of the confidential information to be placed in the public file. Similarly, a commentor must supply a non-confidential summary of the information claimed to be confidential to be placed in the public file. Any information not marked as confidential will be placed in the public file. Information marked confidential will be treated in accordance with the procedures in part 2, subpart B of this title.

[44 FR 31560, Mar. 31, 1979. Redesignated at 81 FR 93636, Dec. 21, 2016]

§ 750.35 Final rule.

(a) [Reserved]

(b) EPA will grant or deny petitions under TSCA section 6(e)(3)(B) submitted pursuant to § 750.31.

(c) In determining whether to grant an exemption to the PCB ban, EPA will apply the two standards enunciated in TSCA section 6(e)(3)(B).

[81 FR 93636, Dec. 21, 2016]

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

Subpart A—General Provisions

Sec.

751.1 Purpose.
751.5 Definitions.
751.7 Exports and imports.
751.9 Enforcement and inspections.

Subpart B—Methylene Chloride

751.101 General.
751.103 Definitions.
751.105 Consumer paint and coating removal.
751.107 Downstream notification.
751.109 Recordkeeping.

Subpart C [Reserved]

AUTHORITY: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

SOURCE: 84 FR 11435, Mar. 27, 2019, unless otherwise noted.

Subpart A—General Provisions

§ 751.1 Purpose.

This part sets forth requirements under section 6(a) of the Toxic Substances Control Act, 15 U.S.C. 2605(a), regulating the manufacture (including import), processing, distribution in commerce, use, or disposal of certain chemical substances and mixtures in order to address unreasonable risks to the extent necessary so that the chemical substance or mixture no longer presents such risk.

§ 751.5 Definitions.

The definitions in section 3 of the Toxic Substances Control Act, 15 U.S.C. 2602, apply to this part except as otherwise established in any subpart under this part.

Act or *TSCA* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq*.

CASRN means Chemical Abstracts Service Registry Number.

EPA means the U.S. Environmental Protection Agency.

Person means any natural person, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal government.

§ 751.7 Exports and imports.

(a) *Exports.* Persons who intend to export a chemical substance identified in any subpart under this part are subject to the export notification provisions of

section 12(b) of the Act. The regulations that interpret section 12(b) appear at 40 CFR part 707, subpart D.

(b) *Imports.* Persons who import a substance identified in any subpart under this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR 12.118 through 12.127. See also 19 CFR 127.28.

§ 751.9 Enforcement and inspections.

(a) *Enforcement.* (1) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit entry or inspection as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(b) *Inspections.* EPA may conduct inspections under section 11 of the Act (15 U.S.C. 2610) to ensure compliance with this part.

Subpart B—Methylene Chloride

§ 751.101 General.

This subpart sets certain restrictions on the manufacture (including import), processing, and distribution in commerce of methylene chloride (CASRN 75–09–2) for consumer paint and coating removal to prevent unreasonable risks of injury to health due to acute human lethality.

§ 751.103 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Consumer paint and coating removal means paint and coating removal performed by any natural person who uses a paint and coating removal product for any personal use without receiving remuneration or other form of payment.

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of §§ 751.107 and 751.109.

Paint and coating removal means application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from a substrate, including objects, vehicles, architectural features, or structures.

Retailer means a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. Any distributor with at least one consumer end user customer is considered a retailer. A person who distributes in commerce or makes available a chemical substance or mixture solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer.

§ 751.105 Consumer paint and coating removal.

(a) After November 22, 2019, all persons are prohibited from manufacturing, processing and distributing in commerce methylene chloride for consumer paint and coating removal.

(b) After November 22, 2019, all persons are prohibited from distributing in commerce methylene chloride, including any methylene chloride containing products, for paint and coating removal to retailers.

(c) After November 22, 2019, all retailers are prohibited from distributing in commerce methylene chloride, including any methylene chloride containing products, for paint and coating removal.

§ 751.107 Downstream notification.

Each person who manufactures, processes, or distributes in commerce methylene chloride for any use after August 26, 2019 must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions described in this subpart. Notification must occur by inserting the following text in the Safety Data Sheet (SDS) provided with the methylene chloride

or with any methylene chloride containing product:

(a) SDS Section 1.(c): ''This chemical/product is not and cannot be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for consumer paint or coating removal.''

(b) SDS Section 15: ''This chemical/product is not and cannot be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for consumer paint or coating removal.''

§ 751.109 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any methylene chloride after August 26, 2019 must retain in one location at the headquarters of the company, or at the facility for which the records were generated, documentation showing:

(1) The name, address, contact, and telephone number of companies to whom methylene chloride was shipped;

(2) A copy of the notification provided under § 751.107; and

(3) The amount of methylene chloride shipped.

(b) The documentation in paragraph (a) of this section must be retained for 3 years from the date of shipment.

Subpart C [Reserved]

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AUTHORITY: 15 U.S.C. 2605, 2607, 2611, 2614, and 2616.

SOURCE: 43 FR 7156, Feb. 17, 1978, unless otherwise noted.

Subpart A—General

§ 761.1 Applicability.

(a) This part establishes prohibitions of, and requirements for, the manufacture, processing, distribution in commerce, use, disposal, storage, and marking of PCBs and PCB Items.

(b)(1) This part applies to all persons who manufacture, process, distribute in commerce, use, or dispose of PCBs or PCB Items. Substances that are regulated by this part include, but are not limited to: dielectric fluids; solvents; oils; waste oils; heat transfer fluids; hydraulic fluids; paints or coatings; sludges; slurries; sediments; dredge spoils; soils; materials containing PCBs as a result of spills; and other chemical substances or combinations of substances, including impurities and byproducts and any byproduct, intermediate, or impurity manufactured at any point in a process.

(2) Unless otherwise noted, PCB concentrations shall be determined on a weight-per-weight basis (e.g., milligrams per kilogram), or for liquids, on a weight-per-volume basis (e.g., milligrams per liter) if the density of the liquid is also reported. Unless otherwise provided, PCBs are quantified based on the formulation of PCBs present in the material analyzed. For example, measure Aroclor™ 1242 PCBs based on a comparison with Aroclor™ 1242 standards. Measure individual congener PCBs based on a comparison with individual PCB congener standards.

(3) Most provisions in this part apply only if PCBs are present in concentrations above a specified level. Provisions that apply to PCBs at concentrations of <50 ppm apply also to contaminated surfaces at PCB concentrations of ≤10 μg/100 cm^2. Provisions that apply to PCBs at concentrations of ≥50 to <500 ppm apply also to contaminated surfaces at PCB concentrations of >10/100 cm^2 to <100 μg/100 cm^2. Provisions that apply to PCBs at concentrations of ≥500 ppm apply also to contaminated surfaces at PCB concentrations of ≥100 μg/100 cm^2.

(4) PCBs can be found in liquid, nonliquid and multi-phasic (combinations of liquid and non-liquid) forms. A person should use the following criteria to determine PCB concentrations to determine which provisions of this part apply to such PCBs.

(i) Any person determining PCB concentrations for non-liquid PCBs must do so on a dry weight basis.

(ii) Any person determining PCB concentrations for liquid PCBs must do so on a wet weight basis. Liquid PCBs containing more than 0.5 percent by weight non-dissolved material shall be analyzed as multi-phasic non-liquid/liquid mixtures.

(iii) Any person determining the PCB concentration of samples containing PCBs and non-dissolved non-liquid materials ≥0.5 percent, must separate the non-dissolved materials into non-liquid PCBs and liquid PCBs. For multi-phasic non-liquid/liquid or liquid/liquid mixtures, the phases shall be separated

before chemical analysis. Following phase separation, the PCB concentration in each non-liquid phase shall be determined on a dry weight basis and the PCB concentration in each liquid phase shall be determined separately on a wet weight basis.

(iv) Any person disposing of multiphasic non-liquid/liquid or liquid/liquid mixtures must use the PCB disposal requirements that apply to the individual phase with the highest PCB concentration except where otherwise noted. Alternatively, phases may be separated and disposed of using the PCB disposal requirements that apply to each separated, single-phase material.

(5) No person may avoid any provision specifying a PCB concentration by diluting the PCBs, unless otherwise specifically provided.

(6) Unless otherwise specified, references to weights or volumes of PCBs in this part apply to the total weight or total volume of the material (oil, soil, debris, etc.) that contains regulated concentrations of PCBs, not the calculated weight or volume of only the PCB molecules contained in the material.

(c) Definitions of the terms used in these regulations are in subpart A. The basic requirements applicable to disposal and marking of PCBs and PCB Items are set forth in subpart D—Disposal of PCBs and PCB Items and in subpart C—Marking of PCBs and PCB Items. Prohibitions applicable to PCB activities are set forth in subpart B—Manufacture, Processing, Distribution in Commerce, and Use of PCBs and PCB Items. Subpart B also includes authorizations from the prohibitions. Subparts C and D set forth the specific requirements for disposal and marking of PCBs and PCB Items.

(d) Section 15 of the Toxic Substances Control Act (TSCA) states that failure to comply with these regulations is unlawful. Section 16 imposes liability for civil penalties upon any person who violates these regulations, and the Administrator can establish appropriate remedies for any violations subject to any limitations included in section 16 of TSCA. Section 16 also subjects a person to criminal prosecution for a violation which is knowing or willful. In addition, section 17 authorizes Federal district courts to enjoin activities prohibited by these regulations, compel the taking of actions required by these regulations, and issue orders to seize PCBs and PCB Items manufactured, processed or distributed in violation of these regulations.

(e) These regulations do not preempt other more stringent Federal statutes and regulations.

(f) Unless and until superseded by any new more stringent regulations issued under EPA authorities, or any permits or any pretreatment requirements issued by EPA, a state or local government that affect release of PCBs to any particular medium:

(1) Persons who inadvertently manufacture or import PCBs generated as unintentional impurities in excluded manufacturing processes, as defined in § 761.3, are exempt from the requirements of subpart B of this part, provided that such persons comply with subpart J of this part, as applicable.

(2) Persons who process, distribute in commerce, or use products containing PCBs generated in excluded manufacturing processes defined in § 761.3 are exempt from the requirements of subpart B provided that such persons comply with subpart J of this part, as applicable.

(3) Persons who process, distribute in commerce, or use products containing recycled PCBs defined in § 761.3, are exempt from the requirements of subpart B of this part, provided that such persons comply with subpart J of this part, as applicable.

(4) Except as provided in § 761.20 (d) and (e), persons who process, distribute in commerce, or use products containing excluded PCB products as defined in § 761.3, are exempt from the requirements of subpart B of this part.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979, as amended at 49 FR 28189, July 10, 1984; 53 FR 24220, June 27, 1988; 63 FR 35436, June 29, 1998; 64 FR 33759, June 24, 1999]

§ 761.2 PCB concentration assumptions for use.

(a)(1) Any person may assume that transformers with <3 pounds (1.36 kilograms (kgs)) of fluid, circuit breakers,

reclosers, oil-filled cable, and rectifiers whose PCB concentration is not established contain PCBs at <50 ppm.

(2) Any person must assume that mineral oil-filled electrical equipment that was manufactured before July 2, 1979, and whose PCB concentration is not established is PCB-Contaminated Electrical Equipment (i.e., contains ≥50 ppm PCB, but <500 ppm PCB). All pole-top and pad-mounted distribution transformers manufactured before July 2, 1979, must be assumed to be mineral-oil filled. Any person may assume that electrical equipment manufactured after July 2, 1979, is non-PCB (i.e., <50 ppm PCBs). If the date of manufacture of mineral oil-filled electrical equipment is unknown, any person must assume it to be PCB-Contaminated.

(3) Any person must assume that a transformer manufactured prior to July 2, 1979, that contains 1.36 kg (3 pounds) or more of fluid other than mineral oil and whose PCB concentration is not established, is a PCB Transformer (i.e., ≥500 ppm). If the date of manufacture and the type of dielectric fluid are unknown, any person must assume the transformer to be a PCB Transformer.

(4) Any person must assume that a capacitor manufactured prior to July 2, 1979, whose PCB concentration is not established contains ≥500 ppm PCBs. Any person may assume that a capacitor manufactured after July 2, 1979, is non-PCB (i.e., <50 ppm PCBs). If the date of manufacture is unknown, any person must assume the capacitor contains ≥500 ppm PCBs. Any person may assume that a capacitor marked at the time of manufacture with the statement ''No PCBs'' in accordance with § 761.40(g) is non-PCB.

(b) PCB concentration may be established by:

(1) Testing the equipment; or

(2)(i) A permanent label, mark, or other documentation from the manufacturer of the equipment indicating its PCB concentration at the time of manufacture; and

(ii) Service records or other documentation indicating the PCB concentration of all fluids used in servicing the equipment since it was first manufactured.

[63 FR 35436, June 29, 1998, as amended at 64 FR 33759, June 24, 1999]

§ 761.3 Definitions.

For the purpose of this part:

Administrator means the Administrator of the Environmental Protection Agency, or any employee of the Agency to whom the Administrator may either herein or by order delegate his authority to carry out his functions, or any person who shall by operation of law be authorized to carry out such functions.

Agency means the United States Environmental Protection Agency.

Air compressor system means air compressors, piping, receiver tanks, volume tanks and bottles, dryers, airlines, and related appurtenances.

Annual document log means the detailed information maintained at the facility on the PCB waste handling at the facility.

Annual report means the written document submitted each year by each disposer and commercial storer of PCB waste to the appropriate EPA Regional Administrator. The annual report is a brief summary of the information included in the annual document log.

ASTM means American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959.

Byproduct means a chemical substance produced without separate commercial intent during the manufacturing or processing of another chemical substance(s) or mixture(s).

Capacitor means a device for accumulating and holding a charge of electricity and consisting of conducting surfaces separated by a dielectric. Types of capacitors are as follows:

(1) *Small capacitor* means a capacitor which contains less than 1.36 kg (3 lbs.) of dielectric fluid. The following assumptions may be used if the actual weight of the dielectric fluid is unknown. A capacitor whose total volume is less than 1,639 cubic centimeters (100 cubic inches) may be considered to contain less than 1.36 kgs (3 lbs.) of dielectric fluid and a capacitor whose total volume is more than 3,278 cubic centimeters (200 cubic inches) must be considered to contain more than 1.36 kg (3

lbs.) of dielectric fluid. A capacitor whose volume is between 1,639 and 3,278 cubic centimeters may be considered to contain less then 1.36 kg (3 lbs.) of dielectric fluid if the total weight of the capacitor is less than 4.08 kg (9 lbs.).

(2) *Large high voltage capacitor* means a capacitor which contains 1.36 kg (3 lbs.) or more of dielectric fluid and which operates at 2,000 volts (a.c. or d.c.) or above.

(3) *Large low voltage capacitor* means a capacitor which contains 1.36 kg (3 lbs.) or more of dielectric fluid and which operates below 2,000 volts (a.c. or d.c.).

CERCLA means the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601-9657).

Certification means a written statement regarding a specific fact or representation that contains the following language:

> Under civil and criminal penalties of law for the making or submission of false or fraudulent statements or representations (18 U.S.C. 1001 and 15 U.S.C. 2615), I certify that the information contained in or accompanying this document is true, accurate, and complete. As to the identified section(s) of this document for which I cannot personally verify truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate, and complete.

Chemical substance, (1) except as provided in paragraph (2) of this definition, means any organic or inorganic substance of a particular molecular identity, including: Any combination of such substances occurring in whole or part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.

(2) Such term does not include: Any mixture; any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or section 4221 or any provisions of such Code); and any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

Chemical waste landfill means a landfill at which protection against risk of injury to health or the environment from migration of PCBs to land, water, or the atmosphere is provided from PCBs and PCB Items deposited therein by locating, engineering, and operating the landfill as specified in § 761.75.

Cleanup site means the areal extent of contamination and all suitable areas in very close proximity to the contamination necessary for implementation of a cleanup of PCB remediation waste, regardless of whether the site was intended for management of waste.

Commerce means trade, traffic, transportation, or other commerce:

(1) Between a place in a State and any place outside of such State, or

(2) Which affects trade, traffic, transportation, or commerce described in paragraph (1) of this definition.

Commercial storer of PCB waste means the owner or operator of each facility that is subject to the PCB storage unit standards of § 761.65(b)(1) or (c)(7) or meets the alternate storage criteria of § 761.65(b)(2), and who engages in storage activities involving either PCB waste generated by others or that was removed while servicing the equipment owned by others and brokered for disposal. The receipt of a fee or any other form of compensation for storage services is not necessary to qualify as a commercial storer of PCB waste. A generator who only stores its own waste is subject to the storage requirements of § 761.65, but is not required to obtain approval as a commercial storer. If a facility's storage of PCB waste generated by others at no time exceeds a total of 500 gallons of liquid and/or non-liquid material containing PCBs at regulated levels, the owner or operator is a commercial storer but is not required to seek EPA approval as a commercial storer of PCB waste. Storage of

one company's PCB waste by a related company is not considered commercial storage. A ''related company'' includes, but is not limited to: a parent company and its subsidiaries; sibling companies owned by the same parent company; companies owned by a common holding company; members of electric cooperatives; entities within the same Executive agency as defined at 5 U.S.C. 105; and a company having a joint ownership interest in a facility from which PCB waste is generated (such as a jointly owned electric power generating station) where the PCB waste is stored by one of the co-owners of the facility. A ''related company'' does not include another voluntary member of the same trade association. Change in ownership or title of a generator's facility, where the generator is storing PCB waste, does not make the new owner of the facility a commercial storer of PCB waste.

Designated facility means the off-site disposer or commercial storer of PCB waste designated on the manifest as the facility that will receive a manifested shipment of PCB waste.

Disposal means intentionally or accidentally to discard, throw away, or otherwise complete or terminate the useful life of PCBs and PCB Items. Disposal includes spills, leaks, and other uncontrolled discharges of PCBs as well as actions related to containing, transporting, destroying, degrading, decontaminating, or confining PCBs and PCB Items.

Disposer of PCB waste, as the term is used in subparts J and K of this part, means any person who owns or operates a facility approved by EPA for the disposal of PCB waste which is regulated for disposal under the requirements of subpart D of this part.

Distribute in commerce and *Distribution in Commerce* when used to describe an action taken with respect to a chemical substance, mixture, or article containing a substance or mixture means to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of the substance, mixture, or article; or to hold or the holding of, the substance, mixture, or article after its introduction into commerce.

DOT means the United States Department of Transportation.

Dry weight means the weight of the sample, excluding the weight of the water in the sample. Prior to chemical analysis the water may be removed by any reproducible method that is applicable to measuring PCBs in the sample matrix at the concentration of concern, such as air drying at ambient temperature, filtration, decantation, heating at low temperature followed by cooling in the presence of a desiccant, or other processes or combinations of processes which would remove water but not remove PCBs from the sample. Analytical procedures which calculate the dry weight concentration by adjusting for moisture content may also be used.

EPA identification number means the 12-digit number assigned to a facility by EPA upon notification of PCB waste activity under § 761.205.

Excluded manufacturing process means a manufacturing process in which quantities of PCBs, as determined in accordance with the definition of inadvertently generated PCBs, calculated as defined, and from which releases to products, air, and water meet the requirements of paragraphs (1) through (5) of this definition, or the importation of products containing PCBs as unintentional impurities, which products meet the requirements of paragraphs (1) and (2) of this definition.

(1) The concentration of inadvertently generated PCBs in products leaving any manufacturing site or imported into the United States must have an annual average of less than 25 ppm, with a 50 ppm maximum.

(2) The concentration of inadvertently generated PCBs in the components of detergent bars leaving the manufacturing site or imported into the United States must be less than 5 ppm.

(3) The release of inadvertently generated PCBs at the point at which emissions are vented to ambient air must be less than 10 ppm.

(4) The amount of inadvertently generated PCBs added to water discharged from a manufacturing site must be less than 100 micrograms per resolvable gas

chromatographic peak per liter of water discharged.

(5) Disposal of any other process wastes above concentrations of 50 ppm PCB must be in accordance with subpart D of this part.

Excluded PCB products means PCB materials which appear at concentrations less than 50 ppm, including but not limited to:

(1) Non-Aroclor inadvertently generated PCBs as a byproduct or impurity resulting from a chemical manufacturing process.

(2) Products contaminated with Aroclor or other PCB materials from historic PCB uses (investment casting waxes are one example).

(3) Recycled fluids and/or equipment contaminated during use involving the products described in paragraphs (1) and (2) of this definition (heat transfer and hydraulic fluids and equipment and other electrical equipment components and fluids are examples).

(4) Used oils, provided that in the cases of paragraphs (1) through (4) of this definition:

(i) The products or source of the products containing <50 ppm concentration PCBs were legally manufactured, processed, distributed in commerce, or used before October 1, 1984.

(ii) The products or source of the products containing <50 ppm concentrations PCBs were legally manufactured, processed, distributed in commerce, or used, i.e., pursuant to authority granted by EPA regulation, by exemption petition, by settlement agreement, or pursuant to other Agency-approved programs;

(iii) The resulting PCB concentration (i.e. below 50 ppm) is not a result of dilution, or leaks and spills of PCBs in concentrations over 50 ppm.

Facility means all contiguous land, and structures, other appurtenances, and improvements on the land, used for the treatment, storage, or disposal of PCB waste. A facility may consist of one or more treatment, storage, or disposal units.

Fluorescent light ballast means a device that electrically controls fluorescent light fixtures and that includes a capacitor containing 0.1 kg or less of dielectric.

Generator of PCB waste means any person whose act or process produces PCBs that are regulated for disposal under subpart D of this part, or whose act first causes PCBs or PCB Items to become subject to the disposal requirements of subpart D of this part, or who has physical control over the PCBs when a decision is made that the use of the PCBs has been terminated and therefore is subject to the disposal requirements of subpart D of this part. Unless another provision of this part specifically requires a site-specific meaning, ''generator of PCB waste'' includes all of the sites of PCB waste generation owned or operated by the person who generates PCB waste.

High occupancy area means any area where PCB remediation waste has been disposed of on-site and where occupancy for any individual not wearing dermal and respiratory protection for a calendar year is: 840 hours or more (an average of 16.8 hours or more per week) for non-porous surfaces and 335 hours or more (an average of 6.7 hours or more per week) for bulk PCB remediation waste. Examples could include a residence, school, day care center, sleeping quarters, a single or multiple occupancy 40 hours per week work station, a school class room, a cafeteria in an industrial facility, a control room, and a work station at an assembly line.

Importer means any person defined as an ''importer'' at § 720.3(l) of this chapter who imports PCBs or PCB Items and is under the jurisdiction of the United States.

Impurity means a chemical substance which is unintentionally present with another chemical substance.

In or Near Commercial Buildings means within the interior of, on the roof of, attached to the exterior wall of, in the parking area serving, or within 30 meters of a non-industrial non-substation building. Commercial buildings are typically accessible to both members of the general public and employees, and include: (1) Public assembly properties, (2) educational properties, (3) institutional properties, (4) residential properties, (5) stores, (6) office buildings, and (7) transportation centers (e.g., airport terminal buildings, subway stations, bus stations, or train stations).

Incinerator means an engineered device using controlled flame combustion to thermally degrade PCBs and PCB Items. Examples of devices used for incineration include rotary kilns, liquid injection incinerators, cement kilns, and high temperature boilers.

Industrial building means a building directly used in manufacturing or technically productive enterprises. Industrial buildings are not generally or typically accessible to other than workers. Industrial buildings include buildings used directly in the production of power, the manufacture of products, the mining of raw materials, and the storage of textiles, petroleum products, wood and paper products, chemicals, plastics, and metals.

Laboratory means a facility that analyzes samples for PCBs and is unaffiliated with any entity whose activities involve PCBs.

Leak or *leaking* means any instance in which a PCB Article, PCB Container, or PCB Equipment has any PCBs on any portion of its external surface.

Liquid PCBs means a homogenous flowable material containing PCBs and no more than 0.5 percent by weight non-dissolved material.

Low occupancy area means any area where PCB remediation waste has been disposed of on-site and where occupancy for any individual not wearing dermal and respiratory protection for a calendar year is: less than 840 hours (an average of 16.8 hours per week) for nonporous surfaces and less than 335 hours (an average of 6.7 hours per week) for bulk PCB remediation waste. Examples could include an electrical substation or a location in an industrial facility where a worker spends small amounts of time per week (such as an unoccupied area outside a building, an electrical equipment vault, or in the non-office space in a warehouse where occupancy is transitory).

Manifest means the shipping document EPA form 8700–22 and any continuation sheet attached to EPA form 8700–22, originated and signed by the generator of PCB waste in accordance with the instructions included with the form and subpart K of this part.

Manned Control Center means an electrical power distribution control room where the operating conditions of a PCB Transformer are continuously monitored during the normal hours of operation (of the facility), and, where the duty engineers, electricians, or other trained personnel have the capability to deenergize a PCB Transformer completely within 1 minute of the receipt of a signal indicating abnormal operating conditions such as an overtemperature condition or overpressure condition in a PCB Transformer.

Manufacture means to produce, manufacture, or import into the customs territory of the United States.

Manufacturing process means all of a series of unit operations operating at a site, resulting in the production of a product.

Mark means the descriptive name, instructions, cautions, or other information applied to PCBs and PCB Items, or other objects subject to these regulations.

Marked means the marking of PCB Items and PCB storage areas and transport vehicles by means of applying a legible mark by painting, fixation of an adhesive label, or by any other method that meets the requirements of these regulations.

Market/Marketers means the processing or distributing in commerce, or the person who processes or distributes in commerce, used oil fuels to burners or other marketers, and may include the generator of the fuel if it markets the fuel directly to the burner.

Mineral Oil PCB Transformer means any transformer originally designed to contain mineral oil as the dielectric fluid and which has been tested and found to contain 500 ppm or greater PCBs.

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical

reaction at the time the chemical substances comprising the combination were combined.

Municipal solid wastes means garbage, refuse, sludges, wastes, and other discarded materials resulting from residential and non-industrial operations and activities, such as household activities, office functions, and commercial housekeeping wastes.

Natural gas pipeline system means natural gas gathering facilities, natural gas pipe, natural gas compressors, natural gas storage facilities, and natural gas pipeline appurtenances (including instrumentation and vessels directly in contact with transported natural gas such as valves, regulators, drips, filter separators, etc., but not including air compressors).

Non-liquid PCBs means materials containing PCBs that by visual inspection do not flow at room temperature (25 °C or 77 °F) or from which no liquid passes when a 100 g or 100 ml representative sample is placed in a mesh number 60 ±5 percent paint filter and allowed to drain at room temperature for 5 minutes.

Non-PCB Transformer means any transformer that contains less than 50 ppm PCB; except that any transformer that has been converted from a PCB Transformer or a PCB-Contaminated Transformer cannot be classified as a non-PCB Transformer until reclassification has occurred, in accordance with the requirements of § 761.30(a)(2)(v).

Non-porous surface means a smooth, unpainted solid surface that limits penetration of liquid containing PCBs beyond the immediate surface. Examples are: smooth uncorroded metal; natural gas pipe with a thin porous coating originally applied to inhibit corrosion; smooth glass; smooth glazed ceramics; impermeable polished building stone such as marble or granite; and high density plastics, such as polycarbonates and melamines, that do not absorb organic solvents.

NTIS means the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

On site means within the boundaries of a contiguous property unit.

Open burning means the combustion of any PCB regulated for disposal, in a manner not approved or otherwise allowed under subpart D of this part, and without any of the following:

(1) Control of combustion air to maintain adequate temperature for efficient combustion.

(2) Containment of the combustion reaction in an enclosed device to provide sufficient residence time and mixing for complete combustion.

(3) Control of emission of the gaseous combustion products.

PCB and *PCBs* means any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees or any combination of substances which contains such substance. Refer to § 761.1(b) for applicable concentrations of PCBs. PCB and PCBs as contained in PCB items are defined in § 761.3. For any purposes under this part, inadvertently generated non-Aroclor PCBs are defined as the total PCBs calculated following division of the quantity of monochlorinated biphenyls by 50 and dichlorinated biphenyls by 5.

PCB Article means any manufactured article, other than a PCB Container, that contains PCBs and whose surface(s) has been in direct contact with PCBs. ''PCB Article'' includes capacitors, transformers, electric motors, pumps, pipes and any other manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the PCB Article.

PCB Article Container means any package, can, bottle, bag, barrel, drum, tank, or other device used to contain PCB Articles or PCB Equipment, and whose surface(s) has not been in direct contact with PCBs.

PCB bulk product waste means waste derived from manufactured products containing PCBs in a non-liquid state, at any concentration where the concentration at the time of designation for disposal was ≥50 ppm PCBs. PCB bulk product waste does not include

PCBs or PCB Items regulated for disposal under §761.60(a) through (c), §761.61, §761.63, or §761.64. PCB bulk product waste includes, but is not limited to:

(1) Non-liquid bulk wastes or debris from the demolition of buildings and other man-made structures manufactured, coated, or serviced with PCBs. PCB bulk product waste does not include debris from the demolition of buildings or other man-made structures that is contaminated by spills from regulated PCBs which have not been disposed of, decontaminated, or otherwise cleaned up in accordance with subpart D of this part.

(2) PCB-containing wastes from the shredding of automobiles, household appliances, or industrial appliances.

(3) Plastics (such as plastic insulation from wire or cable; radio, television and computer casings; vehicle parts; or furniture laminates); preformed or molded rubber parts and components; applied dried paints, varnishes, waxes or other similar coatings or sealants; caulking; adhesives; paper; Galbestos; sound deadening or other types of insulation; and felt or fabric products such as gaskets.

(4) Fluorescent light ballasts containing PCBs in the potting material.

PCB Capacitor means any capacitor that contains ≥500 ppm PCB. Concentration assumptions applicable to capacitors appear under §761.2.

PCB Container means any package, can, bottle, bag, barrel, drum, tank, or other device that contains PCBs or PCB Articles and whose surface(s) has been in direct contact with PCBs.

PCB-Contaminated means a non-liquid material containing PCBs at concentrations ≥50 ppm but <500 ppm; a liquid material containing PCBs at concentrations ≥50 ppm but <500 ppm or where insufficient liquid material is available for analysis, a non-porous surface having a surface concentration >10 μg/100 cm^2 but <100 μg/100 cm^2, measured by a standard wipe test as defined in §761.123.

PCB-Contaminated Electrical Equipment means any electrical equipment including, but not limited to, transformers (including those used in railway locomotives and self-propelled cars), capacitors, circuit breakers, reclosers, voltage regulators, switches (including sectionalizers and motor starters), electromagnets, and cable, that contains PCBs at concentrations of ≥50 ppm and <500 ppm in the contaminating fluid. In the absence of liquids, electrical equipment is PCB-Contaminated if it has PCBs at >10 μg/100 cm^2 and <100 μg/100 cm^2 as measured by a standard wipe test (as defined in §761.123) of a non-porous surface.

PCB Equipment means any manufactured item, other than a PCB Container or a PCB Article Container, which contains a PCB Article or other PCB Equipment, and includes microwave ovens, electronic equipment, and fluorescent light ballasts and fixtures.

PCB field screening test means a portable analytical device or kit which measures PCBs. PCB field screening tests usually report less than or greater than a specific numerical PCB concentration. These tests normally build in a safety factor which increases the probability of a false positive report and decreases the probability of a false negative report. PCB field screening tests do not usually provide: an identity record generated by an instrument; a quantitative comparison record from calibration standards; any identification of PCBs; and/or any indication or identification of interferences with the measurement of the PCBs. PCB field screening test technologies include, but are not limited to, total chlorine colorimetric tests, total chlorine x-ray fluorescence tests, total chlorine microcoulometric tests, and rapid immunoassay tests.

PCB household waste means PCB waste that is generated by residents on the premises of a temporary or permanent residence for individuals (including individually owned or rented units of a multi-unit construction), and that is composed primarily of materials found in wastes generated by consumers in their homes. PCB household waste includes unwanted or discarded non-commercial vehicles (prior to shredding), household items, and appliances or appliance parts and wastes generated on the premises of a residence for individuals as a result of routine household maintenance by or on

behalf of the resident. Bulk or commingled liquid PCB wastes at concentrations of ≥50 ppm, demolition and renovation wastes, and industrial or heavy duty equipment with PCBs are not household wastes.

PCB Item means any PCB Article, PCB Article Container, PCB Container, PCB Equipment, or anything that deliberately or unintentionally contains or has as a part of it any PCB or PCBs.

PCB/radioactive waste means PCBs regulated for disposal under subpart D of this part that also contain source, special nuclear, or byproduct material subject to regulation under the Atomic Energy Act of 1954, as amended, or naturally-occurring or accelerator-produced radioactive material.

PCB remediation waste means waste containing PCBs as a result of a spill, release, or other unauthorized disposal, at the following concentrations: Materials disposed of prior to April 18, 1978, that are currently at concentrations ≥50 ppm PCBs, regardless of the concentration of the original spill; materials which are currently at any volume or concentration where the original source was ≥500 ppm PCBs beginning on April 18, 1978, or ≥50 ppm PCBs beginning on July 2, 1979; and materials which are currently at any concentration if the PCBs are spilled or released from a source not authorized for use under this part. PCB remediation waste means soil, rags, and other debris generated as a result of any PCB spill cleanup, including, but not limited to:

(1) Environmental media containing PCBs, such as soil and gravel; dredged materials, such as sediments, settled sediment fines, and aqueous decantate from sediment.

(2) Sewage sludge containing <50 ppm PCBs and not in use according to § 761.20(a)(4); PCB sewage sludge; commercial or industrial sludge contaminated as the result of a spill of PCBs including sludges located in or removed from any pollution control device; aqueous decantate from an industrial sludge.

(3) Buildings and other man-made structures (such as concrete floors, wood floors, or walls contaminated from a leaking PCB or PCB-Contaminated Transformer), porous surfaces, and non-porous surfaces.

PCB sewage sludge means sewage sludge as defined in 40 CFR 503.9(w) which contains ≥50 ppm PCBs, as measured on a dry weight basis.

PCB Transformer means any transformer that contains ≥500 ppm PCBs. For PCB concentration assumptions applicable to transformers containing 1.36 kilograms (3 lbs.) or more of fluid other than mineral oil, see § 761.2. For provisions permitting reclassification of electrical equipment, including PCB Transformers, containing ≥500 ppm PCBs to PCB-Contaminated Electrical Equipment, see § 761.30(a) and (h).

PCB waste(s) means those PCBs and PCB Items that are subject to the disposal requirements of subpart D of this part.

Performance-based organic decontamination fluid (PODF) means kerosene, diesel fuel, terpene hydrocarbons, and terpene hydrocarbon/alcohol mixtures.

Person means any natural or judicial person including any individual, corporation, partnership, or association; any State or political subdivision thereof; any interstate body; and any department, agency, or instrumentality of the Federal Government.

Porous surface means any surface that allows PCBs to penetrate or pass into itself including, but not limited to, paint or coating on metal; corroded metal; fibrous glass or glass wool; unglazed ceramics; ceramics with a porous glaze; porous building stone such as sandstone, travertine, limestone, or coral rock; low-density plastics such as styrofoam and low-density polyethylene; coated (varnished or painted) or uncoated wood; concrete or cement; plaster; plasterboard; wallboard; rubber; fiberboard; chipboard; asphalt; or tar paper. For purposes of cleaning and disposing of PCB remediation waste, porous surfaces have different requirements than non-porous surfaces.

Posing an exposure risk to food or feed means being in any location where human food or animal feed products could be exposed to PCBs released from a PCB Item. A PCB Item poses an exposure risk to food or feed if PCBs released in any way from the PCB Item have a potential pathway to human

food or animal feed. EPA considers human food or animal feed to include items regulated by the U.S. Department of Agriculture or the Food and Drug Administration as human food or animal feed; this includes direct additives. Food or feed is excluded from this definition if it is used or stored in private homes.

Process means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce:

(1) In the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(2) As part of an article containing the chemical substance or mixture.

Qualified incinerator means one of the following:

(1) An incinerator approved under the provisions of § 761.70. Any level of PCB concentration can be destroyed in an incinerator approved under § 761.70.

(2) A high efficiency boiler which complies with the criteria of § 761.71(a)(1), and for which the operator has given written notice to the appropriate EPA Regional Administrator in accordance with the notification requirements for the burning of mineral oil dielectric fluid under § 761.71(a)(2).

(3) An incinerator approved under section 3005(c) of the Resource Conservation and Recovery Act (42 U.S.C. 6925(c)) (RCRA).

(4) Industrial furnaces and boilers which are identified in 40 CFR 260.10 and 40 CFR 279.61 (a)(1) and (2) when operating at their normal operating temperatures (this prohibits feeding fluids, above the level of detection, during either startup or shutdown operations).

Quantifiable Level/Level of Detection means 2 micrograms per gram from any resolvable gas chromatographic peak, i.e. 2 ppm.

RCRA means the Resource Conservation and Recovery Act (40 U.S.C. 6901 *et seq.*).

Recycled PCBs means those PCBs which appear in the processing of paper products or asphalt roofing materials from PCB-contaminated raw materials. Processes which recycle PCBs must meet the following requirements:

(1) There are no detectable concentrations of PCBs in asphalt roofing material products leaving the processing site.

(2) The concentration of PCBs in paper products leaving any manufacturing site processing paper products, or in paper products imported into the United States, must have an annual average of less than 25 ppm with a 50 ppm maximum.

(3) The release of PCBs at the point at which emissions are vented to ambient air must be less than 10 ppm.

(4) The amount of Aroclor PCBs added to water discharged from an asphalt roofing processing site must at all times be less than 3 micrograms per liter (μg/L) for total Aroclors (roughly 3 parts per billion (3 ppb)). Water discharges from the processing of paper products must at all times be less than 3 micrograms per liter (μg/L) for total Aroclors (roughly 3 ppb), or comply with the equivalent mass-based limitation.

(5) Disposal of any other process wastes at concentrations of 50 ppm or greater must be in accordance with subpart D of this part.

Research and development (R&D) for PCB disposal means demonstrations for commercial PCB disposal approvals, pre-demonstration tests, tests of major modifications to previously approved PCB disposal technologies, treatability studies for PCB disposal technologies which have not been approved, development of new disposal technologies, and research on chemical transformation processes including, but not limited to, biodegradation.

Retrofill means to remove PCB or PCB-contaminated dielectric fluid and to replace it with either PCB, PCB-contaminated, or non-PCB dielectric fluid.

Rupture of a PCB Transformer means a violent or non-violent break in the integrity of a PCB Transformer caused by an overtemperature and/or overpressure condition that results in the release of PCBs.

Sale for purposes other than resale means sale of PCBs for purposes of disposal and for purposes of use, except where use involves sale for distribution in commerce. PCB Equipment which is first leased for purposes of use any

time before July 1, 1979, will be considered sold for purposes other than resale.

Sewage sludge means sewage sludge as defined in § 503.9(w) of this chapter that contains <50 ppm (on a dry weight basis) PCBs.

Small quantities for research and development means any quantity of PCBs (1) that is originally packaged in one or more hermetically sealed containers of a volume of no more than five (5.0) milliliters, and (2) that is used only for purposes of scientific experimentation or analysis, or chemical research on, or analysis of, PCBs, but not for research or analysis for the development of a PCB product.

Soil washing means the extraction of PCBs from soil using a solvent, recovering the solvent from the soil, separating the PCBs from the recovered solvent for disposal, and then disposal or reuse of the solvent.

Standard wipe sample means a sample collected for chemical extraction and analysis using the standard wipe test as defined in § 761.123. Except as designated elsewhere in part 761, the minimum surface area to be sampled shall be 100 cm^2.

Storage for disposal means temporary storage of PCBs that have been designated for disposal.

SW–846 means the document having the title ''SW-846, Test Methods for Evaluating Solid Waste,'' which is available from either the National Technical Information Service (NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, telephone: (703) 487-4650 or the U.S. Government Printing Office (U.S. GPO, 710 North Capitol St., NW., Washington, DC 20401, telephone: (202) 783-3238.

Totally enclosed manner means any manner that will ensure no exposure of human beings or the environment to any concentration of PCBs.

Transfer facility means any transportation-related facility including loading docks, parking areas, and other similar areas where shipments of PCB waste are held during the normal course of transportation. Transport vehicles are not transfer facilities under this definition, unless they are used for the storage of PCB waste, rather than for actual transport activities. Storage areas for PCB waste at transfer facilities are subject to the storage facility standards of § 761.65, but such storage areas are exempt from the approval requirements of § 761.65(d) and the recordkeeping requirements of § 761.180, unless the same PCB waste is stored there for a period of more than 10 consecutive days between destinations.

Transporter of PCB waste means, for the purposes of subpart K of this part, any person engaged in the transportation of regulated PCB waste by air, rail, highway, or water for purposes other than consolidation by a generator.

Transport vehicle means a motor vehicle or rail car used for the transportation of cargo by any mode. Each cargo-carrying body (e.g., trailer, railroad freight car) is a separate transport vehicle.

Treatability Study means a study in which PCB waste is subjected to a treatment process to determine:

(1) Whether the waste is amenable to the treatment process;

(2) What pretreatment (if any) is required;

(3) The optimal process conditions needed to achieve the desired treatment;

(4) The efficiency of a treatment process for the specific type of waste (i.e., soil, sludge, liquid, etc.); or,

(5) The characteristics and volumes of residuals from a particular treatment process. A ''treatability study'' is not a mechanism to commercially treat or dispose of PCB waste. Treatment is a form of disposal under this part.

TSCA means the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*).

TSCA PCB Coordinated Approval means the process used to recognize other Federal or State waste management documents governing the storage, cleanup, treatment, and disposal of PCB wastes. It is the mechanism under TSCA for accomplishing review, coordination, and approval of PCB waste management activities which are conducted outside of the TSCA PCB approval process, but require approval under the TSCA PCB regulations at 40 CFR part 761.

Unit means a particular building, structure, or cell used to manage PCB waste (including, but not limited to, a building used for PCB waste storage, a landfill, an industrial boiler, or an incinerator).

U.S. GPO means the U.S. Government Printing Office, 710 North Capitol St., NW., Washington, DC 20401.

Waste Oil means used products primarily derived from petroleum, which include, but are not limited to, fuel oils, motor oils, gear oils, cutting oils, transmission fluids, hydraulic fluids, and dielectric fluids.

Wet weight means reporting chemical analysis results by including either the weight, or the volume and density, of all liquids.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[49 FR 25239, June 20, 1984, as amended at 49 FR 28189, July 10, 1984; 49 FR 29066, July 18, 1984; 49 FR 44638, Nov. 8, 1984; 50 FR 29199, July 17, 1985; 50 FR 32176, Aug. 9, 1985; 53 FR 24220, June 27, 1988; 53 FR 27327, July 19, 1988; 54 FR 52745, Dec. 21, 1989; 55 FR 26205, June 27, 1990; 58 FR 32061, June 8, 1993; 61 FR 11106, Mar. 18, 1996; 63 FR 35437, June 29, 1998; 64 FR 33759, June 24, 1999]

§ 761.19 References.

The materials listed in this section are incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, a document must be published in the FEDERAL REGISTER and the material must be available to the public. All approved materials are available for inspection at the OPPT Docket in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. These approved materials are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030 or go to *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. In addition, these materials are available from the sources listed below.

(a) *ASTM materials.* Copies of these materials may be obtained from ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959, or by calling (877) 909–ASTM, or at *http://www.astm.org*.

(1) ASTM D93–09 (Approved December 15, 2009), Standard Test Methods for Flash Point by Pensky-Martens Closed Tester, IBR approved for §§ 761.71, 761.75.

(2) ASTM D129–64 (Reapproved 1978), Standard Test Method for Sulfur in Petroleum Products (General Bomb Method), IBR approved for § 761.71.

(3) ASTM D240–87, Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuel by Bomb Calorimeter, IBR approved for § 761.71.

(4) ASTM D482–87, Standard Test Method for Ash from Petroleum Products, IBR approved for § 761.71.

(5) ASTM D524–88, Standard Test Method for Ramsbottom Carbon Residue of Petroleum Products, IBR approved for § 761.71.

(6) ASTM D808–87, Standard Test Method for Chlorine in New and Used Petroleum Products (Bomb Method), IBR approved for § 761.71.

(7) ASTM D923–86, Standard Test Method for Sampling Electrical Insulating Liquids, IBR approved for § 761.60.

(8) ASTM D923–89, Standard Methods of Sampling Electrical Insulating Liquids, IBR approved for § 761.60.

(9) ASTM D1266–87, Standard Test Method for Sulfur in Petroleum Products (Lamp Method), IBR approved for § 761.71.

(10) ASTM D1796–83 (Reapproved 1990), Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method (Laboratory Procedure), IBR approved for § 761.71.

(11) ASTM D2158–89, Standard Test Method for Residues in Liquified Petroleum (LP) Gases, IBR approved for § 761.71.

(12) ASTM D2709–88, Standard Test Method for Water and Sediment in Distillate Fuels by Centrifuge, IBR approved for § 761.71.

(13) ASTM D2784–89, Standard Test Method for Sulfur in Liquified Petroleum Gases (Oxy-hydrogen Burner or Lamp), IBR approved for § 761.71.

(14) ASTM D3178–84, Standard Test Methods for Carbon and Hydrogen in the Analysis Sample of Coke and Coal, IBR approved for § 761.71.

(15) ASTM D3278–89, Standard Test Methods for Flash Point of Liquids by Setaflash Closed-Cup Apparatus, IBR approved for § 761.75.

(16) ASTM E258–67 (Reapproved 1987), Standard Test Method for Total Nitrogen Inorganic Material by Modified KJELDAHL Method, IBR approved for § 761.71.

(b) [Reserved]

[77 FR 2463, Jan. 18, 2012]

Subpart B—Manufacturing, Processing, Distribution in Commerce, and Use of PCBs and PCB Items

§ 761.20 Prohibitions and exceptions.

Except as authorized in § 761.30, the activities listed in paragraphs (a) and (d) of this section are prohibited pursuant to section 6(e)(2) of TSCA. The requirements set forth in paragraph (c) of this section and subpart F of this part concerning export and import of PCBs and PCB Items for disposal are established pursuant to section 6(e)(1) of TSCA. Subject to any exemptions granted pursuant to section 6(e)(3)(B) of TSCA, the activities listed in paragraphs (b) and (c) of this section are prohibited pursuant to section (6)(e)(3)(A) of TSCA. In addition, the Administrator hereby finds, under the authority of section 12(a)(2) of TSCA, that the manufacture, processing, and distribution in commerce of PCBs at concentrations of 50 ppm or greater and PCB Items with PCB concentrations of 50 ppm or greater present an unreasonable risk of injury to health within the United States. This finding is based upon the well-documented human health and environmental hazard of PCB exposure, the high probability of human and environmental exposure to PCBs and PCB Items from manufacturing, processing, or distribution activities; the potential hazard of PCB exposure posed by the transportation of PCBs or PCB Items within the United States; and the evidence that contamination of the environment by PCBs is spread far beyond the areas where they are used. In addition, the Administrator hereby finds, for purposes of section 6(e)(2)(C) of TSCA, that any exposure of human beings or the environment to PCBs, as measured or detected by any scientifically acceptable analytical method, may be significant, depending on such factors as the quantity of PCBs involved in the exposure, the likelihood of exposure to humans and the environment, and the effect of exposure. For purposes of determining which PCB Items are totally enclosed, pursuant to section 6(e)(2)(C) of TSCA, since exposure to such Items may be significant, the Administrator further finds that a totally enclosed manner is a manner which results in no exposure to humans or the environment to PCBs. The following activities are considered totally enclosed: distribution in commerce of intact, nonleaking electrical equipment such as transformers (including transformers used in railway locomotives and self-propelled cars), capacitors, electromagnets, voltage regulators, switches (including sectionalizers and motor starters), circuit breakers, reclosers, and cable that contain PCBs at any concentration and processing and distribution in commerce of PCB Equipment containing an intact, nonleaking PCB Capacitor. See paragraph (c)(1) of this section for provisions allowing the distribution in commerce of PCBs and PCB Items.

(a) No persons may use any PCB, or any PCB Item regardless of concentration, in any manner other than in a totally enclosed manner within the United States unless authorized under § 761.30, except that:

(1) An authorization is not required to use those PCBs or PCB Items which consist of excluded PCB products as defined in § 761.3.

(2) An authorization is not required to use those PCBs or PCB Items resulting from an excluded manufacturing process or recycled PCBs as defined in

§ 761.3, provided all applicable conditions of § 761.1(f) are met.

(3) An authorization is not required to use those PCB Items which contain or whose surfaces have been in contact with excluded PCB products as defined in § 761.3.

(4) An authorization is not required to use sewage sludge where the uses are regulated at parts 257, 258, and 503 of this chapter. No person may blend or otherwise dilute PCBs regulated for disposal, including PCB sewage sludge and sewage sludge not used pursuant to parts 257, 258, and 503 of this chapter, for purposes of use or to avoid disposal requirements under this part. Except as explicitly provided in subpart D of this part, no person may dispose of regulated PCB wastes including, but not limited to, PCB remediation waste, PCB bulk product waste, PCBs, and PCB industrial sludges, into treatment works, as defined in § 503.9(aa) of this chapter.

(b) No person may manufacture PCBs for use within the United States or manufacture PCBs for export from the United States without an exemption, except that: an exemption is not required for PCBs manufactured in an excluded manufacturing process as defined in § 761.3, provided all applicable conditions of § 761.1(f) are met.

(c) No persons may process or distribute in commerce any PCB, or any PCB Item regardless of concentration, for use within the United States or for export from the United States without an exemption, except that an exemption is not required to process or distribute in commerce PCBs or PCB Items resulting from an excluded manufacturing process as defined in § 761.3, or to process or distribute in commerce recycled PCBs as defined in § 761.3, or to process or distribute in commerce excluded PCB products as defined in § 761.3, provided that all applicable conditions of § 761.1(f) are met. In addition, the activities described in paragraphs (c) (1) through (5) of this section may also be conducted without an exemption, under the conditions specified therein.

(1) PCBs at concentrations of 50 ppm or greater, or PCB Items with PCB concentrations of 50 ppm or greater, sold before July 1, 1979 for purposes other than resale may be distributed in commerce only in a totally enclosed manner after that date.

(2) Any person may process and distribute in commerce for disposal PCBs at concentrations of ≥50 ppm, or PCB Items with PCB concentrations of ≥50 ppm, if they comply with the applicable provisions of this part.

(i) Processing activities which are primarily associated with and facilitate storage or transportation for disposal do not require a TSCA PCB storage or disposal approval.

(ii) Processing activities which are primarily associated with and facilitate treatment, as defined in § 260.10 of this chapter, or disposal require a TSCA PCB disposal approval unless they are part of an existing approval, are part of a self-implementing activity under § 761.61(a) or § 761.79 (b) or (c), or are otherwise specifically allowed under subpart D of this part.

(iii) With the exception of provisions in § 761.60 (a)(2) and (a)(3), in order to meet the intent of § 761.1(b), processing, diluting, or otherwise blending of waste prior to being introduced into a disposal unit for purposes of meeting a PCB concentration limit shall be done in accordance with a TSCA PCB disposal approval or comply with the requirements of § 761.79.

(iv) Where the rate of delivering liquids or non-liquids into a PCB disposal unit is an operating parameter, this rate shall be a condition of the TSCA PCB disposal approval for the unit when an approval is required.

(3) PCBs and PCB Items may be exported for disposal in accordance with the requirements of subpart F of this part.

(4) PCBs, at concentrations of less than 50 ppm, or PCB Items, with concentrations of less than 50 ppm, may be processed and distributed in commerce for purposes of disposal.

(5) Decontaminated materials. Any person may distribute in commerce equipment, structures, or other liquid or non-liquid materials that were contaminated with PCBs ≥50 ppm, including those not otherwise authorized for distribution in commerce under this part, provided that one of the following applies:

(i) The materials were decontaminated in accordance with a TSCA PCB disposal approval issued under subpart D of this part, with § 761.79, or with applicable EPA PCB spill cleanup policies in effect at the time of the decontamination.

(ii) If not previously decontaminated, the materials now meet an applicable decontamination standard in § 761.79(b).

(d) The use of waste oil that contains any detectable concentration of PCB as a sealant, coating, or dust control agent is prohibited. Prohibited uses include, but are not limited to, road oiling, general dust control, use as a pesticide or herbicide carrier, and use as a rust preventative on pipes.

(e) In addition to any applicable requirements under 40 CFR part 279, subparts G and H, marketers and burners of used oil who market (process or distribute in commerce) for energy recovery, used oil containing any quantifiable level of PCBs are subject to the following requirements:

(1) *Restrictions on marketing.* Used oil containing any quantifiable level of PCBs (2 ppm) may be marketed only to:

(i) Qualified incinerators as defined in 40 CFR 761.3.

(ii) Marketers who market off-specification used oil for energy recovery only to other marketers who have notified EPA of their used oil management activities, and who have an EPA identification number where an identification number is required by 40 CFR 279.73. This would include persons who market off-specification used oil who are subject to the requirements at 40 CFR part 279 and the notification requirements of 40 CFR 279.73.

(iii) Burners identified in 40 CFR 279.61(a)(1) and (2). Only burners in the automotive industry may burn used oil generated from automotive sources in used oil-fired space heaters provided the provisions of 40 CFR 279.23 are met. The Regional Administrator may grant a variance for a boiler that does not meet the 40 CFR 279.61(a)(1) and (2) criteria after considering the criteria listed in 40 CFR 260.32 (a) through (f). The applicant must address the relevant criteria contained in 40 CFR 260.32 (a) through (f) in an application to the Regional Administrator.

(2) *Testing of used oil fuel.* Used oil to be burned for energy recovery is presumed to contain quantifiable levels (2 ppm) of PCB unless the marketer obtains analyses (testing) or other information that the used oil fuel does not contain quantifiable levels of PCBs.

(i) The person who first claims that a used oil fuel does not contain quantifiable level (2 ppm) PCB must obtain analyses or other information to support that claim.

(ii) Testing to determine the PCB concentration in used oil may be conducted on individual samples, or in accordance with the testing procedures described in § 761.60(g)(2). However, for purposes of this part, if any PCBs at a concentration of 50 ppm or greater have been added to the container or equipment, then the total container contents must be considered as having a PCB concentration of 50 ppm or greater for purposes of complying with the disposal requirements of this part.

(iii) Other information documenting that the used oil fuel does not contain quantifiable levels (2 ppm) of PCBs may consist of either personal, special knowledge of the source and composition of the used oil, or a certification from the person generating the used oil claiming that the oil contains no detectable PCBs.

(3) *Restrictions on burning.* (i) Used oil containing any quantifiable levels of PCB may be burned for energy recovery only in the combustion facilities identified in paragraph (e)(1) of this section when such facilities are operating at normal operating temperatures (this prohibits feeding these fuels during either startup or shutdown operations). Owners and operators of such facilities are ''burners'' of used oil fuels.

(ii) Before a burner accepts from a marketer the first shipment of used oil fuel containing detectable PCBs (2 ppm), the burner must provide the marketer a one-time written and signed notice certifying that:

(A) The burner has complied with any notification requirements applicable to ''qualified incinerators'' (§ 761.3) or to ''burners'' regulated under 40 CFR part 279, subpart G.

(B) The burner will burn the used oil only in a combustion facility identified

in paragraph (e)(1) of this section and identify the class of burner he qualifies.

(4) *Recordkeeping requirements.* The following recordkeeping requirements are in addition to the recordkeeping requirements for marketers found in 40 CFR 279.72(b), 279.74(a), (b) and (c), and 279.75, and for burners found in 40 CFR 279.65 and 279.66.

(i) *Marketers.* Marketers who first claim that the used oil fuel contains no detectable PCBs must include among the records required by 40 CFR 279.72(b) and 279.74(b) and (c), copies of the analysis or other information documenting his claim, and he must include among the records required by 40 CFR 279.74(a) and (c) and 279.75, a copy of each certification notice received or prepared relating to transactions involving PCB-containing used oil.

(ii) *Burners.* Burners must include among the records required by 40 CFR 279.65 and 279.66, a copy of each certification notice required by paragraph (e)(3)(ii) of this section that he sends to a marketer.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020, (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982, and amended at 49 FR 25241, June 20, 1984; 49 FR 28190, July 10, 1984; 49 FR 44638, Nov. 8, 1984; 53 FR 12524, Apr. 15, 1988; 53 FR 24220, June 27, 1988; 58 FR 15435, Mar. 23, 1993; 58 FR 34205, June 23, 1993; 60 FR 34465, July 3, 1995; 61 FR 11106, Mar. 18, 1996; 63 FR 35439, June 29, 1998; 64 FR 33760, June 24, 1999]

§ 761.30 Authorizations.

The following non-totally enclosed PCB activities are authorized pursuant to section 6(e)(2)(B) of TSCA:

(a) *Use in and servicing of transformers (other than railroad transformers).* PCBs at any concentration may be used in transformers (other than in railroad locomotives and self-propelled railroad cars) and may be used for purposes of servicing including rebuilding these transformers for the remainder of their useful lives, subject to the following conditions:

(1) *Use conditions.* (i) As of October 1, 1985, the use and storage for reuse of PCB Transformers that pose an exposure risk to food or feed is prohibited.

(ii) As of October 1, 1990, the use of network PCB Transformers with higher secondary voltages (secondary voltages equal to or greater than 480 volts, including 480/277 volt systems) in or near commercial buildings is prohibited. Network PCB Transformers with higher secondary voltages which are removed from service in accordance with this requirement must either be reclassified to PCB Contaminated or non PCB status, placed into storage for disposal, or disposed.

(iii) Except as otherwise provided, as of October 1, 1985, the installation of PCB Transformers, which have been placed into storage for reuse or which have been removed from another location, in or near commercial buildings is prohibited.

(A) Retrofilled mineral oil PCB Transformers may be installed for reclassification purposes indefinitely after October 1, 1990.

(B) Once a retrofilled transformer has been installed for reclassification purposes, it must be tested 3 months after installation to ascertain the concentration of PCBs. If the PCB concentration is below 50 ppm, the transformer can be reclassified as a non-PCB Transformer. If the PCB concentration is between 50 and 500 ppm, the transformer can be reclassified as a PCB-Contaminated transformer. If the PCB concentration remains at 500 ppm or greater, the entire process must either be repeated until the transformer has been reclassified to a non-PCB or PCB-Contaminated transformer in accordance with paragraph (a)(2)(v) of this section or the transformer must be removed from service.

(iv) As of October 1, 1990, all higher secondary voltage radial PCB Transformers, in use in or near commercial buildings, and lower secondary voltage network PCB Transformers not located in sidewalk vaults in or near commercial buildings (network transformers with secondary voltages below 480 volts) that have not been removed from service as provided in paragraph (a)(1)(iv)(B) of this section, must be equipped with electrical protection to avoid transformer ruptures caused by high current faults. As of February 25, 1991, all lower secondary voltage radial PCB Transformers, in use in or near

commercial buildings, must be equipped with electrical protection to avoid transformer ruptures caused by high current faults.

(A) Current-limiting fuses or other equivalent technology must be used to detect sustained high current faults and provide for the complete deenergization of the transformer (within several hundredths of a second in the case of higher secondary voltage radial PCB Transformers and within tenths of a second in the case of lower secondary voltage network PCB Transformers), before transformer rupture occurs. Lower secondary voltage radial PCB Transformers must be equipped with electrical protection as provided in paragraph (a)(1)(iv)(E) of this section. The installation, setting, and maintenance of current-limiting fuses or other equivalent technology to avoid PCB Transformer ruptures from sustained high current faults must be completed in accordance with good engineering practices.

(B) All lower secondary voltage network PCB Transformers not located in sidewalk vaults (network transformers with secondary voltages below 480 volts), in use in or near commercial buildings, which have not been protected as specified in paragraph (a)(1)(iv)(A) of this section by October 1, 1990, must be removed from service by October 1, 1993.

(C) As of October 1, 1990, owners of lower secondary voltage network PCB Transformers, in use in or near commercial buildings which have not been protected as specified in paragraph (a)(1)(iv)(A) of this section and which are not located in sidewalk vaults, must register in writing those transformers with the EPA Regional Administrator in the appropriate region. The information required to be provided in writing to the Regional Administrator includes:

(*1*) The specific location of the PCB Transformer(s).

(*2*) The address(es) of the building(s) and the physical location of the PCB Transformer(s) on the building site(s).

(*3*) The identification number(s) of the PCB Transformer(s).

(D) As of October 1, 1993, all lower secondary voltage network PCB Transformers located in sidewalk vaults (network transformers with secondary voltages below 480 volts) in use near commercial buildings must be removed from service.

(E) As of February 25, 1991, all lower secondary voltage radial PCB Transformers must be equipped with electrical protection, such as current-limiting fuses or other equivalent technology, to detect sustained high current faults and provide for the complete deenergization of the transformer or complete deenergization of the faulted phase of the transformer within several hundredths of a second. The installation, setting, and maintenance of current-limiting fuses or other equivalent technology to avoid PCB Transformer ruptures from sustained high current faults must be completed in accordance with good engineering practices.

(v) As of October 1, 1990, all radial PCB Transformers with higher secondary voltages (480 volts and above, including 480/277 volt systems) in use in or near commercial buildings must, in addition to the requirements of paragraph (a)(1)(iv)(A) of this section, be equipped with protection to avoid transformer ruptures caused by sustained low current faults.

(A) Pressure and temperature sensors (or other equivalent technology which has been demonstrated to be effective in early detection of sustained low current faults) must be used in these transformers to detect sustained low current faults.

(B) Disconnect equipment must be provided to insure complete deenergization of the transformer in the event of a sensed abnormal condition (e.g., an overpressure or overtemperature condition in the transformer), caused by a sustained low current fault. The disconnect equipment must be configured to operate automatically within 30 seconds to 1 minute of the receipt of a signal indicating an abnormal condition from a sustained low current fault, or can be configured to allow for manual deenergization from a manned on-site control center upon the receipt of an audio or visual signal indicating an abnormal condition caused by a sustained low current fault. Manual deenergization from a manned on-site

control center must occur within 1 minute of the receipt of the audio or visual signal indicating an abnormal condition caused by a sustained low current fault. If automatic operation is selected and a circuit breaker is utilized for disconnection, it must also have the capability to be manually opened if necessary.

(C) The enhanced electrical protective system required for the detection of sustained low current faults and the complete and rapid deenergization of transformers must be properly installed, maintained, and set sensitive enough (in accordance with good engineering practices) to detect sustained low current faults and allow for rapid and total deenergization prior to PCB Transformer rupture (either violent or non violent rupture) and release of PCBs.

(vi)(A) No later than December 28, 1998 all owners of PCB Transformers, including those in storage for reuse, must register their transformers with the Environmental Protection Agency, National Program Chemicals Division, Office of Pollution Prevention and Toxics (7404), 1200 Pennsylvania Ave., NW., Washington, DC 20460. This registration requirement is subject to the limitations in paragraph (a)(1) of this section.

(*1*) A transformer owner who assumes a transformer is a PCB-Contaminated transformer, and discovers after December 28, 1998 that it is a PCB-Transformer, must register the newly-identified PCB Transformer, in writing, with the Environmental Protection Agency no later than 30 days after it is identified as such. This requirement does not apply to transformer owners who have previously registered with the EPA PCB Transformers located at the same address as the transformer that they assumed to be PCB-Contaminated and later determined to be a PCB Transformer.

(*2*) A person who takes possession of a PCB Transformer after December 28, 1998 is not required to register or reregister the transformer with the EPA.

(B) Any person submitting a registration under this section must include:

(*1*) Company name and address.

(*2*) Contact name and telephone number.

(*3*) Address where these transformers are located. For mobile sources such as ships, provide the name of the ship.

(*4*) Number of PCB Transformers and the total weight in kilograms of PCBs contained in the transformers.

(*5*) Whether any transformers at this location contain flammable dielectric fluid (optional).

(*6*) Signature of the owner, operator, or other authorized representative certifying the accuracy of the information submitted.

(C) A transformer owner must retain a record of each PCB Transformer's registration (e.g., a copy of the registration and the return receipt signed by EPA) with the inspection and maintenance records required for each PCB Transformer under paragraph (a)(1)(xii)(I) of this section.

(D) A transformer owner must comply with all requirements of paragraph (a)(1)(vi)(A) of this section to continue the PCB-Transformer's authorization for use, or storage for reuse, pursuant to this section and TSCA section 6(e)(2)(B).

(vii) As of December 1, 1985, PCB Transformers in use in or near commercial buildings must be registered with building owners. For PCB Transformers located in commercial buildings, PCB Transformer owners must register the transformers with the building owner of record. For PCB Transformers located near commercial buildings, PCB Transformer owners must register the transformers with all owners of buildings located within 30 meters of the PCB Transformer(s). Information required to be provided to building owners by PCB Transformer owners includes but is not limited to:

(A) The specific location of the PCB Transformer(s).

(B) The principal constituent of the dielectric fluid in the transformer(s) (e.g., PCBs, mineral oil, or silicone oil).

(C) The type of transformer installation (e.g., 208/120 volt network, 208/120 volt radial, 208 volt radial, 480 volt network, 480/277 volt network, 480 volt radial, 480/277 volt radial).

(viii) As of December 1, 1985, combustible materials, including, but not limited to paints, solvents, plastics, paper, and sawn wood must not be stored within a PCB Transformer enclosure

(i.e., in a transformer vault or in a partitioned area housing a transformer); within 5 meters of a transformer enclosure, or, if unenclosed (unpartitioned), within 5 meters of a PCB Transformer.

(ix) A visual inspection of each PCB Transformer (as defined in the definition of ''PCB Transformer'' under § 761.3) in use or stored for reuse shall be performed at least once every 3 months. These inspections may take place any time during the 3-month periods: January-March, April-June, July-September, and October-December as long as there is a minimum of 30 days between inspections. The visual inspection must include investigation for any leak of dielectric fluid on or around the transformer. The extent of the visual inspections will depend on the physical constraints of each transformer installation and should not require an electrical shutdown of the transformer being inspected.

(x) If a PCB Transformer is found to have a leak which results in any quantity of PCBs running off or about to run off the external surface of the transformer, then the transformer must be repaired or replaced to eliminate the source of the leak. In all cases any leaking material must be cleaned up and properly disposed of according to disposal requirements of subpart D of this part. Cleanup of the released PCBs must be initiated as soon as possible, but in no case later than 48 hours of its discovery. Until appropriate action is completed, any active leak of PCBs must be contained to prevent exposure of humans or the environment and inspected daily to verify containment of the leak. Trenches, dikes, buckets, and pans are examples of proper containment measures.

(xi) If a PCB Transformer is involved in a fire-related incident, the owner of the transformer must immediately report the incident to the National Response Center (toll-free 1–800–424–8802; in Washington, DC 202–426–2675). A fire-related incident is defined as any incident involving a PCB Transformer which involves the generation of sufficient heat and/or pressure (by any source) to result in the violent or nonviolent rupture of a PCB Transformer and the release of PCBs. Information must be provided regarding the type of PCB Transformer installation involved in the fire-related incident (e.g., high or low secondary voltage network transformer, high or low secondary voltage simple radial system, expanded radial system, primary selective system, primary loop system, or secondary selective system or other systems) and the readily ascertainable cause of the fire-related incident (e.g., high current fault in the primary or secondary or low current fault in secondary). The owner of the PCB Transformer must also take measures as soon as practically and safely possible to contain and control any potential releases of PCBs and incomplete combustion products into water. These measures include, but are not limited to:

(A) The blocking of all floor drains in the vicinity of the transformer.

(B) The containment of water runoff.

(C) The control and treatment (prior to release) of any water used in subsequent cleanup operations.

(xii) Records of inspection and maintenance history shall be maintained at least 3 years after disposing of the transformer and shall be made available for inspection, upon request by EPA. Such records shall contain the following information for each PCB Transformer:

(A) Its location.

(B) The date of each visual inspection and the date that leak was discovered, if different from the inspection date.

(C) The person performing the inspection.

(D) The location of any leak(s).

(E) An estimate of the amount of dielectric fluid released from any leak.

(F) The date of any cleanup, containment, repair, or replacement.

(G) A description of any cleanup, containment, or repair performed.

(H) The results of any containment and daily inspection required for uncorrected active leaks.

(I) Record of the registration of PCB Transformer(s).

(J) Records of transfer of ownership in compliance with § 761.180(a)(2)(ix).

(xiii) A reduced visual inspection frequency of at least once every 12 months applies to PCB Transformers that utilize either of the following risk reduction measures. These inspections

may take place any time during the calendar year as long as there is a minimum of 180 days between inspections.

(A) A PCB Transformer which has impervious, undrained, secondary containment capacity of at least 100 percent of the total dielectric fluid volume of all transformers so contained or

(B) A PCB Transformer which has been tested and found to contain less than 60,000 ppm PCBs (after 3 months of in service use if the transformer has been serviced for purposes of reducing the PCB concentration).

(xiv) An increased visual inspection frequency of at least once every week applies to any PCB Transformer in use or stored for reuse which poses an exposure risk to food or feed. The user of a PCB Transformer posing an exposure risk to food is responsible for the inspection, recordkeeping, and maintenance requirements under this section until the user notifies the owner that the transformer may pose an exposure risk to food or feed. Following such notification, it is the owner's ultimate responsibility to determine whether the PCB Transformer poses an exposure risk to food or feed.

(xv) In the event a mineral oil transformer, assumed to contain less than 500 ppm of PCBs as provided in §761.2, is tested and found to be contaminated at 500 ppm or greater PCBs, it will be subject to all the requirements of this part 761. In addition, efforts must be initiated immediately to bring the transformer into compliance in accordance with the following schedule:

(A) Report fire-related incidents, effective immediately after discovery.

(B) Mark the PCB transformer within 7 days after discovery.

(C) Mark the vault door, machinery room door, fence, hallway or other means of access to the PCB Transformer within 7 days after discovery.

(D) Register the PCB Transformer in writing with the building owner within 30 days of discovery.

(E) Install electrical protective equipment on a radial PCB Transformer and a non-sidewalk vault, lower secondary voltage network PCB Transformer in or near a commercial building within 18 months of discovery or by October 1, 1990, whichever is later.

(F) Remove a non-sidewalk vault, lower secondary voltage network PCB Transformer in or near a commercial building, if electrical protective equipment is not installed, within 18 months of discovery or by October 1, 1993, whichever is later.

(G) Remove a lower secondary voltage network PCB Transformer located in a sidewalk vault in or near a commercial building, within 18 months of discovery or by October 1, 1993, whichever is later.

(H) Retrofill and reclassify a radial PCB Transformer or a lower or higher secondary voltage network PCB Transformer, located in other than a sidewalk vault in or near a commercial building, within 18 months or by October 1, 1990, whichever is later. This is an option in lieu of installing electrical protective equipment on a radial or lower secondary voltage network PCB Transformer located in other than a sidewalk vault or of removing a higher secondary voltage network PCB Transformer or a lower secondary voltage network PCB Transformer, located in a sidewalk vault, from service.

(I) Retrofill and reclassify a lower secondary voltage network PCB Transformer, located in a sidewalk vault, in or near a commercial building within 18 months or by October 1, 1993, whichever is later. This is an option in lieu of installing electrical protective equipment or removing the transformer from service.

(J) Retrofill and reclassify a higher secondary voltage network PCB Transformer, located in a sidewalk vault, in or near a commercial building within 18 months or by October 1, 1990, whichever is later. This is an option in lieu of other requirements.

(2) *Servicing conditions.* (i) Transformers classified as PCB-Contaminated Electrical Equipment (as defined in the definition of ''PCB-Contaminated Electrical Equipment'' under §761.3) may be serviced (including rebuilding) only with dielectric fluid containing less than 500 ppm PCB.

(ii) Any servicing (including rebuilding) of PCB Transformers (as defined in the definition of ''PCB Transformer'' under §761.3) that requires the removal of the transformer coil from the transformer casing is prohibited. PCB

Transformers may be serviced (including topping off) with dielectric fluid at any PCB concentration.

(iii) PCBs removed during any servicing activity must be captured and either reused as dielectric fluid or disposed of in accordance with the requirements of § 761.60. PCBs from PCB Transformers must not be mixed with or added to dielectric fluid from PCB-Contaminated Electrical Equipment.

(iv) Regardless of its PCB concentration, dielectric fluids containing less than 500 ppm PCB that are mixed with fluids that contain 500 ppm or greater PCB must not be used as dielectric fluid in any electrical equipment. The entire mixture of dielectric fluid must be considered to be greater than 500 ppm PCB and must be disposed of in an incinerator that meets the requirements in § 761.70.

(v) You may reclassify a PCB Transformer that has been tested and determined to have a concentration of ≥500 ppm PCBs to a PCB-Contaminated transformer (≥50 but <500 ppm) or to a non-PCB transformer (<50 ppm), and you may reclassify a PCB-Contaminated transformer that has been tested and determined to have a concentration of ≥50 ppm but <500 ppm to a non-PCB transformer, as follows:

(A) Remove the free-flowing PCB dielectric fluid from the transformer. Flushing is not required. Either test the fluid or assume it contains ≥1,000 ppm PCBs. Retrofill the transformer with fluid containing known PCB levels according to the following table. Determine the transformer's reclassified status according to the following table (if following this process does not result in the reclassified status you desire, you may repeat the process):

If test results show the PCB concentration (ppm) in the transformer prior to retrofill is . . .	and you retrofill the transformer with dielectric fluid containing . . .	and you . . .	and test results show the PCB concentration (ppm) after retrofill is . . .	then the transformer's reclassified status is. . .
≥1,000 (or untested)	<50 ppm PCBs	operate the transformer electrically under loaded conditions for at least 90-continuous days after retrofill, then test the fluid for PCBs	≥50 but <500	PCB-contaminated
	<50 ppm PCBs	operate the transformer electrically under loaded conditions for at least 90-continuous days after retrofill, then test the fluid for PCBs	<50	non-PCB
≥500 but <1,000	<50 ppm PCBs	test the fluid for PCBs at least 90 days after retrofill	≥50 but <500	PCB-contaminated
	<50 ppm PCBs	test the fluid for PCBs at least 90 days after retrofill	<50	non-PCB
≥50 but <500	≥2 but <50 ppm PCBs	test the fluid for PCBs at least 90 days after retrofill	<50	non-PCB
	<2 ppm PCBs	(no need to test)	(not applicable)	non-PCB

(B) If you discover that the PCB concentration of the fluid in a reclassified transformer has changed, causing the reclassified status to change, the transformer is regulated based on the actual concentration of the fluid. For example, a transformer that was reclassified to non-PCB status is regulated as a PCB-Contaminated transformer if you discover that the concentration of the fluid has increased to ≥50 but <500 ppm PCBs. If you discover that the PCB concentration of the fluid has risen to ≥500 ppm, the transformer is regulated

as a PCB Transformer. Follow paragraphs (a)(1)(xv)(A) through (J) of this section to come into compliance with the regulations applicable to PCB Transformers. You also have the option of repeating the reclassification process.

(C) The Director, National Program Chemicals Division, may, without further rulemaking, grant approval on a case-by-case basis for the use of alternative methods to reclassify transformers. You may request an approval by writing to the Director, National Program Chemicals Division (7404), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Describe the equipment you plan to reclassify, the alternative reclassification method you plan to use, and test data or other evidence on the effectiveness of the method.

(D) You must keep records of the reclassification required by § 761.180(g).

(vi) Any dielectric fluid containing 50 ppm or greater PCB used for servicing transformers must be stored in accordance with the storage for disposal requirements of § 761.65.

(vii) Processing and distribution in commerce of PCBs for purposes of servicing transformers is permitted only for persons who are granted an exemption under TSCA 6(e)(3)(B).

(b) *Use in and servicing of railroad transformers.* PCBs may be used in transformers in railroad locomotives or railroad self-propelled cars (''railroad transformers'') and may be processed and distributed in commerce for purposes of servicing these transformers in a manner other than a totally enclosed manner subject to the following conditions:

(1) *Use restrictions.* After July 1, 1986, use of railroad transformers that contain dielectric fluids with a PCB concentration >1,000 ppm is prohibited.

(2) *Servicing restrictions.* (i) If the coil is removed from the casing of a railroad transformer (e.g., the transformer is rebuilt), after January 1, 1982, the railroad transformer may not be refilled with dielectric fluid containing a PCB concentration greater than 50 ppm;

(ii) After January 1, 1984, railroad transformers may only be serviced with dielectric fluid containing less than 1000 ppm PCB, except as provided in paragraph (b)(2)(i) of this section;

(iii) Dielectric fluid may be filtered through activated carbon or otherwise industrially processed for the purpose of reducing the PCB concentration in the fluid;

(iv) Any PCB dielectric fluid that is used to service PCB railroad transformers must be stored in accordance with the storage for disposal requirements of § 761.65;

(v) After July 1, 1979, processing and distribution in commerce of PCBs for purposes of servicing railroad transformers is permitted only for persons who are granted an exemption under TSCA section 6(e)(3)(B).

(vi) A PCB Transformer may be converted to a PCB-Contaminated Transformer or to a non-PCB Transformer by draining, refilling, and/or otherwise servicing the railroad transformer. In order to reclassify, the railroad transformer's dielectric fluid must contain less than 500 ppm (for conversion to PCB-Contaminated Transformer) or less than 50 ppm PCB (for conversion to a non-PCB Transformer) after a minimum of three months of inservice use subsequent to the last servicing conducted for the purpose of reducing the PCB concentration in the transformer.

(c) *Use in mining equipment.* After January 1, 1982, PCBs may be used in mining equipment only at a concentration level of <50 ppm.

(d) *Use in heat transfer systems.* After July 1, 1984, PCBs may be used in heat transfer systems only at a concentration level of <50 ppm. Heat transfer systems that were in operation after July 1, 1984, with a concentration level of <50 ppm PCBs may be serviced to maintain a concentration level of <50 ppm PCBs. Heat transfer systems may only be serviced with fluids containing <50 ppm PCBs.

(e) *Use in hydraulic systems.* After July 1, 1984, PCBs may be used in hydraulic systems only at a concentration level of <50 ppm. Hydraulic systems that were in operation after July 1, 1984, with a concentration level of <50 ppm PCBs may be serviced to maintain a concentration level of <50 ppm PCBs. Hydraulic systems may only be serviced with fluids containing <50 ppm PCBs.

(f) *Use in carbonless copy paper.* Carbonless copy paper containing PCBs may be used in a manner other than a totally enclosed manner indefinitely.

(g) [Reserved]

(h) *Use in and servicing of electromagnets, switches and voltage regulators.* PCBs at any concentration may be used in electromagnets, switches (including sectionalizers and motor starters), and voltage regulators and may be used for purposes of servicing this equipment (including rebuilding) for the remainder of their useful lives, subject to the following conditions:

(1) *Use conditions.* (i) After October 1, 1985, the use and storage for reuse of any electromagnet which poses an exposure risk to food or feed is prohibited if the electromagnet contains greater than 500 ppm PCBs.

(ii) Use and storage for reuse of voltage regulators which contain 1.36 kilograms (3 lbs) or more of dielectric fluid with a PCB concentration of ≥500 ppm are subject to the following provisions:

(A) The owner of the voltage regulator must mark its location in accordance with § 761.40.

(B) If a voltage regulator is involved in a fire-related incident, the owner must immediately report the incident to the National Response Center (Toll-free: 1–800–424–8802; in Washington, DC: 202–426–2675). A fire-related incident is defined as any incident that involves the generation of sufficient heat and/or pressure, by any source, to result in the violent or non-violent rupture of the voltage regulator and the release of PCBs.

(C) The owner of the voltage regulator must inspect it in accordance with the requirements of paragraphs (a)(1)(ix), (a)(1)(xiii), and (a)(1)(xiv) of this section that apply to PCB Transformers.

(D) The owner of the voltage regulator must comply with the recordkeeping and reporting requirements at § 761.180.

(iii) The owner of a voltage regulator that assumes it contains <500 ppm PCBs as provided in § 761.2, and discovers by testing that it is contaminated at ≥500 ppm PCBs, must comply with paragraph (h)(1)(ii)(A) of this section 7 days after the discovery, and paragraphs (h)(1)(ii)(B), (h)(1)(ii)(C), and (h)(1)(ii)(D) of this section immediately upon discovery.

(2) *Servicing conditions.* (i) Servicing (including rebuilding) any electromagnet, switch, or voltage regulator with a PCB concentration of 500 ppm or greater which requires the removal and rework of the internal components is prohibited.

(ii) Electromagnets, switches, and voltage regulators classified as PCB-Contaminated Electrical Equipment (as defined in the definition of ''PCB-Contaminated Electrical Equipment'' under § 761.3) may be serviced (including rebuilding) only with dielectric fluid containing less than 500 ppm PCB.

(iii) PCBs removed during any servicing activity must be captured and either reused as dielectric fluid or disposed of in accordance with the requirements of § 761.60. PCBs from electromagnets switches, and voltage regulators with a PCB concentration of at least 500 ppm must not be mixed with or added to dielectric fluid from PCB-Contaminated Electrical Equipment.

(iv) Regardless of its PCB concentration, dielectric fluids containing less than 500 ppm PCB that are mixed with fluids that contain 500 ppm or greater PCB must not be used as dielectric fluid in any electrical equipment. The entire mixture of dielectric fluid must be considered to be greater than 500 ppm PCB and must be disposed of in an incinerator that meets the requirements of § 761.70.

(v) You may reclassify an electromagnet, switch, or voltage regulator that has been tested and determined to have a concentration of ≥500 ppm PCBs to PCB-Contaminated status (≥50 but <500 ppm) or to non-PCB status (<50 ppm), and you may reclassify a PCB-Contaminated electromagnet, switch, or voltage regulator that has been tested and determined to have a concentration of ≥50 ppm but <500 ppm to a non-PCB status, as follows:

(A) Remove the free-flowing PCB dielectric fluid from the electromagnet, switch, or voltage regulator. Flushing is not required. Either test the fluid or assume it contains ≥1,000 ppm PCBs. Retrofill the electromagnet, switch, or voltage regulator with fluid containing

known PCB levels according to the following table. Determine the electromagnet, switch, or voltage regulator's reclassified status according to the following table (if following this process does not result in the reclassified status you desire, you may repeat the process):

If test results show the PCB concentration (ppm) in the equipment prior to retrofill is . . .	and you retrofill the equipment with dielectric fluid containing . . .	and you . . .	and test results show the PCB concentration (ppm) after retrofill is . . .	then the electromagnet, switch, or voltage regulator's reclassified status is . . .
≥1,000 (or untested)	<50 ppm PCBs	operate the equipment electrically under loaded conditions for at least 90-continuous days after retrofill, then test the fluid for PCBs	≥50 but <500	PCB-contaminated
	<50 ppm PCBs	operate the equipment electrically under loaded conditions for at least 90-continuous days after retrofill, then test the fluid for PCBs	<50	non-PCB
≥500 but <1,000	<50 ppm PCBs	test the fluid for PCBs at least 90 days after retrofill	≥50 but <500	PCB-contaminated
	<50 ppm PCBs	test the fluid for PCBs at least 90 days after retrofill	<50	non-PCB
≥50 but <500	≥2 but <50 ppm PCBs	test the fluid for PCBs at least 90 days after retrofill	<50	non-PCB
	<2 ppm PCBs	(no need to test)	(not applicable)	non-PCB

(B) If you discover that the PCB concentration of the fluid in a reclassified electromagnet, switch, or voltage regulator has changed, causing the reclassified status to change, the electromagnet, switch, or voltage regulator is regulated based on the actual concentration of the fluid. For example, an electromagnet, switch, or voltage regulator that was reclassified to non-PCB status is regulated as a PCB-Contaminated electromagnet, switch, or voltage regulator if you discover that the concentration of the fluid has increased to ≥50 but <500 ppm PCBs. If you discover that the PCB concentration of the fluid in a voltage regulator has risen to ≥500 ppm, follow paragraph (h)(1)(iii) of this section to come into compliance with the regulations applicable to voltage regulators containing ≥500 ppm PCBs. You also have the option of repeating the reclassification process.

(C) The Director, National Program Chemicals Division may, without further rulemaking, grant approval on a case-by-case basis for the use of alternative methods to reclassify electromagnets, switches or voltage regulators. You may request an approval by writing to the Director, National Program Chemicals Division (7404), Environmental Protection Agency,1200 Pennsylvania Ave., NW., Washington, DC 20460. Describe the equipment you plan to reclassify, the alternative reclassification method you plan to use, and test data or other evidence on the effectiveness of the method.

(D) You must keep records of the reclassification required by § 761.180(g).

(vi) Any dielectric fluid containing 50 ppm or greater PCB used for servicing electromagnets, switches, or voltage regulators must be stored in accordance with the storage for disposal requirements of § 761.65.

(vii) Processing and distribution in commerce of PCBs for purposes of servicing electromagnets, switches or voltage regulators is permitted only for persons who are granted an exemption under TSCA 6(e)(3)(B).

(i) *Use and reuse of PCBs in natural gas pipeline systems; use and reuse of PCB-Contaminated natural gas pipe and appurtenances.* (1)(i) PCBs are authorized for use in natural gas pipeline systems at concentrations <50 ppm.

(ii) PCBs are authorized for use, at concentrations ≥50 ppm, in natural gas pipeline systems not owned or operated by a seller or distributor of natural gas.

(iii)(A) PCBs are authorized for use, at concentrations ≥50 ppm, in natural gas pipeline systems owned or operated by a seller or distributor of natural gas, if the owner or operator:

(*1*) Submits to EPA, upon request, a written description of the general nature and location of PCBs ≥50 ppm in their natural gas pipeline system. Each written description shall be submitted to the EPA Regional Administrator having jurisdiction over the segment or component of the system (or the Director, National Program Chemicals Division, Office of Pollution Prevention and Toxics, if the system is contaminated in more than one region).

(*2*) Within 120 days after discovery of PCBs ≥50 ppm in natural gas pipeline systems, or by December 28, 1998, whichever is later, characterizes the extent of PCB contamination by collecting and analyzing samples to identify the upstream and downstream end points of the segment or component where PCBs ≥50 ppm were discovered.

(*3*) Within 120 days of characterization of the extent of PCB contamination, or by December 28, 1998, whichever is later, samples and analyzes all potential sources of introduction of PCBs into the natural gas pipeline system for PCBs ≥50 ppm. Potential sources include natural gas compressors, natural gas scrubbers, natural gas filters, and interconnects where natural gas is received upstream from the most downstream sampling point where PCBs ≥50 ppm were detected; potential sources exclude valves, drips, or other small liquid condensate collection points.

(*4*) Within 1 year of characterization of the extent of PCB contamination, reduces all demonstrated sources of PCBs ≥50 ppm to <50 ppm, or removes such sources from the natural gas pipeline system; or implements other engineering measures or methods to reduce PCB levels to <50 ppm and to prevent further introduction of PCBs ≥50 ppm into the natural gas pipeline system (e.g., pigging, decontamination, in-line filtration).

(*5*) Repeats sampling and analysis at least annually where PCBs are ≥50 ppm, until sampling results indicate the natural gas pipeline segment or component is <50 ppm PCB in two successive samples with a minimum interval between samples of 180 days.

(*6*) Marks aboveground sources of PCB liquids in natural gas pipeline systems with the M_L Mark in accordance with §761.45(a), where such sources have been demonstrated through historical data or recent sampling to contain PCBs ≥50 ppm.

(B) Owners or operators of natural gas pipeline systems which do not include potential sources of PCB contamination as described in paragraph (i)(1)(iii)(A)(*3*) of this section containing ≥50 ppm PCB are not subject to paragraphs (i)(1)(iii)(A)(*2*), (i)(1)(iii)(A)(*3*), (i)(1)(iii)(A)(*4*), or (i)(1)(iii)(A)(*6*) of this section. Owners or operators of these systems, however, must comply with the other provisions of this section (e.g., sampling of any collected PCB liquids and recordkeeping).

(C) The owner or operator of a natural gas pipeline system must document in writing all data collected and actions taken, or not taken, pursuant to the authorization in paragraph (i)(1)(iii)(A) of this section. They must maintain the information for 3 years after the PCB concentration in the component or segment is reduced to <50 ppm, and make it available to EPA upon request.

(D) The Director, National Program Chemicals Division, after consulting with the appropriate EPA Region(s) may, based on a finding of no unreasonable risk, modify in writing the requirements of paragraph (i)(1)(iii)(A) of this section, including extending any compliance date, approving alternative

formats for documentation, waiving one or more requirements for a segment or component, requiring sampling and analysis, and requiring implementation of engineering measures to reduce PCB concentrations. EPA will make such modifications based on the natural gas pipeline system size, configuration, and current operating conditions; nature, extent or source of contamination; proximity of contamination to end-users; or previous sampling, monitoring, remedial actions or documentation of activities taken regarding compliance with this authorization or other applicable Federal, State, or local laws and regulations. The Director, National Program Chemicals Division, may defer the authority described in this paragraph, upon request, to the appropriate EPA Region.

(E) The owner or operator of a natural gas pipeline system may use historical data to fulfill the requirements of paragraphs (i)(1)(iii)(A)(*1*), (i)(1)(iii)(A)(*2*) and (i)(1)(iii)(A)(*3*) of this section. They may use documented historical actions taken to reduce PCB concentrations in known sources; decontaminate components or segments of natural gas pipeline systems; or otherwise to reduce PCB levels to fulfill the requirements of paragraph (i)(1)(iii)(A)(*4*) of this section.

(2) Any person may reuse PCB-Contaminated natural gas pipe and appurtenances in a natural gas pipeline system, provided all free-flowing liquids have been removed.

(3) Any person may use PCB-Contaminated natural gas pipe, drained of all free-flowing liquids, in the transport of liquids (e.g., bulk hydrocarbons, chemicals, petroleum products, or coal slurry), as casing to provide secondary containment or protection (e.g., protection for electrical cable), as industrial structural material (e.g., fence posts, sign posts, or bridge supports), as temporary flume at construction sites, as equipment skids, as culverts under transportation systems in intermittent flow situations, for sewage service with written consent of the Publicly Owned Treatment Works (POTW), for steam service, as irrigation systems (<20 inch diameter) of less than 200 miles in length, and in a totally enclosed compressed air system.

(4) Any person characterizing PCB contamination in natural gas pipe or natural gas pipeline systems must do so by analyzing organic liquids collected at existing condensate collection points in the pipe or pipeline system. The level of PCB contamination found at a collection point is assumed to extend to the next collection point downstream. Any person characterizing multi-phasic liquids must do so in accordance with §761.1(b)(4); if no liquids are present, they must use standard wipe samples in accordance with subpart M of this part.

(5)(i) Any person disposing of liquids containing PCBs ≥50 ppm removed, spilled, or otherwise released from a natural gas pipeline system must do so in accordance with §761.61(a)(5)(iv) based on the PCB concentration at the time of removal from the system. Any person disposing of materials contaminated by spills or other releases of PCBs ≥50 ppm from a natural gas pipeline systems, must do so in accordance with §§761.61 or 761.79, as applicable.

(ii) Any person who markets or burns for energy recovery liquids containing PCBs at concentrations <50 ppm PCBs at the time of removal from a natural gas pipeline system must do so in accordance with the provisions pertaining to used oil at §761.20(e). No other use of liquid containing PCBs at concentrations above the quantifiable level/level of detection removed from a natural gas pipeline system is authorized.

(j) *Research and development.* For purposes of this section, authorized research and development (R&D) activities include, but are not limited to: the chemical analysis of PCBs, including analyses to determine PCB concentration; determinations of the physical properties of PCBs; studies of environmental transport processes; studies of biochemical transport processes; studies of effects of PCBs on the environment; and studies of the health effects of PCBs, including direct toxicity and toxicity of metabolic products of PCBs. Authorized R&D activities do not include research, development, or analysis for the development of any PCB product. Any person conducting R&D

activities under this section is also responsible for determining and complying with all other applicable Federal, State, and local laws and regulations. Although the use of PCBs and PCBs in analytical reference samples derived from waste material is authorized in conjunction with PCB-disposal related activities, R&D for PCB disposal (as defined under § 761.3) is addressed in § 761.60(j). PCBs and PCBs in analytical reference samples derived from waste materials are authorized for use, in a manner other than a totally enclosed manner, provided that:

(1) They obtain the PCBs and PCBs in analytical reference samples derived from waste materials from sources authorized under § 761.80 to manufacture, process, and distribute PCBs in commerce and the PCBs are packaged in compliance with the Hazardous Materials Regulations at 49 CFR parts 171 through 180.

(2) They store all PCB wastes resulting from R&D activities (e.g., spent laboratory samples, residuals, contaminated media such as clothing, etc.) in compliance with § 761.65(b) and dispose of all PCB wastes in compliance with § 761.64.

(3) [Reserved]

(4) No person may manufacture, process, or distribute in commerce PCBs for research and development unless they have been granted an exemption to do so under TSCA section 6(e)(3)(B).

(k) *Use in scientific instruments.* PCBs may be used indefinitely in scientific instruments, for example, in oscillatory flow birefringence and viscoelasticity instruments for the study of the physical properties of polymers, as microscopy mounting fluids, as microscopy immersion oil, and as optical liquids in a manner other than a totally enclosed manner. No person may manufacture, process, or distribute in commerce PCBs for use in scientific instruments unless they have been granted an exemption to do so under TSCA section 6(e)(3)(B).

(l) *Use in capacitors.* PCBs at any concentration may be used in capacitors, subject to the following conditions:

(1) *Use conditions.* (i) After October 1, 1988, the use and storage for reuse of PCB Large High Voltage Capacitors and PCB Large Low Voltage Capacitors which pose an exposure risk to food or feed is prohibited.

(ii) After October 1, 1988, the use of PCB Large High Voltage Capacitors and PCB Large Low Voltage Capacitors is prohibited unless the capacitor is used within a restricted-access electrical substation or in a contained and restricted-access indoor installation. A restricted-access electrical substation is an outdoor, fenced or walled-in facility that restricts public access and is used in the transmission or distribution of electric power. A contained and restricted-access indoor installation does not have public access and has an adequate roof, walls, and floor to contain any release of PCBs within the indoor location.

(2) [Reserved]

(m) *Use in and servicing of circuit breakers, reclosers and cable.* PCBs at any concentration may be used in circuit breakers, reclosers, and cable and may be used for purposes of servicing this electrical equipment (including rebuilding) for the remainder of their useful lives, subject to the following conditions:

(1) *Servicing conditions.* (i) Circuit breakers, reclosers, and cable may be serviced (including rebuilding) only with dielectric fluid containing less than 50 ppm PCB.

(ii) Any circuit breaker, recloser or cable found to contain at least 50 ppm PCBs may be serviced only in accordance with the conditions contained in 40 CFR 761.30(h)(2).

(2) [Reserved]

(n)–(o) [Reserved]

(p) *Continued use of porous surfaces contaminated with PCBs regulated for disposal by spills of liquid PCBs.* (1) Any person may use porous surfaces contaminated by spills of liquid PCBs at concentrations >10 μg/100 cm^2 for the remainder of the useful life of the surfaces and subsurface material if the following conditions are met:

(i) The source of PCB contamination is removed or contained to prevent further release to porous surfaces.

(ii) If the porous surface is accessible to superficial surface cleaning:

(A) The double wash rinse procedure in subpart S of this part is conducted on the surface to remove surface PCBs.

(B) The treated surface is allowed to dry for 24 hours.

(iii) After accessible surfaces have been cleaned according to paragraph (p)(1)(ii) of this section and for all surfaces inaccessible to cleanup:

(A) The surface is completely covered to prevent release of PCBs with:

(*1*) Two solvent resistant and water repellent coatings of contrasting colors to allow for a visual indication of wear through or loss of outer coating integrity; or

(*2*) A solid barrier fastened to the surface and covering the contaminated area or all accessible parts of the contaminated area. Examples of inaccessible areas are underneath a floor-mounted electrical transformer and in an impassible space between an electrical transformer and a vault wall.

(B) The surface is marked with the M_L Mark in a location easily visible to individuals present in the area; the M_L Mark shall be placed over the encapsulated area or the barrier to the encapsulated area.

(C) M_L Marks shall be replaced when worn or illegible.

(2) Removal of a porous surface contaminated with PCBs from its location or current use is prohibited except for removal for disposal in accordance with §§ 761.61 or 761.79 for surfaces contaminated by spills, or § 761.62 for manufactured porous surfaces.

(q) [Reserved]

(r) *Use in and servicing of rectifiers.* Any person may use PCBs at any concentration in rectifiers for the remainder of the PCBs' useful life, and may use PCBs <50 ppm in servicing (including rebuilding) rectifiers.

(s) *Use of PCBs in air compressor systems.* (1) Any person may use PCBs in air compressor systems at concentrations <50 ppm.

(2) Any person may use PCBs in air compressor systems (or components thereof) at concentrations ≥50 ppm provided that:

(i) All free-flowing liquids containing PCBs ≥50 ppm are removed from the air compressor crankcase and the crankcase is refilled with non-PCB liquid.

(ii) Other air compressor system components contaminated with PCBs ≥50 ppm, are decontaminated in accordance with § 761.79 or disposed of in accordance with subpart D of this part.

(iii) Air compressor piping with a nominal inside diameter of <2 inches is decontaminated by continuous flushing for 4 hours, at no <300 gallons per hour (§ 761.79 contains solvent requirements).

(3) The requirements in paragraph (s)(2) of this section must be completed by August 30, 1999 or within 1 year of the date of discovery of PCBs at ≥50 ppm in the air compressor system, whichever is later. The EPA Regional Administrator for the EPA Region in which an air compressor system is located may, at his/her discretion and in writing, extend this timeframe.

(t) *Use of PCBs in other gas or liquid transmission systems.* (1) PCBs are authorized for use in intact and non-leaking gas or liquid transmission systems at concentrations <50 ppm PCBs.

(2) PCBs are authorized for use at concentrations ≥50 ppm in intact and non-leaking gas or liquid transmission systems not owned or operated by a seller or distributor of the gas or liquid transmitted in the system.

(3) Any person may use PCBs at concentrations ≥50 ppm in intact and non-leaking gas or liquid transmission systems, with the written approval of the Director, National Program Chemicals Division, subject to the requirements applicable to natural gas pipeline systems at paragraphs (i)(1)(iii)(A), (i)(1)(iii)(C) through (i)(1)(iii)(E), and (i)(2) through (i)(5) of this section.

(u) *Use of decontaminated materials.* (1) Any person may use equipment, structures, other non-liquid or liquid materials that were contaminated with PCBs during manufacture, use, servicing, or because of spills from, or proximity to, PCBs ≥50 ppm, including those not otherwise authorized for use under this part, provided:

(i) The materials were decontaminated in accordance with:

(A) A TSCA PCB disposal approval issued under subpart D of this part;

(B) Section 761.79; or

(C) Applicable EPA PCB spill cleanup policies (e.g., TSCA, RCRA, CERCLA, EPA regional) in effect at the time of the decontamination; or

(ii) If not previously decontaminated, the materials now meet an applicable decontamination standard in § 761.79(b).

(2) No person shall use or reuse materials decontaminated in accordance with paragraph (u)(1)(i) of this section or meeting an applicable decontamination standard in paragraph (u)(1)(ii) of this section, in direct contact with food, feed, or drinking water unless otherwise allowed under this section or this part.

(3) Any person may use water containing PCBs at concentrations ≤0.5μg/L PCBs without restriction.

(4) Any person may use water containing PCBs at concentrations <200 μg/L (i.e., <200 ppb PCBs) for non-contact use in a closed system where there are no releases (e.g., as a non-contact cooling water).

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020, 2025 (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 761.30, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 761.35 Storage for reuse.

(a) The owner or operator of a PCB Article may store it for reuse in an area which is not designed, constructed, and operated in compliance with § 761.65(b), for no more than 5 years after the date the Article was originally removed from use (e.g., disconnected electrical equipment) or 5 years after August 28, 1998, whichever is later, if the owner or operator complies with the following conditions:

(1) Follows all use requirements at § 761.30 and marking requirements at subpart C of this part that are applicable to the PCB Article.

(2) Maintains records starting at the time the PCB Article is removed from use or August 28, 1998. The records must indicate:

(i) The date the PCB Article was removed from use or August 28, 1998, if the removal date is not known.

(ii) The projected location and the future use of the PCB Article.

(iii) If applicable, the date the PCB Article is scheduled for repair or servicing.

(b) The owner or operator of a PCB Article may store it for reuse in an area that does not comply with § 761.65(b) for a period longer than 5 years, provided that the owner or operator has received written approval from the EPA Regional Administrator for the Region in which the PCB Article is stored. An owner or operator of a PCB Article seeking approval to extend the 5–year period must submit a request for extension to the EPA Regional Administrator at least 6 months before the 5-year storage for reuse period expires and must include an item-by-item justification for the desired extension. The EPA Regional Administrator may include any conditions to such approval deemed necessary to protect health or the environment. The owner or operator of the PCB Article being stored for reuse must comply with the other applicable provisions of this part, including the record retention requirements at § 761.180(a).

(c) Any person may store a PCB Article for reuse indefinitely in:

(1) A unit in compliance with § 761.65(b).

(2) A unit permitted under section 3004 of RCRA to manage hazardous wastes in containers.

(3) A unit permitted by a State authorized under section 3006 of RCRA to manage hazardous waste.

[63 FR 35443, June 29, 1998]

Subpart C—Marking of PCBs and PCB Items

§ 761.40 Marking requirements.

(a) Each of the following items in existence on or after July 1, 1978 shall be marked as illustrated in Figure 1 in § 761.45(a): The mark illustrated in Figure 1 is referred to as M_L throughout this subpart.

(1) PCB Containers;

(2) PCB Transformers at the time of manufacture, at the time of distribution in commerce if not already marked, and at the time of removal from use if not already marked. [Marking of PCB-Contaminated Electrical Equipment is not required];

(3) PCB Large High Voltage Capacitors at the time of manufacture, at the time of distribution in commerce if not already marked, and at the time of removal from use if not already marked;

(4) Equipment containing a PCB Transformer or a PCB Large High Voltage Capacitor at the time of manufacture, at the time of distribution in commerce if not already marked, and at the time of removal of the equipment from use if not already marked;

(5) PCB Large Low Voltage Capacitors at the time of removal from use (see also paragraph (k) of this section).

(6) Electric motors using PCB coolants (See also paragraph (e) of this section).

(7) Hydraulic systems using PCB hydraulic fluid (See also paragraph (e) of this section);

(8) Heat transfer systems (other than PCB Transformers) using PCBs (See also paragraph (e) of this section);

(9) PCB Article Containers containing articles or equipment that must be marked under paragraphs (a)(1) through (8) of this section;

(10) Each storage area used to store PCBs and PCB Items for disposal.

(b) As of October 1, 1978, each transport vehicle loaded with PCB Containers that contain more than 45 kg (99.4 lbs.) of liquid PCBs at concentrations of ≥50 ppm or with one or more PCB Transformers shall be marked on each end and each side with the M_L mark as described in §761.45(a).

(c) As of January 1, 1979, the following PCB Articles shall be marked with mark M_L as described in §761.45(a):

(1) All PCB Transformers not marked under paragraph (a) of this section [marking of PCB-Contaminated Electrical Equipment is not required];

(2) All PCB Large High Voltage Capacitors not marked under paragraph (a) of this section

(i) Will be marked individually with mark M_L, or

(ii) If one or more PCB Large High Voltage Capacitors are installed in a protected location such as on a power pole, or structure, or behind a fence; the pole, structure, or fence shall be marked with mark M_L, and a record or procedure identifying the PCB Capacitors shall be maintained by the owner or operator at the protected location.

(d) As of January 1, 1979, all PCB Equipment containing a PCB Small Capacitor shall be marked at the time of manufacture with the statement, ''This equipment contains PCB Capacitor(s)''. The mark shall be of the same size as the mark M_L.

(e) As of October 1, 1979, applicable PCB Items in paragraphs (a)(1), (a)(6), (a)(7), and (a)(8) of this section containing PCBs in concentrations of 50 to 500 ppm shall be marked with the M_L mark as described in §761.45(a).

(f) Where mark M_L is specified but the PCB Article or PCB Equipment is too small to accomodate the smallest permissible size of mark M_L, mark M_S as described in §761.45(b), may be used instead of mark M_L.

(g) Each large low voltage capacitor, each small capacitor normally used in alternating current circuits, and each fluorescent light ballast manufactured (''manufactured'', for purposes of this sentence, means built) between July 1, 1978 and July 1, 1998 that do not contain PCBs shall be marked by the manufacturer at the time of manufacture with the statement, ''No PCBs''. The mark shall be of similar durability and readability as other marking that indicate electrical information, part numbers, or the manufacturer's name. For purposes of this paragraph marking requirement only is applicable to items built domestically or abroad after June 30, 1978.

(h) All marks required by this subpart must be placed in a position on the exterior of the PCB Items, storage units, or transport vehicles so that the marks can be easily read by any persons inspecting or servicing the marked PCB Items, storage units, or transport vehicles.

(i) Any chemical substance or mixture that is manufactured after the effective date of this rule and that contains less than 500 ppm PCB (0.05% on a dry weight basis), including PCB that is a byproduct or impurity, must be marked in accordance with any requirements contained in the exemption granted by EPA to permit such manufacture and is not subject to any other requirement in this subpart unless so specified in the exemption. This paragraph applies only to containers of chemical substances or mixtures. PCB articles and equipment into which the chemical substances or mixtures are processed, are subject to the marking

requirements contained elsewhere in this subpart.

(j) PCB Transformer locations shall be marked as follows:

(1) Except as provided in paragraph (j)(2) of this section, as of December 1, 1985, the vault door, machinery room door, fence, hallway, or means of access, other than grates and manhole covers, to a PCB Transformer must be marked with the mark M_L as required by paragraph (a) of this section.

(2) A mark other than the M_L mark may be used provided all of the following conditions are met:

(i) The program using such an alternative mark was initiated prior to August 15, 1985, and can be substantiated with documentation.

(ii) Prior to August 15, 1985, coordination between the transformer owner and the primary fire department occurred, and the primary fire department knows, accepts, and recognizes what the alternative mark means, and that this can be substantiated with documentation.

(iii) The EPA Regional Administrator in the appropriate region is informed in writing of the use of the alternative mark by October 3, 1988 and is provided with documentation that the program began before August 15, 1985, and documentation that demonstrates that prior to that date the primary fire department knew, accepted and recognized the meaning of the mark, and included this information in firefighting training.

(iv) The Regional Administrator will either approve or disapprove in writing the use of an alternative mark within 30 days of receipt of the documentation of a program.

(3) Any mark placed in accordance with the requirements of this section must be placed in the locations described in paragraph (j)(1) of this section and in a manner that can be easily read by emergency response personnel fighting a fire involving this equipment.

(k) As of April 26, 1999 the following PCB Items shall be marked with the M_L mark as described in §761.45(a):

(1) All PCB Large Low Voltage Capacitors not marked under paragraph (a) of this section shall be marked individually, or if one or more PCB Large Low Voltage Capacitors are installed in a protected location such as on a power pole, or structure, or behind a fence, then the owner or operator shall mark the pole, structure, or fence with the M_L mark, and maintain a record or procedure identifying the PCB Capacitors at the protected location. PCB Large Low Voltage Capacitors in inaccessible locations inside equipment need not be marked individually, provided the owner or operator marks the equipment in accordance with paragraph (k)(2) of this section, and marks the individual capacitors at the time of removal from use in accordance with paragraph (a) of this section.

(2) All equipment not marked under paragraph (a) of this section containing a PCB Transformer or a PCB Large High or Low Voltage Capacitor.

(l)(1) All voltage regulators which contain 1.36 kilograms (3 lbs.) or more of dielectric fluid with a PCB concentration of ≥500 ppm must be marked individually with the M_L mark as described in §761.45(a).

(2) Locations of voltage regulators which contain 1.36 kilograms (3 lbs.) or more of dielectric fluid with a PCB concentration of ≥500 ppm shall be marked as follows: The vault door, machinery room door, fence, hallway, or means of access, other than grates or manhole covers, must be marked with the M_L mark as described in §761.45(a).

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982, and amended at 47 FR 37359, Aug. 25, 1982; 50 FR 29201, July 17, 1985; 50 FR 32176, Aug. 9, 1985; 53 FR 12524, Apr. 15, 1988; 53 FR 27329, July 19, 1988; 63 FR 35443, June 29, 1998; 64 FR 33760, June 24, 1999]

§761.45 Marking formats.

The following formats shall be used for marking:

(a) *Large PCB Mark—M_L.* Mark M_L shall be as shown in Figure 1, letters and striping on a white or yellow background and shall be sufficiently durable to equal or exceed the life (including storage for disposal) of the PCB Article, PCB Equipment, or PCB Container. The size of the mark shall be at least 15.25 cm (6 inches) on each side. If the PCB Article or PCB Equipment is too small to accommodate this size,

the mark may be reduced in size proportionately down to a minimum of 5 cm (2 inches) on each side.

(b) *Small PCB Mark—M_s.* Mark M_s shall be as shown in Figure 2, letters and striping on a white or yellow background, and shall be sufficiently durable to equal or exceed the life (including storage for disposal) of the PCB Article, PCB Equipment, or PCB Container. The mark shall be a rectangle 2.5 by 5 cm (1 inch by 2 inches). If the PCB Article or PCB Equipment is too small to accommodate this size, the mark may be reduced in size proportionately down to a minimum of 1 by 2 cm (.4 by .8 inches).

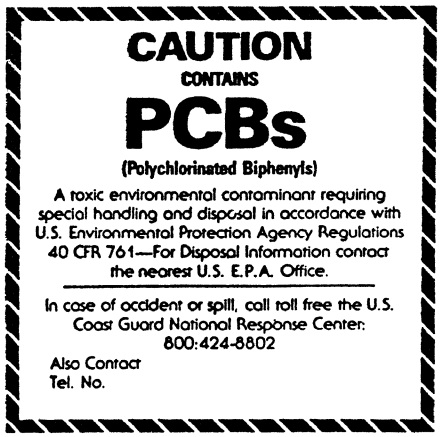

Figure 1

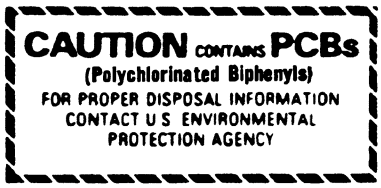

Figure 2

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982]

Subpart D—Storage and Disposal

§ 761.50 Applicability.

(a) *General PCB disposal requirements.* Any person storing or disposing of PCB waste must do so in accordance with subpart D of this part. The following prohibitions and conditions apply to all PCB waste storage and disposal:

(1) No person may open burn PCBs. Combustion of PCBs approved under § 761.60 (a) or (e), or otherwise allowed under part 761, is not open burning.

(2) No person may process liquid PCBs into non-liquid forms to circumvent the high temperature incineration requirements of § 761.60(a).

(3) No person may discharge water containing PCBs to a treatment works (as defined § 503.9(aa) of this chapter) or to navigable waters unless the PCB concentration is <3 μg/L (approximately 3 ppb), or unless the discharge is in accordance with a PCB discharge limit included in a permit issued under section 307(b) or 402 of the Clean Water Act.

(4) Spills and other uncontrolled discharges of PCBs at concentrations of ≥50 ppm constitute the disposal of PCBs.

(5) Any person land disposing of non-liquid PCBs may avoid otherwise-applicable sampling requirements by presuming that the PCBs disposed of are ≥500 ppm (or ≥100 μg/100 cm^2 if no free-flowing liquids are present).

(6) Any person storing or disposing of PCBs is also responsible for determining and complying with all other applicable Federal, State, and local laws and regulations.

(b) *PCB waste*—(1) *PCB liquids.* Any person removing PCB liquids from use (i.e., not PCB remediation waste) must dispose of them in accordance with § 761.60(a), or decontaminate them in accordance with § 761.79.

(2) *PCB Items.* Any person removing from use a PCB Item containing an intact and non-leaking PCB Article must dispose of it in accordance with § 761.60(b), or decontaminate it in accordance with § 761.79. PCB Items where the PCB Articles are no longer intact and non-leaking are regulated for disposal as PCB bulk product waste under § 761.62(a) or (c).

(i) Fluorescent light ballasts containing PCBs only in an intact and non-leaking PCB Small Capacitor are regulated for disposal under § 761.60(b)(2)(ii).

(ii) Fluorescent light ballasts containing PCBs in the potting material

are regulated for disposal as PCB bulk product waste under § 761.62.

(3) *PCB remediation waste.* PCB remediation waste, including PCB sewage sludge, is regulated for cleanup and disposal in accordance with § 761.61.

(i) Any person responsible for PCB waste at as-found concentrations ≥50 ppm that was either placed in a land disposal facility, spilled, or otherwise released into the environment prior to April 18, 1978, regardless of the concentration of the spill or release; or placed in a land disposal facility, spilled, or otherwise released into the environment on or after April 18, 1978, but prior to July 2, 1979, where the concentration of the spill or release was ≥50 ppm but <500 ppm, must dispose of the waste as follows:

(A) Sites containing these wastes are presumed not to present an unreasonable risk of injury to health or the environment from exposure to PCBs at the site. However, the EPA Regional Administrator may inform the owner or operator of the site that there is reason to believe that spills, leaks, or other uncontrolled releases or discharges, such as leaching, from the site constitute ongoing disposal that may present an unreasonable risk of injury to health or the environment from exposure to PCBs at the site, and may require the owner or operator to generate data necessary to characterize the risk. If after reviewing any such data, the EPA Regional Administrator makes a finding, that an unreasonable risk exists, then he or she may direct the owner or operator of the site to dispose of the PCB remediation waste in accordance with § 761.61 such that an unreasonable risk of injury no longer exists.

(B) Unless directed by the EPA Regional Administrator to dispose of PCB waste in accordance with paragraph (b)(3)(i)(A) of this section, any person responsible for PCB waste at as-found concentrations ≥50 ppm that was either placed in a land disposal facility, spilled, or otherwise released into the environment prior to April 18, 1978, regardless of the concentration of the spill or release; or placed in a land disposal facility, spilled, or otherwise released into the environment on or after April 18, 1978, but prior to July 2, 1979, where the concentration of the spill or release was ≥50 ppm but <500 ppm, who unilaterally decides to dispose of that waste (for example, to obtain insurance or to sell the property), is not required to clean up in accordance with § 761.61. Disposal of the PCB remediation waste must comply with § 761.61. However, cleanup of those wastes that is not in complete compliance with § 761.61 will not afford the responsible party with relief from the applicable PCB regulations for that waste.

(ii) Any person responsible for PCB waste at as-found concentrations ≥50 ppm that was either placed in a land disposal facility, spilled, or otherwise released into the environment on or after April 18, 1978, but prior to July 2, 1979, where the concentration of the spill or release was ≥500 ppm; or placed in a land disposal facility, spilled, or otherwise released into the environment on or after July 2, 1979, where the concentration of the spill or release was ≥50 ppm, must dispose of it in accordance with either of the following:

(A) In accordance with the PCB Spill Cleanup Policy (Policy) at subpart G of this part, for those PCB remediation wastes that meet the criteria of the Policy. Consult the Policy for a description of the spills it covers and its notification and timing requirements.

(B) In accordance with § 761.61. Complete compliance with § 761.61 does not create a presumption against enforcement action for penalties for any unauthorized PCB disposal.

(iii) The owner or operator of a site containing PCB remediation waste has the burden of proving the date that the waste was placed in a land disposal facility, spilled, or otherwise released into the environment, and the concentration of the original spill.

(4) *PCB bulk product waste*—(i) *General.* Any person disposing of PCB bulk product waste must do so in accordance with § 761.62. PCB bulk product waste, as that term is defined in § 761.3, is waste that was ≥50 ppm when originally removed from service, even if its current PCB concentration is <50 ppm. PCB bulk product waste is regulated for disposal based on the risk from the waste once disposed of. For waste which is land disposed, the waste is regulated based on how readily the

waste is released from disposal to the environment, in particular by leaching out from the land disposal unit.

(ii) *Metal surfaces in contact with PCBs.* Any person disposing of metal surfaces in contact with PCBs (e.g., painted metal) may use thermal decontamination procedures in accordance with §761.79(c)(6) (see §761.62(a)(6)).

(5) *PCB household waste.* Any person storing or disposing of PCB household waste, as that term is defined in §761.3, must do so in accordance with §761.63.

(6) *PCB research and development waste.* Any person disposing of PCB wastes generated during and as a result of research and development for use under §761.30(j), or for disposal under §761.60(j), must do so in accordance with §761.64.

(7) *PCB/Radioactive waste.* (i) Any person storing PCB/radioactive waste ≥50 ppm PCBs must do so taking into account both its PCB concentration and its radioactive properties, except as provided in §761.65(a)(1), (b)(1)(ii), and (c)(6)(i).

(ii) Any person disposing of PCB/radioactive waste must do so taking into account both its PCB concentration and its radioactive properties. If, taking into account only the properties of the PCBs in the waste (and not the radioactive properties of the waste), the waste meets the requirements for disposal in a facility permitted, licensed, or registered by a State as a municipal or non-municipal non-hazardous waste landfill (e.g., PCB bulk product waste under §761.62(b)(1)), then the person may dispose of the PCB/radioactive waste, without regard to the PCB component of the waste, on the basis of its radioactive properties in accordance with all applicable requirements for the radioactive component of the waste.

(8) *Porous surfaces.* In most cases a person must dispose of porous surfaces as materials where PCBs have penetrated far beneath the surface, rather than a simple surface contamination. Any person disposing of porous surfaces on which PCBs have been spilled and meeting the definition of PCB remediation waste at §761.3 must do so in accordance with §761.61. Any person disposing of porous surfaces which are part of manufactured non-liquid products containing PCBs and meeting the definition of PCB bulk product waste at §761.3 must do so in accordance with §761.62. Any person may decontaminate concrete surfaces upon which PCBs have been spilled in accordance with §761.79(b)(4), if the decontamination procedure is commenced within 72 hours of the initial spill of PCBs to the concrete or portion thereof being decontaminated. Any person may decontaminate porous non-liquid PCBs in contact with non-porous surfaces, such as underground metal fuel tanks coated with fire retardant resin or pitch, for purposes of unrestricted use or disposal in a smelter in accordance with §761.79(b)(3).

(c) *Storage for disposal.* Any person who holds PCB waste must store it in accordance with §761.65.

(d) *Performance specifications for disposal technologies*—(1) *Incinerators.* Any person using an incinerator to dispose of PCBs must use an incinerator that meets the criteria set forth in §761.70.

(2) *High efficiency boilers.* Any person using a high efficiency boiler to dispose of PCBs must use a boiler that meets the criteria set forth in §761.71.

(3) *Scrap metal recovery ovens and smelters.* Any person using scrap metal recovery ovens and smelters to dispose of PCBs must use a device that meets the criteria set forth in §761.72.

(4) *Chemical waste landfills.* Any person using a chemical waste landfill to dispose of PCBs must use a chemical waste landfill that meets the criteria set forth in §761.75.

(e) *TSCA PCB Coordinated Approval.* Any person seeking a TSCA PCB Coordinated Approval must follow the procedures set forth in §761.77.

[63 FR 35444, June 29, 1998, as amended at 64 FR 33760, June 24, 1999]

§761.60 Disposal requirements.

(a) *PCB liquids.* PCB liquids at concentrations ≥50 ppm must be disposed of in an incinerator which complies with §761.70, except that PCB liquids at concentrations ≥50 ppm and <500 ppm may be disposed of as follows:

(1) For mineral oil dielectric fluid, in a high efficiency boiler according to §761.71(a).

(2) For liquids other than mineral oil dielectric fluid, in a high efficiency boiler according to § 761.71(b).

(3) For liquids from incidental sources, such as precipitation, condensation, leachate or load separation and are associated with PCB Articles or non-liquid PCB wastes, in a chemical waste landfill which complies with § 761.75 if:

(i) [Reserved]

(ii) Information is provided to or obtained by the owner or operator of the chemical waste landfill that shows that the liquids do not exceed 500 ppm PCB and are not an ignitable waste as described in § 761.75(b)(8)(iii).

(b) *PCB Articles.* This paragraph does not authorize disposal that is otherwise prohibited in § 761.20 or elsewhere in this part.

(1) *Transformers.* (i) PCB Transformers shall be disposed of in accordance with either of the following:

(A) In an incinerator that complies with § 761.70; or

(B) In a chemical waste landfill approved under § 761.75; provided that all free-flowing liquid is removed from the transformer, the transformer is filled with a solvent, the transformer is allowed to stand for at least 18 continuous hours, and then the solvent is thoroughly removed. Any person disposing of PCB liquids that are removed from the transformer (including the dielectric fluid and all solvents used as a flush), shall do so in an incinerator that complies with § 761.70 of this part, or shall decontaminate them in accordance with § 761.79. Solvents may include kerosene, xylene, toluene, and other solvents in which PCBs are readily soluble. Any person disposing of these PCB liquids must ensure that the solvent flushing procedure is conducted in accordance with applicable safety and health standards as required by Federal or State regulations.

(ii) [Reserved]

(2) *PCB Capacitors.* (i) The disposal of any capacitor shall comply with all requirements of this subpart unless it is known from label or nameplate information, manufacturer's literature (including documented communications with the manufacturer), or chemical analysis that the capacitor does not contain PCBs.

(ii) Any person may dispose of PCB Small Capacitors as municipal solid waste, unless that person is subject to the requirements of paragraph (b)(2)(iv) of this section.

(iii) Any PCB Large High or Low Voltage Capacitor which contains 500 ppm or greater PCBs, owned by any person, shall be disposed of in accordance with either of the following:

(A) Disposal in an incinerator that complies with § 761.70; or

(B) Until March 1, 1981, disposal in a chemical waste landfill that complies with § 761.75.

(iv) Any person who manufactures or at any time manufactured PCB Capacitors or PCB Equipment, and acquired the PCB Capacitor in the course of such manufacturing, shall place the PCB Small Capacitors in a container meeting the DOT packaging requirements at 49 CFR parts 171 through 180 and dispose of them in accordance with either of the following:

(A) Disposal in an incinerator which complies with § 761.70; or

(B) Until March 1, 1981, disposal in a chemical waste landfill which complies with § 761.75.

(v) Notwithstanding the restrictions imposed by paragraph (b)(2)(iii)(B) or (b)(2)(iv)(B) of this section, PCB capacitors may be disposed of in PCB chemical waste landfills that comply with § 761.75 subsequent to March 1, 1981, if EPA publishes a notice in the FEDERAL REGISTER declaring that those landfills are available for such disposal and explaining the reasons for the extension or reopening. An extension or reopening for disposal of PCB capacitors that is granted under this subsection shall be subject to such terms and conditions as the Assistant Administrator may prescribe and shall be in effect for such period as the Assistant Administrator may prescribe. EPA may permit disposal of PCB capacitors in EPA-approved chemical waste landfills after March 1, 1981, if in its opinion,

(A) Adequate incineration capability for PCB capacitors is not available, or

(B) The incineration of PCB capacitors will significantly interfere with the incineration of liquid PCBs, or

(C) There is other good cause shown.

As part of this evaluation, the Assistant Administrator will consider the

impact of his action on the incentives to construct or expand PCB incinerators.

(vi) Any person disposing of large PCB capacitors or small PCB capacitors described in paragraph (b)(2)(iv) of this section in a chemical waste landfill approved under §761.75, shall first place them in a container meeting the DOT packaging requirements at 49 CFR parts 171 through 180. In all cases, the person must fill the interstitial space in the container with sufficient absorbent material (such as soil) to absorb any liquid PCBs remaining in the capacitors.

(3) *PCB hydraulic machines.* (i) Any person disposing of PCB hydraulic machines containing PCBs at concentrations of ≥50 ppm, such as die casting machines, shall do so by one of the following methods:

(A) In accordance with §761.79.

(B) In a facility which is permitted, licensed, or registered by a State to manage municipal solid waste subject to part 258 of this chapter or non-municipal non-hazardous waste subject to §§257.5 through 257.30 of this chapter, as applicable (excluding thermal treatment units).

(C) In a scrap metal recovery oven or smelter operating in compliance with §761.72.

(D) In a disposal facility approved under this part.

(ii) All free-flowing liquid must be removed from each machine and the liquid must be disposed of in accordance with the provisions of paragraph (a) of this section. If the PCB liquid contains ≥1,000 ppm PCB, then the hydraulic machine must be decontaminated in accordance with §761.79 or flushed prior to disposal with a solvent listed at paragraph (b)(1)(i)(B) of this section which contains <50 ppm PCB. The solvent must be disposed of in accordance with paragraph (a) of this section or §761.79.

(4) *PCB-Contaminated Electrical Equipment.* Any person disposing of PCB-Contaminated Electrical Equipment, except capacitors, shall do so in accordance with paragraph (b)(6)(ii)(A) of this section. Any person disposing of Large Capacitors that contain ≥50 ppm but <500 ppm PCBs shall do so in a disposal facility approved under this part.

(5) *Natural gas pipeline systems containing PCBs.* The owner or operator of natural gas pipeline systems containing ≥50 ppm PCBs, when no longer in use, shall dispose of the system either by abandonment in place of the pipe under paragraph (b)(5)(i) of this section or removal with subsequent action under paragraph (b)(5)(ii) of this section. Any person determining the PCB concentrations in natural gas pipeline systems shall do so in accordance with paragraph (b)(5)(iii) of this section.

(i) *Abandonment.* Natural gas pipe containing ≥50 ppm PCBs may be abandoned in place under one or more of the following provisions:

(A) Natural gas pipe having a nominal inside diameter of ≤4 inches, and containing PCBs at any concentration but no free-flowing liquids, may be abandoned in the place it was used to transport natural gas if each end is sealed closed and the pipe is either:

(*1*) Included in a public service notification program, such as a ''one-call'' system under 49 CFR 192.614(a) and (b).

(*2*) Filled to 50 percent or more of the volume of the pipe with grout (such as a hardening slurry consisting of cement, bentonite, or clay) or high density polyurethane foam.

(B) PCB-Contaminated natural gas pipe of any diameter, where the PCB concentration was determined after the last transmission of gas through the pipe or at the time of abandonment, that contains no free-flowing liquids may be abandoned in the place it was used to transport natural gas if each end is sealed closed.

(C) Natural gas pipe of any diameter which contains PCBs at any concentration but no free-flowing liquids, may be abandoned in the place it was used to transport natural gas, if each end is sealed closed, and either:

(*1*) The interior surface is decontaminated with one or more washes of a solvent in accordance with the use and disposal requirements of §761.79(d). This decontamination process must result in a recovery of 95 percent of the solvent volume introduced into the system, and the PCB concentration of the recovered wash must be <50 ppm (see §761.79(a)(1) for requirements on

use and disposal of decontaminating fluids).

(*2*) The pipe is filled to 50 percent or more of the volume of the pipe with grout (such as a hardening slurry-like cement, bentonite, or clay) or high density polyurethane foam (except that only cement shall be used as grout under rivers or streams) and each end is sealed closed.

(D) Natural gas pipe of any diameter which contains PCBs at any concentration may be abandoned in place after decontamination in accordance with §761.79(c)(3), (c)(4) or (h) or a PCB disposal approval issued under §761.60(e) or §761.61(c).

(ii) *Removal with subsequent action.* Natural gas pipeline systems may be disposed of under one of the following provisions:

(A) The following classifications of natural gas pipe containing no free-flowing liquids may be disposed of in a facility permitted, licensed, or registered by a State to manage municipal solid waste subject to part 258 of this chapter or non-municipal non-hazardous waste subject to §§257.5 through 257.30 of this chapter, as applicable (excluding thermal treatment units); a scrap metal recovery oven or smelter operating in compliance with the requirements of §761.72; or a disposal facility approved under this part:

(*1*) PCB-Contaminated natural gas pipe of any diameter where the PCB concentration was determined after the last transmission of gas through the pipe or during removal from the location it was used to transport natural gas.

(*2*) Natural gas pipe containing PCBs at any concentration and having a nominal inside diameter ≤4 inches.

(B) Any component of a natural gas pipeline system may be disposed of under one of the following provisions:

(*1*) In an incinerator operating in compliance with §761.70.

(*2*) In a chemical waste landfill operating in compliance with §761.75, provided that all free-flowing liquid PCBs have been thoroughly drained.

(*3*) As a PCB remediation waste in compliance with §761.61.

(*4*) In accordance with §761.79.

(iii) *Characterization of natural gas pipeline systems by PCB concentration in condensate.* (A) Any person disposing of a natural gas pipeline system under paragraphs (b)(5)(i)(B) or (b)(5)(ii)(A)(*1*) of this section must characterize it for PCB contamination by analyzing organic liquids collected at existing condensate collection points in the natural gas pipeline system. The level of PCB contamination found at a collection point is assumed to extend to the next collection point downstream. If no organic liquids are present, drain free-flowing liquids and collect standard wipe samples according to subpart M of this part. Collect condensate within 72 hours of the final transmission of natural gas through the part of the system to be abandoned or removed. Collect wipe samples after the last transmission of gas through the pipe or during removal from the location it was used to transport natural gas.

(B) PCB concentration of the organic phase of multi-phasic liquids shall be determined in accordance with §761.1(b)(4).

(iv) *Disposal of pipeline liquids.* (A) Any person disposing of liquids containing PCBs ≥50 ppm removed, spilled, or otherwise released from a natural gas pipeline system must do so in accordance with §761.61(a)(5)(iv) based on the PCB concentration at the time of removal from the system. Any person disposing of material contaminated by spills or other releases of PCBs ≥50 ppm from a natural gas pipeline system, must do so in accordance with §761.61 or §761.79, as applicable.

(B) Any person who markets or burns for energy recovery liquid containing PCBs at concentrations <50 ppm PCBs at the time of removal from a natural gas pipeline system must do so in accordance with the provisions pertaining to used oil at §761.20(e). No other use of liquid containing PCBs at concentrations above the quantifiable level/level of detection removed from a natural gas pipeline system is authorized.

(6) *Other PCB Articles.* (i) PCB articles with concentrations at 500 ppm or greater must be disposed of:

(A) In an incinerator that complies with §761.70; or

(B) In a chemical waste landfill that complies with §761.75, provided that all free-flowing liquid PCBs have been

thoroughly drained from any articles before the articles are placed in the chemical waste landfill and that the drained liquids are disposed of in an incinerator that complies with § 761.70.

(ii)(A) Except as specifically provided in paragraphs (b)(1) through (b)(5) of this section, any person disposing of a PCB-Contaminated Article must do so by removing all free-flowing liquid from the article, disposing of the liquid in accordance with paragraph (a) of this section, and disposing of the PCB-Contaminated Article with no free-flowing liquid by one of the following methods:

(*1*) In accordance with § 761.79.

(*2*) In a facility permitted, licensed, or registered by a State to manage municipal solid waste subject to part 258 of this chapter or non-municipal non-hazardous waste subject to §§ 257.5 through 257.30 of this chapter, as applicable (excluding thermal treatment units).

(*3*) In a scrap metal recovery oven or smelter operating in compliance with § 761.72.

(*4*) In a disposal facility approved under this part.

(B) Storage for disposal of PCB-Contaminated Articles from which all free-flowing liquids have been removed is not regulated under subpart D of this part.

(C) Requirements in subparts J and K of this part do not apply to PCB-Contaminated Articles from which all free-flowing liquids have been removed.

(iii) Fluorescent light ballasts containing PCBs in their potting material must be disposed of in a TSCA-approved disposal facility, as bulk product waste under § 761.62, as household waste under § 761.63 (where applicable), or in accordance with the decontamination provisions of § 761.79.

(7) *Storage of PCB Articles.* Except for a PCB Article described in paragraph (b)(2)(ii) of this section and hydraulic machines that comply with the municipal solid waste disposal provisions described in paragraph (b)(3) of this section, any PCB Article, with PCB concentrations at 50 ppm or greater, shall be stored in accordance with § 761.65 prior to disposal.

(8) Persons disposing of PCB Articles must wear or use protective clothing or equipment to protect against dermal contact with or inhalation of PCBs or materials containing PCBs.

(c) *PCB Containers.* (1) Unless decontaminated in compliance with § 761.79 or as provided in paragraph (c)(2) of this section, a PCB container with PCB concentrations at 500 ppm or greater shall be disposed of:

(i) In an incinerator which complies with § 761.70, or

(ii) In a chemical waste landfill that complies with § 761.75; provided that if there are PCBs in a liquid state, the PCB Container shall first be drained and the PCB liquid disposed of in accordance with paragraph (a) of this section.

(2) Any PCB Container used to contain only PCBs at a concentration less than 500 ppm shall be disposed of as municipal solid wastes; provided that if the PCBs are in a liquid state, the PCB Container shall first be drained and the PCB liquid shall be disposed of in accordance with paragraph (a) of this section.

(3) Prior to disposal, a PCB container with PCB concentrations at 50 ppm or greater shall be stored in a unit which complies with § 761.65.

(d) [Reserved]

(e) Any person who is required to incinerate any PCBs and PCB items under this subpart and who can demonstrate that an alternative method of destroying PCBs and PCB items exists and that this alternative method can achieve a level of performance equivalent to an incinerator approved under § 761.70 or a high efficiency boiler operating in compliance with § 761.71, must submit a written request to the Regional Administrator or the Director, Office of Resource Conservation and Recovery, for a waiver from the incineration requirements of § 761.70 or § 761.71. Requests for approval of alternate methods that will be operated in more than one Region must be submitted to the Director, Office of Resource Conservation and Recovery, except for research and development activities involving less than 500 pounds of PCB material (see paragraph (i)(2) of this section). Requests for approval of

alternate methods that will be operated in only one Region must be submitted to the appropriate EPA Regional Administrator. The applicant must show that his or her method of destroying PCBs will not present an unreasonable risk of injury to health or the environment. On the basis of such information and any available information, EPA may, in its discretion, approve the use of the alternate method if it finds that the alternate disposal method provides PCB destruction equivalent to disposal in a §761.60 incinerator or a §761.61 high efficiency boiler and will not present an unreasonable risk of injury to health or the environment. Any approval must be stated in writing and may include such conditions and provisions as EPA deems appropriate. The person to whom such waiver is issued must comply with all limitations contained in such determination. No person may use the alternate method of destroying PCBs or PCB items prior to obtaining permission from the appropriate EPA official.

(f)(1) Each operator of a chemical waste landfill, incinerator, or alternative to incineration approved under paragraph (e) of this section shall give the following written notices to the state and local governments within whose jurisdiction the disposal facility is located:

(i) Notice at least thirty (30) days before a facility is first used for disposal of PCBs required by these regulations; and

(ii) At the request of any state or local government, annual notice of the quantities and general description of PCBs disposed of during the year. This annual notice shall be given no more than thirty (30) days after the end of the year covered.

(iii) The Regional Administrator may reduce the notice period required by paragraph (f)(1)(i) of this section from thirty days to a period of no less than five days in order to expedite interim approval of the chemical waste landfill located in Sedgwick County, Kansas.

(2) [Reserved]

(g) *Testing procedures.* (1) Owners or users of mineral oil dielectric fluid electrical equipment may use the following procedures to determine the concentration of PCBs in the dielectric fluid:

(i) Dielectric fluid removed from mineral oil dielectric fluid electrical equipment may be collected in a common container, provided that no other chemical substances or mixtures are added to the container. This common container option does not permit dilution of the collected oil. Mineral oil that is assumed or known to contain at least 50 ppm PCBs must not be mixed with mineral oil that is known or assumed to contain less than 50 ppm PCBs to reduce the concentration of PCBs in the common container. If dielectric fluid from untested, oil-filled circuit breakers, reclosers, or cable is collected in a common container with dielectric fluid from other oil-filled electrical equipment, the entire contents of the container must be treated as PCBs at a concentration of at least 50 ppm, unless all of the fluid from the other oil-filled electrical equipment has been tested and shown to contain less than 50 ppm PCBs.

(ii) For purposes of complying with the marking and disposal requirements, representative samples may be taken from either the common containers or the individual electrical equipment to determine the PCB concentration, except that if any PCBs at a concentration of 500 ppm or greater have been added to the container or equipment then the total container contents must be considered as having a PCB concentration of 500 ppm or greater for purposes of complying with the disposal requirements of this subpart. For purposes of this subparagraph, representative samples of mineral oil dielectric fluid are either samples taken in accordance with ASTM D 923–86 or ASTM D 923–89 or samples taken from a container that has been thoroughly mixed in a manner such that any PCBs in the container are uniformly distributed throughout the liquid in the container.

(iii) Unless otherwise specified in this part, any person conducting the chemical analysis of PCBs shall do so using gas chromatography. Any gas chromatographic method that is appropriate for the material being analyzed may be used, including EPA Method 608, ''Organochlorine Pesticides and

PCBs'' at 40 CFR part 136, Appendix A;'' EPA Method 8082, ''Polychlorinated Biphenyls (PCBs) by Capillary Column Gas Chromatography'' of SW-846, ''OSW Test Methods for Evaluating Solid Waste,'' which is available from NTIS; and ASTM Standard D-4059, ''Standard Test Method for Analysis of Polychlorinated Biphenyls in Insulating Liquids by Gas Chromatography,'' which is available from ASTM.

(2) Owners or users of waste oil may use the following procedures to determine the PCB concentration of waste oil:

(i) Waste oil from more than one source may be collected in a common container, provided that no other chemical substances or mixtures, such as non-waste oils, are added to the container.

(ii) For purposes of complying with the marking and disposal requirements, representative samples may be taken from either the common containers or the individual electrical equipment to determine the PCB concentration. *Except,* That if any PCBs at a concentration of 500 ppm or greater have been added to the container or equipment then the total container contents must be considered as having a PCB concentration of 500 ppm or greater for purposes of complying with the disposal requirements of this subpart. For purposes of this paragraph, representative samples of mineral oil dielectric fluid are either samples taken in accordance with ASTM D 923–86 or ASTM D 923–89 or samples taken from a container that has been thoroughly mixed in a manner such that any PCBs in the container are uniformly distributed throughout the liquid in the container.

(iii) Unless otherwise specified in this part, any person conducting the chemical analysis of PCBs shall do so using gas chromatography. Any gas chromatographic method that is appropriate for the material being analyzed may be used, including those indicated in paragraph (g)(1)(iii) of this section.

(h) Requirements for export and import of PCBs and PCB Items for disposal are found in subpart F of this part.

(i) *Approval authority for disposal methods.* (1) The officials designated in paragraph (e) of this section and §761.70(a) and (b) to receive requests for approval of PCB disposal activities are the primary approval authorities for these activities. Notwithstanding, EPA may, at its discretion, assign the authority to review and approve any aspect of a disposal system to the Office of Land and Emergency Management or to a Regional Administrator.

(2) Except for activity authorized under paragraph (j) of this section, research and development (R&D) for PCB disposal using a total of <500 pounds of PCB material (regardless of PCB concentration) will be reviewed and approved by the EPA Regional Administrator for the Region where the R&D will be conducted, and R&D for PCB disposal using 500 pounds or more of PCB material (regardless of PCB concentration) will be reviewed and approved by the EPA.

(j) *Self-implementing requirements for research and development (R&D) for PCB disposal.* (1) Any person may conduct R&D for PCB disposal without prior written approval from EPA if they meet the following conditions:

(i) File a notification and obtain an EPA identification number pursuant to subpart K of this part.

(ii) Notify in writing the EPA Regional Administrator, the State environmental protection agency, and local environmental protection agency, having jurisdiction where the R&D for PCB disposal activity will occur at least 30 days prior to the commencement of any R&D for PCB disposal activity conducted under this section. Each written notification shall include the EPA identification number of the site where the R&D for PCB disposal activities will be conducted, the quantity of PCBs to be treated, the type of R&D technology to be used, the general physical and chemical properties of material being treated, and an estimate of the duration of the PCB activity. The EPA Regional Administrator, the State environmental protection agency, and the local environmental protection agency may waive notification in writing prior to commencement of the research.

(iii) The amount of material containing PCBs treated annually by the facility during R&D for PCB disposal activities does not exceed 500 gallons or 70 cubic feet of liquid or non-liquid PCBs and does not exceed a maximum concentration of 10,000 ppm PCBs.

(iv) No more than 1 kilogram total of pure PCBs per year is disposed of in all R&D for PCB disposal activities at a facility.

(v) Each R&D for PCB disposal activity under this section lasts no more than 1 calendar year.

(vi) Store all PCB wastes (treated and untreated PCB materials, testing samples, spent laboratory samples, residuals, untreated samples, contaminated media or instrumentation, clothing, etc.) in compliance with § 761.65(b) and dispose of them according to the undiluted PCB concentration prior to treatment. However, PCB materials not treated in the R&D for PCB disposal activity may be returned either to the physical location where the samples were collected or a location where other regulated PCBs from the physical location where the samples were collected are being stored for disposal.

(vii) Use manifests pursuant to subpart K of this part for all R&D PCB wastes being transported from the R&D facility to an approved PCB storage or disposal facility. However, §§ 761.207 through 761.219 do not apply if the residuals or treated samples are returned either to the physical location where the samples were collected or a location where other regulated PCBs from the physical location where the samples were collected are being stored for disposal.

(viii) Package and ship all PCB wastes pursuant to DOT requirements under 49 CFR parts 171 through 180.

(ix) Comply with the recordkeeping requirements of § 761.180.

(2) Do not exceed material limitations set out in paragraphs (j)(1) (iii) and (iv) of this section and the time limitation set out in paragraph (j)(1)(v) of this section without prior written approval from EPA. Requests for approval to exceed the material limitations for PCBs in R&D for PCB disposal activities as specified in this section must be submitted in writing to the EPA Regional Administrator for the Region in which the facility conducting R&D for PCB disposal activities is located. Each request shall specify the quantity or concentration requested or additional time needed for disposal and include a justification for each increase. For extensions to the duration of the R&D for PCB disposal activity, the request shall also include a report on the accomplishments and progress of the previously authorized R&D for PCB disposal activity for which the extension is sought. The EPA Regional Administrator may grant a waiver in writing for an increase in the volume of PCB material, the maximum concentration of PCBs, the total amount of pure PCBs, or the duration of the R&D activity. Approvals will state all requirements applicable to the R&D for PCB disposal activity.

(3) The EPA Regional Administrator for the Region in which an R&D for PCB disposal activity is conducted may determine, at any time, that an R&D PCB disposal approval is required under paragraphs (e) and (i)(2) of this section or § 761.70(d) to ensure that any R&D for PCB disposal activity does not present an unreasonable risk of injury to health or the environment.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 761.60, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 761.61 PCB remediation waste.

This section provides cleanup and disposal options for PCB remediation waste. Any person cleaning up and disposing of PCBs managed under this section shall do so based on the concentration at which the PCBs are found. This section does not prohibit any person from implementing temporary emergency measures to prevent, treat, or contain further releases or mitigate migration to the environment of PCBs or PCB remediation waste.

(a) *Self-implementing on-site cleanup and disposal of PCB remediation waste.* EPA designed the self-implementing procedure for a general, moderately-

sized site where there should be low residual environmental impact from remedial activities. The procedure may be less practical for larger or environmentally diverse sites. For these other sites, the self-implementing procedure still applies, but an EPA Regional Administrator may authorize more practical procedures through paragraph (c) of this section. Any person may conduct self-implementing cleanup and disposal of PCB remediation waste in accordance with the following requirements without prior written approval from EPA.

(1) *Applicability.* (i) The self-implementing procedures may not be used to clean up:

(A) Surface or ground waters.

(B) Sediments in marine and freshwater ecosystems.

(C) Sewers or sewage treatment systems.

(D) Any private or public drinking water sources or distribution systems.

(E) Grazing lands.

(F) Vegetable gardens.

(ii) The self-implementing cleanup provisions shall not be binding upon cleanups conducted under other authorities, including but not limited to, actions conducted under section 104 or section 106 of CERCLA, or section 3004(u) and (v) or section 3008(h) of RCRA.

(2) *Site characterization.* Any person conducting self-implementing cleanup of PCB remediation waste must characterize the site adequately to be able to provide the information required by paragraph (a)(3) of this section. Subpart N of this part provides a method for collecting new site characterization data or for assessing the sufficiency of existing site characterization data.

(3) *Notification and certification.* (i) At least 30 days prior to the date that the cleanup of a site begins, the person in charge of the cleanup or the owner of the property where the PCB remediation waste is located shall notify, in writing, the EPA Regional Administrator, the Director of the State or Tribal environmental protection agency, and the Director of the county or local environmental protection agency where the cleanup will be conducted. The notice shall include:

(A) The nature of the contamination, including kinds of materials contaminated.

(B) A summary of the procedures used to sample contaminated and adjacent areas and a table or cleanup site map showing PCB concentrations measured in all pre-cleanup characterization samples. The summary must include sample collection and analysis dates. The EPA Regional Administrator may require more detailed information including, but not limited to, additional characterization sampling or all sample identification numbers from all previous characterization activities at the cleanup site.

(C) The location and extent of the identified contaminated area, including topographic maps with sample collection sites cross referenced to the sample identification numbers in the data summary from paragraph (a)(3)(i)(B) of this section.

(D) A cleanup plan for the site, including schedule, disposal technology, and approach. This plan should contain options and contingencies to be used if unanticipated higher concentrations or wider distributions of PCB remediation waste are found or other obstacles force changes in the cleanup approach.

(E) A written certification, signed by the owner of the property where the cleanup site is located and the party conducting the cleanup, that all sampling plans, sample collection procedures, sample preparation procedures, extraction procedures, and instrumental/chemical analysis procedures used to assess or characterize the PCB contamination at the cleanup site, are on file at the location designated in the certificate, and are available for EPA inspection. Persons using alternate methods for chemical extraction and chemical analysis for site characterization must include in the certificate a statement that such a method will be used and that a comparison study which meets or exceeds the requirements of subpart Q of this part, and for which records are on file, has been completed prior to verification sampling.

(ii) Within 30 calendar days of receiving the notification, the EPA Regional Administrator will respond in writing approving of the self-implementing

cleanup, disapproving of the self-implementing cleanup, or requiring additional information. If the EPA Regional Administrator does not respond within 30 calendar days of receiving the notice, the person submitting the notification may assume that it is complete and acceptable and proceed with the cleanup according to the information the person provided to the EPA Regional Administrator. Once cleanup is underway, the person conducting the cleanup must provide any proposed changes from the notification to the EPA Regional Administrator in writing no less than 14 calendar days prior to the proposed implementation of the change. The EPA Regional Administrator will determine in his or her discretion whether to accept the change, and will respond to the change notification verbally within 7 calendar days and in writing within 14 calendar days of receiving it. If the EPA Regional Administrator does not respond verbally within 7 calendar days and in writing within 14 calendar days of receiving the change notice, the person who submitted it may deem it complete and acceptable and proceed with the cleanup according to the information in the change notice provided to the EPA Regional Administrator.

(iii) Any person conducting a cleanup activity may obtain a waiver of the 30-day notification requirement, if they receive a separate waiver, in writing, from each of the agencies they are required to notify under this section. The person must retain the original written waiver as required in paragraph (a)(9) of this section.

(4) *Cleanup levels.* For purposes of cleaning, decontaminating, or removing PCB remediation waste under this section, there are four general waste categories: bulk PCB remediation waste, non-porous surfaces, porous surfaces, and liquids. Cleanup levels are based on the kind of material and the potential exposure to PCBs left after cleanup is completed.

(i) *Bulk PCB remediation waste.* Bulk PCB remediation waste includes, but is not limited to, the following non-liquid PCB remediation waste: soil, sediments, dredged materials, muds, PCB sewage sludge, and industrial sludge.

(A) *High occupancy areas.* The cleanup level for bulk PCB remediation waste in high occupancy areas is ≤1 ppm without further conditions. High occupancy areas where bulk PCB remediation waste remains at concentrations >1 ppm and ≤10 ppm shall be covered with a cap meeting the requirements of paragraphs (a)(7) and (a)(8) of this section.

(B) *Low occupancy areas.* (*1*) The cleanup level for bulk PCB remediation waste in low occupancy areas is ≤25 ppm unless otherwise specified in this paragraph.

(*2*) Bulk PCB remediation wastes may remain at a cleanup site at concentrations >25 ppm and ≤50 ppm if the site is secured by a fence and marked with a sign including the M_L mark.

(*3*) Bulk PCB remediation wastes may remain at a cleanup site at concentrations >25 ppm and ≤100 ppm if the site is covered with a cap meeting the requirements of paragraphs (a)(7) and (a)(8) of this section.

(ii) *Non-porous surfaces.* In high occupancy areas, the surface PCB cleanup standard is ≤10 μg/100 cm^2 of surface area. In low occupancy areas, the surface cleanup standard is <100 μg/100 cm^2 of surface area. Select sampling locations in accordance with subpart P of this part or a sampling plan approved under paragraph (c) of this section.

(iii) *Porous surfaces.* In both high and low occupancy areas, any person disposing of porous surfaces must do so based on the levels in paragraph (a)(4)(i) of this section. Porous surfaces may be cleaned up for use in accordance with § 761.79(b)(4) or § 761.30(p).

(iv) *Liquids.* In both high and low occupancy areas, cleanup levels are the concentrations specified in § 761.79(b)(1) and (b)(2).

(v) *Change in the land use for a cleanup site.* Where there is an actual or proposed change in use of an area cleaned up to the levels of a low occupancy area, and the exposure of people or animal life in or at that area could reasonably be expected to increase, resulting in a change in status from a low occupancy area to a high occupancy area, the owner of the area shall clean up the

area in accordance with the high occupancy area cleanup levels in paragraphs (a)(4)(i) through (a)(4)(iv) of this section.

(vi) The EPA Regional Administrator, as part of his or her response to a notification submitted in accordance with §761.61(a)(3) of this part, may require cleanup of the site, or portions of it, to more stringent cleanup levels than are otherwise required in this section, based on the proximity to areas such as residential dwellings, hospitals, schools, nursing homes, playgrounds, parks, day care centers, endangered species habitats, estuaries, wetlands, national parks, national wildlife refuges, commercial fisheries, and sport fisheries.

(5) *Site cleanup.* In addition to the options set out in this paragraph, PCB disposal technologies approved under §§761.60 and 761.70 are acceptable for on-site self-implementing PCB remediation waste disposal within the confines of the operating conditions of the respective approvals.

(i) *Bulk PCB remediation waste.* Any person cleaning up bulk PCB remediation waste shall do so to the levels in paragraph (a)(4)(i) of this section.

(A) Any person cleaning up bulk PCB remediation waste on-site using a soil washing process may do so without EPA approval, subject to all of the following:

(*1*) A non-chlorinated solvent is used.

(*2*) The process occurs at ambient temperature.

(*3*) The process is not exothermic.

(*4*) The process uses no external heat.

(*5*) The process has secondary containment to prevent any solvent from being released to the underlying or surrounding soils or surface waters.

(*6*) Solvent disposal, recovery, and/or reuse is in accordance with relevant provisions of approvals issued according to paragraphs (b)(1) or (c) of this section or applicable paragraphs of §761.79.

(B) Bulk PCB remediation waste may be sent off-site for decontamination or disposal in accordance with this paragraph, provided the waste is either dewatered on-site or transported off-site in containers meeting the requirements of the DOT Hazardous Materials Regulations (HMR) at 49 CFR parts 171 through 180.

(*1*) Removed water shall be disposed of according to paragraph (b)(1) of this section.

(*2*) Any person disposing off-site of dewatered bulk PCB remediation waste shall do so as follows:

(*i*) Unless sampled and analyzed for disposal according to the procedures set out in §§761.283, 761.286, and 761.292, the bulk PCB remediation waste shall be assumed to contain ≥50 ppm PCBs.

(*ii*) Bulk PCB remediation wastes with a PCB concentration of <50 ppm shall be disposed of in accordance with paragraph (a)(5)(v)(A) of this section.

(*iii*) Bulk PCB remediation wastes with a PCB concentration ≥50 ppm shall be disposed of in a hazardous waste landfill permitted by EPA under section 3004 of RCRA, or by a State authorized under section 3006 of RCRA, or a PCB disposal facility approved under this part.

(*iv*) The generator must provide written notice, including the quantity to be shipped and highest concentration of PCBs (using extraction EPA Method 3500B/3540C or Method 3500B/3550B followed by chemical analysis using EPA Method 8082 in SW-846 or methods validated under subpart Q of this part) at least 15 days before the first shipment of bulk PCB remediation waste from each cleanup site by the generator, to each off-site facility where the waste is destined for an area not subject to a TSCA PCB Disposal Approval.

(*3*) Any person may decontaminate bulk PCB remediation waste in accordance with §761.79 and return the waste to the cleanup site for disposal as long as the cleanup standards of paragraph (a)(4) of this section are met.

(ii) *Non-porous surfaces.* PCB remediation waste non-porous surfaces shall be cleaned on-site or off-site for disposal on-site, disposal off-site, or use, as follows:

(A) For on-site disposal, non-porous surfaces shall be cleaned on-site or off-site to the levels in paragraph (a)(4)(ii) of this section using:

(*1*) Procedures approved under §761.79.

(*2*) Technologies approved under §761.60(e).

(*3*) Procedures or technologies approved under paragraph (c) of this section.

(B) For off-site disposal, non-porous surfaces:

(*1*) Having surface concentrations <100 μg/100 cm^2 shall be disposed of in accordance with paragraph (a)(5)(i)(B)(*2*)(*ii*) of this section. Metal surfaces may be thermally decontaminated in accordance with § 761.79(c)(6)(i).

(*2*) Having surface concentrations ≥100 μg/100 cm^2 shall be disposed of in accordance with paragraph (a)(5)(i)(B)(*2*)(*iii*) of this section. Metal surfaces may be thermally decontaminated in accordance with § 761.79(c)(6)(ii).

(C) For use, non-porous surfaces shall be decontaminated on-site or off-site to the standards specified in § 761.79(b)(3) or in accordance with § 761.79(c).

(iii) *Porous surfaces.* Porous surfaces shall be disposed on-site or off-site as bulk PCB remediation waste according to paragraph (a)(5)(i) of this section or decontaminated for use according to § 761.79(b)(4), as applicable.

(iv) *Liquids.* Any person disposing of liquid PCB remediation waste shall either:

(A) Decontaminate the waste to the levels specified in § 761.79(b)(1) or (b)(2).

(B) Dispose of the waste in accordance with paragraph (b) of this section or an approval issued under paragraph (c) of this section.

(v) *Cleanup wastes.* Any person generating the following wastes during and from the cleanup of PCB remediation waste shall dispose of or reuse them using one of the following methods:

(A) Non-liquid cleaning materials and personal protective equipment waste at any concentration, including non-porous surfaces and other non-liquid materials such as rags, gloves, booties, other disposable personal protective equipment, and similar materials resulting from cleanup activities shall be either decontaminated in accordance with § 761.79(b) or (c), or disposed of in one of the following facilities, without regard to the requirements of subparts J and K of this part:

(*1*) A facility permitted, licensed, or registered by a State to manage municipal solid waste subject to part 258 of this chapter.

(*2*) A facility permitted, licensed, or registered by a State to manage non-municipal non-hazardous waste subject to §§ 257.5 through 257.30 of this chapter, as applicable.

(*3*) A hazardous waste landfill permitted by EPA under section 3004 of RCRA, or by a State authorized under section 3006 of RCRA.

(*4*) A PCB disposal facility approved under this part.

(B) Cleaning solvents, abrasives, and equipment may be reused after decontamination in accordance with § 761.79.

(6) *Cleanup verification*—(i) *Sampling and analysis.* Any person collecting and analyzing samples to verify the cleanup and on-site disposal of bulk PCB remediation wastes and porous surfaces must do so in accordance with subpart O of this part. Any person collecting and analyzing samples from non-porous surfaces must do so in accordance with subpart P of this part. Any person collecting and analyzing samples from liquids must do so in accordance with § 761.269. Any person conducting interim sampling during PCB remediation waste cleanup to determine when to sample to verify that cleanup is complete, may use PCB field screening tests.

(ii) *Verification.* (A) Where sample analysis results in a measurement of PCBs less than or equal to the levels specified in paragraph (a)(4) of this section, self-implementing cleanup is complete.

(B) Where sample analysis results in a measurement of PCBs greater than the levels specified in paragraph (a)(4) of this section, self-implementing cleanup of the sampled PCB remediation waste is not complete. The owner or operator of the site must either dispose of the sampled PCB remediation waste, or reclean the waste represented by the sample and reinitiate sampling and analysis in accordance with paragraph (a)(6)(i) of this section.

(7) *Cap requirements.* A cap means, when referring to on-site cleanup and disposal of PCB remediation waste, a uniform placement of concrete, asphalt, or similar material of minimum thickness spread over the area where remediation waste was removed or left

in place in order to prevent or minimize human exposure, infiltration of water, and erosion. Any person designing and constructing a cap must do so in accordance with §264.310(a) of this chapter, and ensure that it complies with the permeability, sieve, liquid limit, and plasticity index parameters in §761.75(b)(1)(ii) through (b)(1)(v). A cap of compacted soil shall have a minimum thickness of 25 cm (10 inches). A concrete or asphalt cap shall have a minimum thickness of 15 cm (6 inches). A cap must be of sufficient strength to maintain its effectiveness and integrity during the use of the cap surface which is exposed to the environment. A cap shall not be contaminated at a level ≥1 ppm PCB per Aroclor™ (or equivalent) or per congener. Repairs shall begin within 72 hours of discovery for any breaches which would impair the integrity of the cap.

(8) *Deed restrictions for caps, fences and low occupancy areas.* When a cleanup activity conducted under this section includes the use of a fence or a cap, the owner of the site must maintain the fence or cap, in perpetuity. In addition, whenever a cap, or the procedures and requirements for a low occupancy area, is used, the owner of the site must meet the following conditions:

(i) Within 60 days of completion of a cleanup activity under this section, the owner of the property shall:

(A) Record, in accordance with State law, a notation on the deed to the property, or on some other instrument which is normally examined during a title search, that will in perpetuity notify any potential purchaser of the property:

(*1*) That the land has been used for PCB remediation waste disposal and is restricted to use as a low occupancy area as defined in §761.3.

(*2*) Of the existence of the fence or cap and the requirement to maintain the fence or cap.

(*3*) The applicable cleanup levels left at the site, inside the fence, and/or under the cap.

(B) Submit a certification, signed by the owner, that he/she has recorded the notation specified in paragraph (a)(8)(i)(A) of this section to the EPA Regional Administrator.

(ii) The owner of a site being cleaned up under this section may remove a fence or cap after conducting additional cleanup activities and achieving cleanup levels, specified in paragraph (a)(4) of this section, which do not require a cap or fence. The owner may remove the notice on the deed no earlier than 30 days after achieving the cleanup levels specified in this section which do not require a fence or cap.

(9) *Recordkeeping.* For paragraphs (a)(3), (a)(4), and (a)(5) of this section, recordkeeping is required in accordance with §761.125(c)(5).

(b) *Performance-based disposal.* (1) Any person disposing of liquid PCB remediation waste shall do so according to §761.60(a) or (e), or decontaminate it in accordance with §761.79.

(2) Any person disposing of non-liquid PCB remediation waste shall do so by one of the following methods:

(i) Dispose of it in a high temperature incinerator approved under §761.70(b), an alternate disposal method approved under §761.60(e), a chemical waste landfill approved under §761.75, or in a facility with a coordinated approval issued under §761.77.

(ii) Decontaminate it in accordance with §761.79.

(3) Any person may manage or dispose of material containing <50 ppm PCBs that has been dredged or excavated from waters of the United States:

(i) In accordance with a permit that has been issued under section 404 of the Clean Water Act, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers at 33 CFR part 320.

(ii) In accordance with a permit issued by the U.S. Army Corps of Engineers under section 103 of the Marine Protection, Research, and Sanctuaries Act, or the equivalent of such a permit as provided for in regulations of the U.S. Army Corps of Engineers at 33 CFR part 320.

(c) *Risk-based disposal approval.* (1) Any person wishing to sample, cleanup, or dispose of PCB remediation waste in a manner other than prescribed in paragraphs (a) or (b) of this section, or store PCB remediation waste in a manner other than prescribed in §761.65, must apply in writing to the Regional Administrator in the Region where the

sampling, cleanup, disposal, or storage site is located, for sampling, cleanup, disposal, or storage occurring in a single EPA Region; or to the Director, Office of Resource Conservation and Recovery, for sampling, cleanup, disposal, or storage occurring in more than one EPA Region. Each application must include information described in the notification required by paragraph (a)(3) of this section. EPA may request other information that it believes necessary to evaluate the application. No person may conduct cleanup activities under this paragraph prior to obtaining written approval by EPA.

(2) EPA will issue a written decision on each application for a risk-based method for PCB remediation wastes. EPA will approve such an application if it finds that the method will not pose an unreasonable risk of injury to health or the environment.

[63 FR 35448, June 29, 1998, as amended at 64 FR 33761, June 24, 1999; 72 FR 57239, Oct. 9, 2007; 74 FR 30232, June 25, 2009]

§ 761.62 Disposal of PCB bulk product waste.

PCB bulk product waste shall be disposed of in accordance with paragraph (a), (b), or (c) of this section. Under some of these provisions, it may not be necessary to determine the PCB concentration or leaching characteristics of the PCB bulk product waste. When it is necessary to analyze the waste to make either of these determinations, use the applicable procedures in subpart R of this part to sample the waste for analysis, unless EPA approves another sampling plan under paragraph (c) of this section.

(a) *Performance-based disposal.* Any person disposing of PCB bulk product waste may do so as follows:

(1) In an incinerator approved under § 761.70.

(2) In a chemical waste landfill approved under § 761.75.

(3) In a hazardous waste landfill permitted by EPA under section 3004 of RCRA, or by a State authorized under section 3006 of RCRA.

(4) Under an alternate disposal approval under § 761.60(e).

(5) In accordance with the decontamination provisions of § 761.79.

(6) For metal surfaces in contact with PCBs, in accordance with the thermal decontamination provisions of § 761.79(c)(6).

(7) In accordance with a TSCA PCB Coordinated Approval issued under § 761.77.

(b) *Disposal in solid waste landfills.* (1) Any person may dispose of the following PCB bulk product waste in a facility permitted, licensed, or registered by a State as a municipal or non-municipal non-hazardous waste landfill:

(i) Plastics (such as plastic insulation from wire or cable; radio, television and computer casings; vehicle parts; or furniture laminates); preformed or molded rubber parts and components; applied dried paints, varnishes, waxes or other similar coatings or sealants; caulking; Galbestos; non-liquid building demolition debris; or non-liquid PCB bulk product waste from the shredding of automobiles or household appliances from which PCB small capacitors have been removed (shredder fluff).

(ii) Other PCB bulk product waste, sampled in accordance with the protocols set out in subpart R of this part, that leaches PCBs at <10 μg/L of water measured using a procedure used to simulate leachate generation.

(2) Any person may dispose of PCB bulk product waste other than those materials meeting the conditions of paragraph (b)(1) of this section, (e.g., paper or felt gaskets contaminated by liquid PCBs in a facility that is permitted, licensed, or registered by a State to manage municipal solid waste subject to part 258 of this chapter or non-municipal non-hazardous waste subject to §§ 257.5 through 257.30 of this chapter, as applicable, if:

(i) The PCB bulk product waste is segregated from organic liquids disposed of in the landfill unit.

(ii) Leachate is collected from the landfill unit and monitored for PCBs.

(3) Any release of PCBs (including but not limited to leachate) from the landfill unit shall be cleaned up in accordance with § 761.61.

(4)(i) Any person disposing off-site of PCB bulk product waste regulated under paragraph (b)(1) of this section at a waste management facility not having a commercial PCB storage or

disposal approval must provide written notice to the facility a minimum of 15 days in advance of the first shipment from the same disposal waste stream. The notice shall state that the PCB bulk product waste may include components containing PCBs at ≥50 ppm based on analysis of the waste in the shipment or application of a general knowledge of the waste stream (or similar material) which is known to contain PCBs at those levels, and that the PCB bulk product waste is known or presumed to leach <10 μg/L PCBs.

(ii) Any person disposing off-site of PCB bulk product waste regulated under paragraph (b)(2) of this section at a waste management facility not having a commercial PCB storage or disposal approval must provide written notice to the facility a minimum of 15 days in advance of the first shipment from the same disposal waste stream and with each shipment thereafter. The notice shall state that the PCB bulk product waste may include components containing PCBs at ≥50 ppm based on analysis of the waste in the shipment or application of a general knowledge of the waste stream (or similar material) which is known to contain PCBs at those levels, and that the PCB bulk product waste is known or presumed to leach ≥10 μg/L PCBs.

(5) Any person disposing of PCB bulk product waste must maintain a written record of all sampling and analysis of PCBs or notifications made under this paragraph for 3 years from the date of the waste's generation. The records must be made available to EPA upon request.

(6) Requirements in subparts C, J, and K of this part do not apply to waste disposed of under paragraph (b) of this section.

(c) *Risk-based disposal approval.* (1) Any person wishing to sample or dispose of PCB bulk product waste in a manner other than prescribed in paragraphs (a) or (b) of this section, or store PCB bulk product waste in a manner other than prescribed in §761.65, must apply in writing to the Regional Administrator in the Region where the sampling, disposal, or storage site is located, for sampling, disposal, or storage occurring in a single EPA Region; or to the Director, Office of Resource Conservation and Recovery, for sampling, disposal, or storage occurring in more than one EPA Region. Each application must contain information indicating that, based on technical, environmental, or waste-specific characteristics or considerations, the proposed sampling, disposal, or storage methods or locations will not pose an unreasonable risk or injury to health or the environment. EPA may request other information that it believes necessary to evaluate the application. No person may conduct sampling, disposal, or storage activities under this paragraph prior to obtaining written approval by EPA.

(2) EPA will issue a written decision on each application for a risk-based sampling, disposal, or storage method for PCB bulk product wastes. EPA will approve such an application if it finds that the method will not pose an unreasonable risk of injury to health or the environment.

(d) *Disposal as daily landfill cover or roadbed.* Bulk product waste described in paragraph (b)(1) of this section may be disposed of:

(1) As daily landfill cover as long as the daily cover remains in the landfill and is not released or dispersed by wind or other action; or

(2) Under asphalt as part of a road bed.

[63 FR 35451, June 29, 1998, as amended at 64 FR 33761, June 24, 1999; 72 FR 57239, Oct. 9, 2007; 74 FR 30232, June 25, 2009]

§761.63 PCB household waste storage and disposal.

PCB household waste, as defined at §761.3, managed in a facility permitted, licensed, or registered by a State to manage municipal or industrial solid waste, or in a facility with an approval to dispose of PCB bulk product waste under §761.62(c), is not subject to any other requirements of part 761 of this chapter. PCB household waste stored in a unit regulated for storage of PCB waste must not be commingled with PCB waste.

[63 FR 35452, June 29, 1998]

§ 761.64 Disposal of wastes generated as a result of research and development activities authorized under § 761.30(j) and chemical analysis of PCBs.

This section provides disposal requirements for wastes generated during and as a result of research and development authorized under § 761.30(j). This section also provides disposal requirements for wastes generated during the chemical analysis of samples containing PCBs under part 761, including §§ 761.30, 761.60, 761.61, 761.62, and 761.79. For determining the presence of PCBs in samples, chemical analysis includes: sample preparation, sample extraction, extract cleanup, extract concentration, addition of PCB standards, and instrumental analysis.

(a) Portions of samples of a size designated in a chemical extraction and analysis method for PCBs and extracted for purposes of determining the presence of PCBs or concentration of PCBs are unregulated for PCB disposal under this part.

(b) All other wastes generated during these activities are regulated for disposal based on their concentration at the time of disposal as follows:

(1) Liquid wastes, including rinse solvents, must be disposed of according to § 761.61(a)(5)(iv).

(2) Non-liquid wastes must be disposed of in the same manner as non-liquid cleaning materials and personal protective equipment waste according to § 761.61(a)(5)(v)(A).

[63 FR 35452, June 29, 1998]

§ 761.65 Storage for disposal.

This section applies to the storage for disposal of PCBs at concentrations of 50 ppm or greater and PCB Items with PCB concentrations of 50 ppm or greater.

(a)(1) *Storage limitations.* Any PCB waste shall be disposed of as required by subpart D of this part within 1-year from the date it was determined to be PCB waste and the decision was made to dispose of it. This date is the date of removal from service for disposal and the point at which the 1-year time frame for disposal begins. PCB/radioactive waste removed from service for disposal is exempt from the 1-year time limit provided that the provisions at paragraphs (a)(2)(ii) and (a)(2)(iii) of this section are followed and the waste is managed in accordance with all other applicable Federal, State, and local laws and regulations for the management of radioactive material.

(2) *One-year extension.* Any person storing PCB waste that is subject to the 1-year time limit for storage and disposal in paragraph (a)(1) of this section may provide written notification to the EPA Regional Administrator for the Region in which the PCB waste is stored that their continuing attempts to dispose of or secure disposal for their waste within the 1-year time limit have been unsuccessful. Upon receipt of the notice by the EPA Regional Administrator, the time for disposal is automatically extended for 1 additional year (2 years total) if the following conditions are met:

(i) The notification is received by the EPA Regional Administrator at least 30 days before the initial 1-year time limit expires and the notice identifies the storer, the types, volumes, and locations of the waste and the reasons for failure to meet the initial 1-year time limit.

(ii) A written record documenting all continuing attempts to secure disposal is maintained until the waste is disposed of.

(iii) The written record required by paragraph (a)(2)(ii) of this section is available for inspection or submission if requested by EPA.

(iv) Continuing attempts to secure disposal were initiated within 270 days after the time the waste was first subject to the 1-year time limit requirement, as specified in paragraph (a)(1) of this section. Failure to initiate and continue attempts to secure disposal throughout the total time the waste is in storage shall automatically disqualify the notifier from receiving an automatic extension under this section.

(3) *Additional extensions.* Upon written request, the EPA Regional Administrator for the Region in which the wastes are stored or the appropriate official at EPA Headquarters, may grant additional extensions beyond the 1-year extension authorized in paragraph (a)(2) of this section. At the time of the

request, the requestor must supply specific justification for the additional extension and indicate what measures the requestor is taking to secure disposal of the waste or indicate why disposal could not be conducted during the period of the prior extension. The EPA Regional Administrator or the appropriate official at EPA Headquarters may require, as a condition to granting any extension under this section, specific actions including, but not limited to, marking, inspection, recordkeeping, or financial assurance to ensure that the waste does not pose an unreasonable risk of injury to health or the environment.

(4) *Storage at an approved facility.* Increased time for storage may be granted as a condition of any TSCA PCB storage or disposal approval, by the EPA Regional Administrator for the Region in which the PCBs or PCB Items are to be stored or disposed of, or by the appropriate official at EPA Headquarters, if EPA determines that there is a demonstrated need or justification for additional time, that the owner or operator of the facility is pursuing relevant treatment or disposal options, and that no unreasonable risk of injury to health or the environment will result from the increased storage time. In making this determination, EPA will consider such factors as absence of any approved treatment technology and insufficient time to complete the treatment or destruction process. EPA may require as a condition of the approval that the owner or operator submit periodic progress reports.

(b) Except as provided in paragraphs (b)(2), (c)(1), (c)(7), (c)(9), and (c)(10) of this section, after July 1, 1978, owners or operators of any facilities used for the storage of PCBs and PCB Items designated for disposal shall comply with the following storage unit requirements:

(1) The facilities shall meet the following criteria:

(i) Adequate roof and walls to prevent rain water from reaching the stored PCBs and PCB Items;

(ii) An adequate floor that has continuous curbing with a minimum 6 inch high curb. The floor and curbing must provide a containment volume equal to at least two times the internal volume of the largest PCB Article or PCB Container or 25 percent of the total internal volume of all PCB Articles or PCB Containers stored there, whichever is greater. PCB/radioactive wastes are not required to be stored in an area with a minimum 6 inch high curbing. However, the floor and curbing must still provide a containment volume equal to at least two times the internal volume of the largest PCB Container or 25 percent of the total internal volume of all PCB Containers stored there, whichever is greater.

(iii) No drain valves, floor drains, expansion joints, sewer lines, or other openings that would permit liquids to flow from the curbed area;

(iv) Floors and curbing constructed of Portland cement, concrete, or a continuous, smooth, non-porous surface as defined at §761.3, which prevents or minimizes penetration of PCBs.

(v) Not located at a site that is below the 100-year flood water elevation.

(2) No person may store PCBs and PCB Items designated for disposal in a storage unit other than one approved pursuant to paragraph (d) of this section or meeting the design requirements of paragraph (b) of this section, unless the unit meets one of the following conditions:

(i) Is permitted by EPA under section 3004 of RCRA to manage hazardous waste in containers, and spills of PCBs are cleaned up in accordance with subpart G of this part.

(ii) Qualifies for interim status under section 3005 of RCRA to manage hazardous waste in containers, meets the requirements for containment at §264.175 of this chapter, and spills of PCBs are cleaned up in accordance with subpart G of this part.

(iii) Is permitted by a State authorized under section 3006 of RCRA to manage hazardous waste in containers, and spills of PCBs are cleaned up in accordance with subpart G of this part.

(iv) Is approved or otherwise regulated pursuant to a State PCB waste management program no less stringent in protection of health or the environment than the applicable TSCA requirements found in this part.

(v) Is subject to a TSCA Coordinated Approval, which includes provisions for

storage of PCBs, issued pursuant to § 761.77.

(vi) Has a TSCA PCB waste management approval, which includes provisions for storage, issued pursuant to § 761.61(c) or § 761.62(c).

(c)(1) The following PCB Items may be stored temporarily in an area that does not comply with the requirements of paragraph (b) of this section for up to thirty days from the date of their removal from service, provided that a notation is attached to the PCB Item or a PCB Container (containing the item) indicating the date the item was removed from service:

(i) Non-leaking PCB Articles and PCB Equipment;

(ii) Leaking PCB Articles and PCB Equipment if the PCB Items are placed in a non-leaking PCB Container that contains sufficient sorbent materials to absorb any liquid PCBs remaining in the PCB Items;

(iii) PCB Containers containing non-liquid PCBs such as contaminated soil, rags, and debris; and

(iv) PCB containers containing liquid PCBs at concentrations of ≥50 ppm, provided a Spill Prevention, Control and Countermeasure Plan has been prepared for the temporary storage area in accordance with part 112 of this chapter and the liquid PCB waste is in packaging authorized in the DOT Hazardous Materials Regulations at 49 CFR parts 171 through 180 or stationary bulk storage tanks (including rolling stock such as, but not limited to, tanker trucks, as specified by DOT).

(2) Non-leaking and structurally undamaged PCB Large High Voltage Capacitors and PCB-Contaminated Electrical Equipment that have not been drained of free flowing dielectric fluid may be stored on pallets next to a storage facility that meets the requirements of paragraph (b) of this section. PCB-Contaminated Electrical Equipment that has been drained of free flowing dielectric fluid is not subject to the storage provisions of § 761.65. Storage under this subparagraph will be permitted only when the storage facility has immediately available unfilled storage space equal to 10 percent of the volume of capacitors and equipment stored outside the facility. The capacitors and equipment temporarily stored outside the facility shall be checked for leaks weekly.

(3) Any storage area subject to the requirements of paragraph (b) or paragraph (c)(1) of this section shall be marked as required in subpart C § 761.40(a)(10).

(4) No item of movable equipment that is used for handling PCBs and PCB Items in the storage units and that comes in direct contact with PCBs shall be removed from the storage unit area unless it has been decontaminated as specified in § 761.79.

(5) All PCB Items in storage shall be checked for leaks at least once every 30 days. Any leaking PCB Items and their contents shall be transferred immediately to properly marked non-leaking containers. Any spilled or leaked materials shall be immediately cleaned up and the materials and residues containing PCBs shall be disposed of in accordance with § 761.61. Records of inspections, maintenance, cleanup and disposal must be maintained in accordance with § 761.180(a) and (b).

(6) Except as provided in paragraphs (c)(6)(i) and (c)(6)(ii) of this section, any container used for the storage of liquid or non-liquid PCB waste shall be in accordance with the requirements set forth in the DOT Hazardous Materials Regulations (HMR) at 49 CFR parts 171 through 180. PCB waste not subject to the HMR (i.e., PCB wastes at concentrations of <20 ppm or <1 pound of PCBs regardless of concentration) must be packaged in accordance with Packaging Group III, unless other hazards associated with the PCB waste cause it to require packaging in accordance with Packaging Groups I or II. For purposes of describing PCB waste not subject to DOT's HMR on a manifest, one may use the term ''Non-DOT Regulated PCBs.''

(i) Containers other than those meeting HMR performance standards may be used for storage of PCB/radioactive waste provided the following requirements are met:

(A) Containers used for storage of liquid PCB/radioactive wastes must be non-leaking.

(B) Containers used for storage of non-liquid PCB/ radioactive wastes must be designed to prevent the build-up of liquids if such containers are

stored in an area meeting the containment requirements of paragraph (b)(1)(ii) of this section, as well as all other applicable State or Federal regulations or requirements for control of radioactive materials.

(C) Containers used to store both liquid and non-liquid PCB/radioactive wastes must meet all regulations and requirements pertaining to nuclear criticality safety. Acceptable container materials currently include polyethylene and stainless steel provided that the container material is chemically compatible with the wastes being stored. Other containers may be used to store both liquid and non-liquid PCB/radioactive wastes if the users are able to demonstrate, to the appropriate Regional Administrator and other appropriate regulatory authorities (i.e., Nuclear Regulatory Commission, Department of Energy or the Department of Transportation), that the use of such containers is protective of health and the environment as well as public health and safety.

(ii) The following DOT specification containers that conform to the requirements of 49 CFR, chapter I, subchapter C in effect on September 30, 1991, may be used for storage and transportation activities that are not subject to DOT regulation, and may be used on a transitional basis as permitted at 49 CFR 171.14. For liquid PCBs: Specification 5 container without removable head, Specification 5B container without removable head, Specification 6D overpack with Specification 2S or 2SL polyethylene containers, or Specification 17E container. For non-liquid PCBs: Specification 5 container, Specification 5B container, or Specification 17C container.

(7) Stationary storage containers for liquid PCBs can be larger than the containers specified in paragraph (c)(6) of this section provided that:

(i) The containers are designed, constructed, and operated in compliance with Occupational Safety and Health Standards, 29 CFR 1910.106, *Flammable and combustible liquids*. Before using these containers for storing PCBs, the design of the containers must be reviewed to determine the effect on the structural safety of the containers that will result from placing liquids with the specific gravity of PCBs into the containers (see 29 CFR 1910.106(b)(1)(i)(*f*)).

(ii) The owners or operators of any facility using containers described in paragraph (c)(7)(i) of this section, shall prepare and implement a Spill Prevention Control and Countermeasure (SPCC) Plan as described in part 112 of this title. In complying with 40 CFR part 112, the owner or operator shall read ''oil(s)'' as ''PCB(s)'' whenever it appears. The exemptions for storage capacity, 40 CFR 112.1(d)(2), and the amendment of SPCC plans by the Regional Administrator, 40 CFR 112.4, shall not apply unless some fraction of the liquids stored in the container are oils as defined by section 311 of the Clean Water Act.

(8) PCB Items shall be dated on the item when they are removed from service for disposal. The storage shall be managed so that the PCB Items can be located by this date. Storage containers provided in paragraph (c)(7) of this section, shall have a record that includes for each batch of PCBs the quantity of the batch and date the batch was added to the container. The record shall also include the date, quantity, and disposition of any batch of PCBs removed from the container.

(9) Bulk PCB remediation waste or PCB bulk product waste may be stored at the clean-up site or site of generation for 180 days subject to the following conditions:

(i) The waste is placed in a pile designed and operated to control dispersal of the waste by wind, where necessary, by means other than wetting.

(ii) The waste must not generate leachate through decomposition or other reactions.

(iii) The storage site must have:

(A) A liner that is designed, constructed, and installed to prevent any migration of wastes off or through the liner into the adjacent subsurface soil, ground water or surface water at any time during the active life (including the closure period) of the storage site. The liner may be constructed of materials that may allow waste to migrate into the liner. The liner must be:

(*1*) Constructed of materials that have appropriate chemical properties and sufficient strength and thickness

to prevent failure due to pressure gradients (including static head and external hydrogeologic forces), physical contact with the waste or leachate to which they are exposed, climatic conditions, the stress of installation, and the stress of daily operation.

(*2*) Placed upon a foundation or base capable of providing support to the liner and resistance to pressure gradients above and below the liner to prevent failure of the liner due to settlement, compression, or uplift.

(*3*) Installed to cover all surrounding earth likely to be in contact with the waste.

(B) A cover that meets the requirements of paragraph (c)(9)(iii)(A) of this section, is installed to cover all of the stored waste likely to be contacted with precipitation, and is secured so as not to be functionally disabled by winds expected under normal seasonal meteorological conditions at the storage site.

(C) A run-on control system designed, constructed, operated, and maintained such that:

(*1*) It prevents flow onto the stored waste during peak discharge from at least a 25-year storm.

(*2*) It collects and controls at least the water volume resulting from a 24-hour, 25-year storm. Collection and holding facilities (e.g., tanks or basins) must be emptied or otherwise managed expeditiously after storms to maintain design capacity of the system.

(iv) The provisions of this paragraph may be modified under § 761.61(c).

(10) Owners or operators of storage facilities shall establish and maintain records as provided in § 761.180.

(d) *Approval of commercial storers of PCB waste.* (1) All commercial storers of PCB waste shall have interim approval to operate commercial facilities for the storage of PCB waste until August 2, 1990. Commercial storers of PCB waste are prohibited from storing any PCB waste at their facilities after August 2, 1990 unless they have submitted by August 2, 1990 a complete application for a final storage approval under paragraph (d)(2) of this section. The period of interim approval shall continue until EPA makes a final decision on the storage application at which time such interim approval shall terminate.

(2) The Regional Administrator for the region in which the storage facility is located (or the appropriate official at EPA Headquarters, if the commercial storage area is ancillary to a disposal facility for which an official at EPA Headquarters has approval authority)shall grant written, final approval to engage in the commercial storage of PCB waste upon a determination that the criteria in paragraph (d)(2)(i) through (d)(2)(vii) of this section have been met by the applicant:

(i) The applicant, its principals, and its key employees responsible for the establishment or operation of the commercial storage facility are qualified to engage in the business of commercial storage of PCB waste.

(ii) The facility possesses the capacity to handle the quantity of PCB waste which the owner or operator of the facility has estimated will be the maximum quantity of PCB waste that will be handled at any one time at the facility.

(iii) The owner or operator of the unit has certified compliance with the storage facility standards in paragraphs (b) and (c)(7) of this section.

(iv) The owner or operator has developed a written closure plan for the facility that is deemed acceptable by the Regional Administrator (or the appropriate official at EPA Headquarters, if the commercial storage area is ancillary to a disposal facility permitted by an official at EPA Headquarters) under the closure plan standards of paragraph (e) of this section.

(v) The owner or operator has included in the application for final approval a demonstration of financial responsibility for closure that meets the financial responsibility standards of paragraph (g) of this section.

(vi) The operation of the storage facility will not pose an unreasonable risk of injury to health or the environment.

(vii) The environmental compliance history of the applicant, its principals, and its key employees may be deemed to constitute a sufficient basis for denial of approval whenever in the judgment of the appropriate EPA official

that history of environmental civil violations or criminal convictions evidences a pattern or practice of noncompliance that demonstrates the applicant's unwillingness or inability to achieve and maintain compliance with the regulations.

(3) Applicants for storage approvals shall submit a written application that includes any relevant information bearing upon the qualifications of the facility's principals and key employees to engage in the business of commercial storage of PCB wastes. This information shall include, but is not limited to:

(i) The identification of the owner and the operator of the facility, including all general partners of a partnership, any limited partner of a partnership, any stockholder of a corporation or any participant in any other type of business organization or entity who owns or controls, directly or indirectly, more than 5 percent of each partnership, corporation, or other business organization and all officials of the facility who have direct management responsibility for the facility.

(ii) The identification of the person responsible for the overall operations of the facility (i.e., a plant manager, superintendent, or a person of similar responsibility) and the supervisory employees who are or will be responsible for the operation of the facility.

(iii) Information concerning the technical qualifications and experience of the persons responsible for the overall operation of the facility and the employees responsible for handling PCB waste or other wastes.

(iv) Information concerning any past State or Federal environmental violations involving the same business or another business with which the principals or supervisory employees were affiliated directly that occurred within 5 years preceding the date of submission and which relate directly to violations that resulted in either a civil penalty (irrespective of whether the matter was disposed of by an adjudication or by a without prejudice settlement) or judgment of conviction whether entered after trial or a plea, either of guilt or nolo contendere or civil injunctive relief and involved storage, disposal, transport, or other waste handling activities.

(v) A list of all companies currently owned or operated in the past by the principals or key employees identified in paragraphs (d)(3)(i) and (d)(3)(ii) of this section that are or were directly or indirectly involved with waste handling activities.

(vi) The owner's or operator's estimate of maximum PCB waste quantity to be handled at the facility.

(vii) A written statement certifying compliance with paragraph (b) or (c) of this section and containing a certification as defined in § 761.3.

(viii) A written closure plan for the facility, as described in paragraph (e) of this section.

(ix) The current closure cost estimate for the facility, as described in paragraph (f) of this section.

(x) A demonstration of financial responsibility to close the facility, as described in paragraph (g) of this section.

(4) The written approval issued by EPA shall include, but not be limited to, the following:

(i) The determination that the applicant has satisfied the requirements set forth in paragraph (d)(2) of this section, and a brief statement setting forth the basis for the determination.

(ii) Incorporation of the closure plan submitted by the facility owner or operator and approved by EPA.

(iii) A condition imposing a maximum PCB storage capacity which the facility shall not exceed during its PCB waste storage operations. The maximum storage capacity imposed under this condition shall not be greater than the estimated maximum inventory of PCB waste included in the owner's or operator's application for final approval.

(iv) Such other conditions as deemed necessary by EPA to ensure that the operations of the PCB storage facility will not pose an unreasonable risk of injury to health or the environment.

(5) Storage areas at transfer facilities are exempt from the requirement to obtain approval as a commercial storer of PCB waste under this paragraph, unless the same PCB waste is stored at these facilities for a period of time greater than 10 consecutive days between destinations.

(6) Storage areas at RCRA-permitted facilities may be exempt from the separate TSCA storage approval requirements in this paragraph (d) upon a showing to the Regional Administrator's satisfaction that the facility's existing RCRA closure plan is substantially equivalent to this rule's closure plan standards, and that such facility's closure cost estimate and financial assurance demonstration account for maximum PCB waste inventories, and the requirements of paragraph (d)(3)(i) through (d)(3)(v) and (d)(3)(vii) of this section are met. A pay-in period of longer than 3 years after approval of the storage facility pursuant to this rule, will be acceptable to EPA if that pay-in period has already been established for a valid RCRA facility or previously approved TSCA facility.

(7) Storage areas ancillary to TSCA-approved disposal facilities may be exempt from a separate facility approval provided all of the following conditions are met:

(i) The current disposal approval contains an expiration date.

(ii) The current disposal approval's closure and financial responsibility conditions specifically extend to storage areas ancillary to disposal.

(iii) The current disposal approval's closure and financial responsibility conditions provide for annual adjustments for inflation, and for modification when changes in operation would affect closure costs.

(iv) The current disposal approval contains conditions on closure and financial responsibility that are at least as stringent as those in paragraphs (e) and (g) of this section. However, the provision for a 3-year closure trust pay-in period, as specified in paragraph (g)(1)(i) of this section, would be waived in a case in which an approved TSCA facility or RCRA facility that covers PCB storage has a longer pay-in period for the trust.

(v) The current disposal approval satisfies the requirements of paragraph (d)(3)(i) through (d)(3)(v) of this section.

(8) The approval of any existing TSCA-approved disposal facility ancillary to a commercial storage facility that is deficient in any of the conditions of paragraph (d)(7)(i) through (d)(7)(v) of this section shall be called in by the Regional Administrator (or the appropriated official at EPA Headquarters, if approval was granted by an official at EPA Headquarters). The approval shall be modified to meet the requirements of paragraph (d)(7) of this section within 180 days of the effective date of this final rule, or a separate application for approval of the storage facility may be submitted to the Regional Administrator or the Director, Office of Resource Conservation and Recovery, in the cases where an official at EPA Headquarters issued the approval.

(e) *Closure.* (1) A commercial storer of PCB waste shall have a written closure plan that identifies the steps that the owner or operator of the facility shall take to close the PCB waste storage facility in a manner that eliminates the potential for post-closure releases of PCBs which may present an unreasonable risk to human health or the environment. An acceptable closure plan must include, at a minimum, all of the following:

(i) A description of how the PCB storage areas of the facility will be closed in a manner that eliminates the potential for post-closure releases of PCBs into the environment.

(ii) An identification of the maximum extent of storage operations that will be open during the active life of the facility, including an identification of the extent of PCB storage operations at the facility relative to other wastes that will be handled at the facility.

(iii) An estimate of the maximum inventory of PCB wastes that could be handled at one time at the facility over its active life, and a detailed description of the methods or arrangements to be used during closure for removing, transporting, storing, or disposing of the facility's inventory of PCB waste, including an identification of any offsite facilities that will be used.

(iv) A detailed description of the steps needed to remove or decontaminate PCB waste residues and contaminated containment system components, equipment, structures, and soils during closure in accordance with the levels specified in the PCB Spills Cleanup Policy in subpart G of this part, including a description of the

methods for sampling and testing of surrounding soils, and the criteria for determining the extent of removal or decontamination.

(v) A detailed description of other activities necessary during the closure period to ensure that any post-closure releases of PCBs will not present unreasonable risks to human health or the environment. This includes activities such as ground-water monitoring, run-on and run-off control, and facility security.

(vi) A schedule for closure of each area of the facility where PCB waste is stored or handled, including the total time required to close each area of PCB waste storage or handling, and the time required for any intervening closure activities.

(vii) An estimate of the expected year of closure of the PCB waste storage areas, if a trust fund is opted for as the financial mechanism.

(2) A written closure plan determined to be acceptable by EPA under this section shall become a condition of any approval granted under paragraph (d) of this section.

(3) A separate and new closure plan need not be submitted in cases where a facility is currently covered by a TSCA approval or a RCRA permit, upon a showing to the satisfaction of the Regional Administrator (or the appropriate official at EPA Headquarters, if the commercial storage area is ancillary to a disposal facility for which an official at EPA Headquarters has approval authority) that the existing closure plan is substantially equivalent to closure plans required under paragraphs (d) through (g) of this section, and that the plan adequately accounts for PCB waste inventories.

(4) The commercial storer of PCB waste shall submit a written request to the Regional Administrator (or the Director, Office of Resource Conservation and Recovery, if an official at EPA Headquarters approved the closure plan) for a modification to its storage approval to amend its closure plan, whenever:

(i) Changes in ownership, operating plans, or facility design affect the existing closure plan.

(ii) There is a change in the expected date of closure, if applicable.

(iii) In conducting closure activities, unexpected events require a modification of the approved closure plan.

(5) The Regional Administrator or the Director, appropriate official at EPA Headquarters, if an official at EPA Headquarters approved the closure plan, may modify the existing closure plan under the conditions described in paragraph (e)(4) of this section.

(6) Commercial storers of PCB waste shall comply with the following closure schedule:

(i) The commercial storer shall notify in writing the Regional Administrator or the Director, Office of Resource Conservation and Recovery, if an official at EPA Headquarters approved the closure plan, at least 60 days prior to the date on which final closure of its PCB storage facility is expected to begin.

(ii) The date when a commercial storer of PCB waste ''expects to begin closure'' shall be no later than 30 days after the date on which the storage facility received its final quantities of PCB waste. For good cause shown, EPA may extend the date for commencement of closure for an additional 30-day period.

(iii) Within 90 days after receiving the final quantity of PCB waste for storage, a commercial storer of PCB waste shall remove all PCB waste in storage at the facility from the facility in accordance with the approved closure plan. For good cause shown, EPA may approve a reasonable extension to the period for removal of the PCB waste.

(iv) A commercial storer of PCB waste shall complete closure activities in accordance with the approved closure plan and within 180 days after receiving the final quantity of PCB waste for storage at the facility. For good cause shown, EPA may approve a reasonable extension to the closure period.

(7) During the closure period, all contaminated system component equipment, structures, and soils shall be disposed of in accordance with the disposal requirements of subpart D of this part, or, if applicable, decontaminated in accordance with the levels specified in the PCB Spills Cleanup Policy at subpart G of this part. When PCB waste

is removed from the storage facility during closure, the owner or operator becomes a generator of PCB waste subject to the generator requirements of subpart J of this part.

(8) Within 60 days of completion of closure of each facility for the storage of PCB waste, the commercial storer of PCB waste shall submit to the Regional Administrator (or the Director, Office of Resource Conservation and Recovery, if an official at EPA Headquarters approved the closure plan), by registered mail, a certification that the PCB storage facility has been closed in accordance with the approved closure plan. The certification shall be signed by the owner or operator and by an independent registered professional engineer.

(f) *Closure cost estimate.* (1) A commercial storer of PCB wastes shall have a detailed estimate, in current dollars, of the cost of closing the facility in accordance with its approved closure plan. The closure cost estimate shall be in writing, be certified by the person preparing it (using the certification defined in § 761.3) and comply with all of the following criteria:

(i) The closure cost estimate shall equal the cost of final closure at the point in the PCB storage facility's active life when the extent and manner of PCB storage operations would make closure the most expensive, as indicated by the facility's closure plan.

(ii) The closure cost estimate shall be based on the costs to the owner or operator of hiring a third party to close the facility, and the third party shall not be either a corporate parent or subsidiary of the owner or operator, or member in joint ownership of the facility.

(iii) The owner or operator shall include in the estimate the current market costs for off-site commercial disposal of the facility's maximum estimated inventory of PCB wastes, except that on-site disposal costs may be used if on-site disposal capacity will exist at the facility at all times over the life of the PCB storage facility.

(iv) The closure cost estimate may not incorporate any salvage value that may be realized with the sale of wastes, facility structures or equipment, land, or other assets associated with the facility at the time of closure.

(2) During the active life of the PCB storage facility, the commercial storer of PCB waste shall adjust annually for inflation the closure cost estimate within 60 days prior to the anniversary date of the establishment of the financial instruments used to demonstrate financial responsibility for closure, except that owners or operators who use the financial test or corporate guarantee shall adjust their closure cost estimates for inflation within 30 days after the close of the storer's fiscal year. The adjustment may be made by recalculating the maximum costs of closure in current dollars, or by using an inflation factor derived from the most recent Implicit Price Deflator for Gross National Product published by the U.S. Department of Commerce in its *Survey of Current Business.* The Implicit Price Deflator for Gross National Product is included in a monthly publication titled *Economic Indicators,* which is available from the Superintendent of Documents, Government Printing Office, Washington, DC 20402. The inflation factor used in the latter method is the result of dividing the latest published annual Deflator by the Deflator for the previous year. The adjustment to the closure cost estimate is then made by multiplying the most recent closure cost estimate by the latest inflation factor.

(3) Where EPA approves a modification to the facility's closure plan, and that modification increases the cost of closure, the owner or operator shall revise the closure cost estimate no later than 30 days after the modification is approved. Any such revision shall also be adjusted for inflation in accordance with paragraph (f)(2) of this section.

(4) The owner or operator of the facility shall keep at the facility during its operating life the most recent closure cost estimate, including any adjustments resulting from inflation or from modifications to the closure plan.

(g) *Financial assurance for closure.* A commercial storer of PCB waste shall establish financial assurance for closure of each PCB storage facility that he owns or operates. In establishing financial assurance for closure, the commercial storer of PCB waste may

choose from the following financial assurance mechanisms or any combination of mechanisms:

(1) The ''closure trust fund,'' as specified in §264.143(a) of this chapter, except for paragraph (a)(3) of §264.143. For purposes of this paragraph, the following provisions also apply:

(i) Payments into the trust fund shall be made annually by the owner or operator over the remaining operating life of the facility as estimated in the closure plan, or over 3 years, whichever period is shorter. This period of time is hereafter referred to as the ''pay-in period.'' For an existing facility, the first payment must be made within 30 calendar days after EPA has notified the facility of its conditional approval. Interim approval to operate is canceled and the application is denied if EPA does not receive verification that the payment was made in that 30-day period.

(ii) For a new facility, the first payment into the closure trust fund shall be made before EPA grants final approval of the application and before the facility may accept the initial shipment of PCB waste for commercial storage. A receipt from the trustee shall be submitted by the owner or operator to the Regional Administrator (or the Director, Office of Resource Conservation and Recovery, if the commercial storage area is ancillary to a disposal facility approved by an official at EPA Headquarters) before this initial delivery of PCB waste. The first payment shall be at least equal to the current closure cost estimate, divided by the number of years in the pay-in period, except as provided in paragraph (g)(7) of this section for multiple mechanisms. Subsequent payments shall be made no later than 30 days after each anniversary date of the first payment. The amount of each subsequent payment shall be determined by subtracting the current value of the trust fund from the current closure cost estimate, and dividing this difference by the number of years remaining in the pay-in period.

(iii) If an owner or operator of a facility existing on the effective date of this paragraph establishes a trust fund to meet the financial assurance requirements of this paragraph, and the value of the trust fund is less than the current closure cost estimate when a final approval is granted for the facility, the amount of the current closure cost estimate still to be paid into the trust fund shall be paid in over the pay-in period as defined in paragraph (g)(1)(i) of this section. Payments shall continue to be made no later than 30 days after each anniversary date of the first payment made into the trust fund. The amount of each payment shall be determined by subtracting the current value of the trust fund from the current closure cost estimate, and dividing this difference by the number of years remaining in the pay-in period.

(iv) The submission of a trust agreement with the wording specified in §264.151(a)(1) of this chapter, including any reference to hazardous waste management facilities, shall be deemed to be in compliance with the requirement to submit a trust agreement under this subpart.

(2) The ''surety bond guaranteeing payment into a closure trust fund,'' as specified in §264.143(b) of this chapter, including the use of the surety bond instrument specified at §264.151(b) of this chapter and the standby trust specified at §264.143(b)(3) of this chapter. The use of the surety bonds, surety bond instruments, and standby trust agreements specified in §§264.143(b) and 264.151(b) of this chapter shall be deemed to be in compliance with this subpart.

(3)(i) The ''surety bond guaranteeing performance of closure,'' as specified at §264.143(c) of this chapter, except for paragraph (c)(5) of §264.143 of this chapter. The submission and use of the surety bond instrument specified at §264.151(c) of this chapter and the standby trust specified at §264.143(c)(3) of this chapter shall be deemed to be in compliance with the requirements under this subpart relating to the use of surety bonds and standby trust funds.

(ii) For the purposes of this paragraph, and under the terms of the bond, the surety shall become liable on the bond obligation when the owner or operator fails to perform as guaranteed by the bond. Liability is established by a final administrative determination pursuant to section 16 of TSCA that

the owner or operator has failed to perform final closure in accordance with the closure plan and other approval or regulatory requirements when required to do so.

(4)(i) The ''closure letter of credit'' specified in § 264.143(d) of this chapter, except for paragraph (d)(8). The submission and use of the irrevocable letter of credit instrument specified in § 264.151(d) of this chapter and the standby trust specified in § 264.143(d)(3) of this chapter shall be deemed to be in compliance with the requirements of this subpart relating to the use of letters of credit and standby trust funds.

(ii) For the purposes of this paragraph, the Regional Administrator (or the appropriate official at EPA Headquarters, if the commercial storage area is ancillary to a disposal facility for which an official at EPA Headquarters has approval authority) may draw on the letter of credit following a final administrative determination pursuant to section 16 of TSCA that the owner or operator has failed to perform final closure in accordance with the closure plan and other approval or regulatory requirements when required to do so.

(5) ''Closure insurance,'' as specified in § 264.143(e) of this chapter, utilizing the certificate of insurance for closure specified at § 264.151(e) of this chapter. The use of closure insurance as specified in § 264.143(e) of this chapter and the submission and use of the certificate of insurance specified in § 264.151(e) of this chapter shall be deemed to be in compliance with the requirements of this subpart relating to the use of closure insurance.

(6) The ''financial test and corporate guarantee for closure,'' as described in § 264.143(f) of this chapter, including a letter signed by the owner's or operator's chief financial officer as specified at § 264.151(f) of this chapter and, if applicable, the written corporate guarantee specified at § 264.151(h) of this chapter. The use of the financial test and corporate guarantee specified in § 264.143(f) of this chapter, the submission and use of the letter specified in § 264.151(f) of this chapter, and the submission and use of the written corporate guarantee specified at § 264.151(h) of this chapter shall be deemed to be in compliance with the requirements of this subpart relating to the use of financial tests and corporate guarantees.

(7) The corporate guarantee as specified in § 264.143(f)(10) of this chapter.

(8) The use of multiple financial mechanisms, as specified in § 264.143(g) of this chapter is permitted.

(9) A modification to a facility storing PCB waste that increases the maximum storage capacity indicated in the permit requires that a new financial assurance mechanism be established or an existing one be amended. When such a modification occurs, the Director of the Federal or State issuing authority must be notified in writing no later than 30 days from the completion of the modification. The new or revised financial assurance mechanism must be established and activated no later than 30 days after the Director of the Federal or State issuing authority is notified of the completion of the modification, but prior to the use of the modified portion of the facility.

(h) *Release of owner or operator.* Within 60 days after receiving certifications from the owner or operator and an independent registered professional engineer that final closure has been completed in accordance with the approved closure plan, EPA will notify the owner or operator in writing that the owner or operator is no longer required by this section to maintain financial assurance for final closure of the facility, unless EPA has reason to believe that final closure has not been completed in accordance with the approved closure plan. EPA shall provide the owner or operator with a detailed written statement stating the reasons why EPA shall provide the owner or operator with a detailed written statement stating the reasons why he believed closure was not conducted in accordance with the approved closure plan.

(i) *Laboratories and samples.* (1) A laboratory is conditionally exempt from the notification and approval requirements for a commercial storer under § 761.65 (d) through (h) when it stores samples held for disposal in a facility that complies with the standards in § 761.65 (b)(1)(i) through (b)(1)(iv).

(2) A laboratory sample is exempt from the manifesting requirements in §§ 761.210 through 761.213 when:

(i) The sample is being transported to a laboratory for the purpose of testing.

(ii) The sample is being transported back to the sample collector after testing.

(iii) The sample is being stored by the sample collector before transport to a laboratory for testing.

(iv) The sample is being stored in a laboratory before testing.

(v) The sample is being stored in a laboratory after testing but before it is returned to the sample collector.

(vi) The sample is being stored temporarily in the laboratory after testing for a specific purpose (for example, until conclusion of a court case or enforcement action where further testing of the sample may be necessary).

(3) In order to qualify for the exemption in paragraph (i)(2)(i) and (i)(2)(ii) of this section, a sample collector shipping samples to a laboratory and a laboratory returning samples to a sample collector must:

(i) Comply with applicable U.S. Department of Transportation (DOT) or U.S. Postal Service (USPS) shipping requirements, found respectively in 49 CFR 173.345 and U.S. Postal Regulations 652.2 and 652.3.

(ii) Assure that the following information accompanies the sample:

(A) The sample collector's name, mailing address, and telephone number.

(B) The laboratory's name, mailing address, and telephone number.

(C) The quantity of the sample.

(D) The date of shipment.

(E) A description of the sample.

(iii) Package the sample so that it does not leak, spill, or vaporize from its packaging.

(4) When the concentration of the PCB sample has been determined, and its use is terminated, the sample must be properly disposed. A laboratory must either manifest the PCB waste to a disposer or commercial storer, as required under §§ 761.210 through 761.213, retain a copy of each manifest, as required under §§ 761.213 and 761.214, and follow up on exception reporting, as required under § 761.217, or return the sample to the sample collector who must then properly dispose of the sample. If the laboratory returns the sample to the sample collector, the laboratory must comply with the shipping requirements set forth in paragraphs (i)(3)(i) through (i)(3)(iii) of this section.

(j) *Changes in ownership or operational control of a commercial storage facility.* The date of transfer of interim status or final approval shall be the date the EPA Regional Administrator (or appropriate official at EPA Headquarters) provides written approval of the transfer. EPA will provide a final written decision within 90 days of receipt of the complete new or amended application. The Agency will approve the transfer if the following conditions are met:

(1) The transferee has established financial assurance for closure pursuant to paragraph (g) of this section using a mechanism effective as of the date of final approval so that there will be no lapse in financial assurance for the transferred facility.

(2) The transferor or transferee has resolved any deficiencies (e.g., technical operations, closure plans, cost estimates, etc.) the Agency has identified in the transferor's application.

(k) *States and the Federal Government.* States and the Federal Government are exempt from the requirements of paragraphs (f) and (g) of this section.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982, and amended at 47 FR 37359, Aug. 8, 1982; 49 FR 28191, July 10, 1984; 53 FR 12524, Apr. 15, 1988; 54 FR 52746, Dec. 21, 1989; 55 FR 695, Jan. 8, 1990; 55 FR 26205, June 27, 1990; 58 FR 15809, Mar. 24, 1993; 58 FR 34205, June 23, 1993; 58 FR 59374, Nov. 9, 1993; 63 FR 35439, 35452, June 29, 1998; 72 FR 57239, 57240 Oct. 9, 2007; 74 FR 30232, June 25, 2009; 77 FR 54830, Sept. 6, 2012]

§ 761.70 Incineration.

This section applies to facilities used to incinerate PCBs required to be incinerated by this part.

(a) *Liquid PCBs.* An incinerator used for incinerating PCBs shall be approved by EPA pursuant to paragraph (d) of this section. Requests for approval of incinerators to be used in more than one region must be submitted to the

Director, Office of Resource Conservation and Recovery, except for research and development involving less than 500 pounds of PCB material (see § 761.60(i)(2)). Requests for approval of incinerators to be used in only one region must be submitted to the appropriate Regional Administrator. The incinerator shall meet all of the requirements specified in paragraphs (a)(1) through (9) of this section, unless a waiver from these requirements is obtained pursuant to paragraph (d)(5) of this section, In addition, the incinerator shall meet any other requirements which may be prescribed pursuant to paragraph (d)(4) of this section.

(1) Combustion criteria shall be either of the following:

(i) Maintenance of the introduced liquids for a 2-second dwell time at 1200 °C (±100 °C) and 3 percent excess oxygen in the stack gas; or

(ii) Maintenance of the introduced liquids for a 1½ second dwell time at 1600 °C(±100 °C) and 2 percent excess oxygen in the stack gas.

(2) Combustion efficiency shall be at least 99.9 percent computed as follows:

$$\text{Combustion efficiency} = [Cco_2/(Cco_2 + Cco)]100$$

where

Cco_2 = Concentration of carbon dioxide.
Cco = Concentration of carbon monoxide.

(3) The rate and quantity of PCBs which are fed to the combustion system shall be measured and recorded at regular intervals of no longer than 15 minutes.

(4) The temperatures of the incineration process shall be continuously measured and recorded. The combustion temperature of the incineration process shall be based on either direct (pyrometer) or indirect (wall thermocouple-pyrometer correlation) temperature readings.

(5) The flow of PCBs to the incinerator shall stop automatically whenever the combustion temperature drops below the temperatures specified in paragraph (a)(1) of this section.

(6) Monitoring of stack emission products shall be conducted:

(i) When an incinerator is first used for the disposal of PCBs under the provisions of this regulation;

(ii) When an incinerator is first used for the disposal of PCBs after the incinerator has been modified in a manner which may affect the characteristics of the stack emission products; and

(iii) At a minimum such monitoring shall be conducted for the following parameters:

(*a*) O_2; (*b*) CO; (*c*) CO_2; (*d*) Oxides of Nitrogen (NO_X); (*e*) Hydrochloric Acid (HCl); (*f*) Total Chlorinated Organic Content (RCl); (*g*) PCBs; and (*h*) Total Particulate Matter.

(7) At a minimum monitoring and recording of combustion products and incineration operations shall be conducted for the following parameters whenever the incinerator is incinerating PCBs:

(i) O_2; (ii) CO; and (iii) CO_2. The monitoring for O_2 and CO shall be continuous. The monitoring for CO_2 shall be periodic, at a frequency specified by the Regional Administrator or appropriate official at EPA Headquarters.

(8) The flow of PCBs to the incinerator shall stop automatically when any one or more of the following conditions occur, unless a contingency plan is submitted by the incinerator owner or operator and approved by the Regional Administrator or appropriate official at EPA Headquarters. The contingency plan indicates what alternative measures the incinerator owner or operator would take if any of the following conditions occur:

(i) Failure of monitoring operations specified in paragraph (a)(7) of this section;

(ii) Failure of the PCB rate and quantity measuring and recording equipment specified in paragraph (a)(3) of this section; or

(iii) Excess oxygen falls below the percentage specified in paragraph (a)(1) of this section.

(9) Water scrubbers shall be used for HCl control during PCB incineration and shall meet any performance requirements specified by EPA. Scrubber effluent shall be monitored and shall comply with applicable effluent or pretreatment standards, and any other State and Federal laws and regulations. An alternate method of HCl control may be used if the alternate method has been approved by EPA. (The HCl neutralizing capability of cement kilns

is considered to be an alternate method.)

(b) *Nonliquid PCBs.* An incinerator used for incinerating nonliquid PCBs, PCB Articles, PCB Equipment, or PCB Containers shall be approved by EPA pursuant to paragraph (d) of this section. Requests for approval of incinerators to be used in more than one region must be submitted to the Director, Office of Resource Conservation and Recovery except for research and development involving less that 500 pounds of PCB material (see §761.60(i)(2)). Requests for approval of incinerators to be used in only one region must be submitted to the appropriate Regional Administrator. The incinerator shall meet all of the requirements specified in paragraphs (b)(1) and (2) of this section unless a waiver from these requirements is obtained pursuant to paragraph (d)(5) of this section. In addition, the incinerator shall meet any other requirements that may be prescribed pursuant to paragraph (d)(4) of this section.

(1) The mass air emissions from the incinerator shall be no greater than 0.001g PCB/kg of the PCB introduced into the incinerator.

(2) The incinerator shall comply with the provisions of paragraphs (a)(2), (3), (4), (6), (7), (8)(i) and (ii), and (9) of this section.

(c) *Maintenance of data and records.* All data and records required by this section shall be maintained in accordance with §761.180, Records and monitoring.

(d) *Approval of incinerators.* Prior to the incineration of PCBs and PCB Items the owner or operator of an incinerator shall receive the written approval of the Agency Regional Administrator for the region in which the incinerator is located, or the appropriate official at EPA Headquarters. Approval from the appropriate official at EPA Headquarters may be effective in all ten EPA regions. Such approval shall be obtained in the following manner:

(1) *Application.* The owner or operator shall submit to the Regional Administrator or the Director, Office of Resource Conservation and Recovery an application which contains:

(i) The location of the incinerator;

(ii) A detailed description of the incinerator including general site plans and design drawings of the incinerator;

(iii) Engineering reports or other information on the anticipated performance of the incinerator;

(iv) Sampling and monitoring equipment and facilities available;

(v) Waste volumes expected to be incinerated;

(vi) Any local, State, or Federal permits or approvals; and

(vii) Schedules and plans for complying with the approval requirements of this regulation.

(2) *Trial burn.* (i) Following receipt of the application described in paragraph (d)(1) of this section, EPA shall determine if a trial burn is required and notify the person who submitted the report whether a trial burn of PCBs and PCB Items must be conducted. EPA may require the submission of any other information that EPA finds to be reasonably necessary to determine the need for a trial burn. Such other information shall be restricted to the types of information required in paragraphs (d)(1)(i) through (vii) of this section.

(ii) If EPA determines that a trail burn must be held, the person who submitted the report described in paragraph (d)(1) of this section shall submit to the Regional Administrator or the Director, Office of Resource Conservation and Recovery a detailed plan for conducting and monitoring the trail burn. At a minimum, the plan must include:

(A) Date trial burn is to be conducted;

(B) Quantity and type of PCBs and PCB Items to be incinerated;

(C) Parameters to be monitored and location of sampling points;

(D) Sampling frequency and methods and schedules for sample analyses; and

(E) Name, address, and qualifications of persons who will review analytical results and other pertinent data, and who will perform a technical evaluation of the effectiveness of the trial burn.

(iii) Following receipt of the plan described in paragraph (d)(2)(ii) of this section, EPA will approve the plan, require additions or modifications to the plan, or disapprove the plan. If the plan

is disapproved, EPA will notify the person who submitted the plan of such disapproval, together with the reasons why it is disapproved. That person may thereafter submit a new plan in accordance with paragraph (d)(2)(ii) of this section. If the plan is approved (with any additions or modifications which EPA may prescribe), EPA will notify the person who submitted the plan of the approval. Thereafter, the trial burn shall take place at a date and time to be agreed upon between EPA and the person who submitted the plan.

(3) *Other information.* In addition to the information contained in the report and plan described in paragraphs (d)(1) and (2) of this section, EPA may require the owner or operator to submit any other information that the EPA finds to be reasonably necessary to determine whether an incinerator shall be approved.

NOTE: The Regional Administrator will have available for review and inspection an Agency manual containing information on sampling methods and analytical procedures for the parameters required in § 761.70(a) (3), (4), (6), and (7) plus any other parameters he/she may determine to be appropriate. Owners or operators are encouraged to review this manual prior to submitting any report required in § 761.70.

(4) *Contents of approval.* (i) Except as provided in paragraph (d)(5) of this section, the Regional Administrator or the appropriate official at EPA Headquarters may not approve an incinerator for the disposal of PCBs and PCB Items unless he finds that the incinerator meets all of the requirements of paragraphs (a) and/or (b) of this section.

(ii) In addition to the requirements of paragraphs (a) and/or (b) of this section, EPA may include in an approval any other requirements that EPA finds are necessary to ensure that operation of the incinerator does not present an unreasonable risk of injury to health or the environment from PCBs. Such requirements may include a fixed period of time for which the approval is valid.

(5) *Waivers.* An owner or operator of the incinerator may submit evidence to the Regional Administrator or the Director, Office of Resource Conservation and Recovery that operation of the incinerator will not present an unreasonable risk of injury to health or the environment from PCBs, when one or more of the requirements of paragraphs (a) and/or (b) of this section are not met. On the basis of such evidence and any other available information, EPA may, in its discretion, find that any requirement of paragraphs (a) and (b) of this section is not necessary to protect against such a risk, and may waive the requirements in any approval for that incinerator. Any finding and waiver under this paragraph must be stated in writing and included as part of the approval.

(6) *Persons approved.* An approval will designate the persons who own and who are authorized to operate the incinerator, and will apply only to such persons, except as provided in paragraph (d)(8) of this section.

(7) *Final approval.* Approval of an incinerator will be in writing and signed by the appropriate EPA official. The approval will state all requirements applicable to the approved incinerator.

(8) *Transfer of property.* Any person who owns or operates an approved incinerator must notify EPA at least 30 days before transferring ownership in the incinerator or the property it stands upon, or transferring the right to operate the incinerator. The transferor must also submit to EPA, at least 30 days before such transfer, a notarized affidavit signed by the transferee which states that the transferee will abide by the transferor's EPA incinerator approval. Within 30 days of receiving such notification and affidavit, EPA will issue an amended approval substituting the transferee's name for the transferor's name, or EPA may require the transferee to apply for a new incinerator approval. In the latter case, the transferee must abide by the transferor's EPA approval until EPA issues the new approval to the transferee.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982, and amended at 48 FR 13185, Mar. 30, 1983; 49 FR 28191, July 10, 1984; 53 FR 12524, Apr. 15, 1988; 58 FR 15809, Mar. 24, 1993; 63 FR 35439, June 29, 1998; 72 FR 57240, Oct. 9, 2007; 74 FR 30233, June 25, 2009]

§ 761.71 High efficiency boilers.

(a) To burn mineral oil dielectric fluid containing a PCB concentration of ≥50 ppm, but <500 ppm:

(1) The boiler shall comply with the following criteria:

(i) The boiler is rated at a minimum of 50 million BTU hours.

(ii) If the boiler uses natural gas or oil as the primary fuel, the carbon monoxide concentration in the stack is ≤50 ppm and the excess oxygen is at least 3 percent when PCBs are being burned.

(iii) If the boiler uses coal as the primary fuel, the carbon monoxide concentration in the stack is ≤100 ppm and the excess oxygen is at least 3 percent when PCBs are being burned.

(iv) The mineral oil dielectric fluid does not comprise more than 10 percent (on a volume basis) of the total fuel feed rate.

(v) The mineral oil dielectric fluid is not fed into the boiler unless the boiler is operating at its normal operating temperature (this prohibits feeding these fluids during either start up or shut down operations).

(vi) The owner or operator of the boiler:

(A) Continuously monitors and records the carbon monoxide concentration and excess oxygen percentage in the stack gas while burning mineral oil dielectric fluid; or

(B) If the boiler will burn <30,000 gallons of mineral oil dielectric fluid per year, measures and records the carbon monoxide concentration and excess oxygen percentage in the stack gas at regular intervals of no longer than 60 minutes while burning mineral oil dielectric fluid.

(vii) The primary fuel feed rates, mineral oil dielectric fluid feed rates, and total quantities of both primary fuel and mineral oil dielectric fluid fed to the boiler are measured and recorded at regular intervals of no longer than 15 minutes while burning mineral oil dielectric fluid.

(viii) The carbon monoxide concentration and the excess oxygen percentage are checked at least once every hour that mineral oil dielectric fluid is burned. If either measurement falls below the levels specified in this section, the flow of mineral oil dielectric fluid to the boiler shall be stopped immediately.

(2) Thirty days before any person burns mineral oil dielectric fluid in the boiler, the person gives written notice to the EPA Regional Administrator for the EPA Region in which the boiler is located and that the notice contains the following information:

(i) The name and address of the owner or operator of the boiler and the address of the boiler.

(ii) The boiler rating in units of BTU/hour.

(iii) The carbon monoxide concentration and the excess oxygen percentage in the stack of the boiler when it is operated in a manner similar to the manner in which it will be operated when mineral oil dielectric fluid is burned.

(iv) The type of equipment, apparatus, and procedures to be used to control the feed of mineral oil dielectric fluid to the boiler and to monitor and record the carbon monoxide concentration and excess oxygen percentage in the stack.

(3) When burning mineral oil dielectric fluid, the boiler must operate at a level of output no less than the output at which the measurements required under paragraph (a)(2)(iii) of this section were taken.

(4) Any person burning mineral oil dielectric fluid in a boiler obtains the following information and retains the information for 5 years at the boiler location:

(i) The data required to be collected under paragraphs (a)(1)(vi) and (vii) of this section.

(ii) The quantity of mineral oil dielectric fluid burned in the boiler each month.

(b) To burn liquids, other than mineral oil dielectric fluid, containing a PCB concentration of ≥50 ppm, but <500 ppm:

(1) The boiler shall comply with the following criteria:

(i) The boiler is rated at a minimum of 50 million BTU/hour.

(ii) If the boiler uses natural gas or oil as the primary fuel, the carbon monoxide concentration in the stack is ≤50 ppm and the excess oxygen is at least 3 percent when PCBs are being burned.

(iii) If the boiler uses coal as the primary fuel, the carbon monoxide concentration in the stack is ≤100 ppm and the excess oxygen is at least 3 percent when PCBs are being burned.

(iv) The waste does not comprise more than 10 percent (on a volume basis) of the total fuel feed rate.

(v) The waste is not fed into the boiler unless the boiler is operating at its normal operating temperature (this prohibits feeding these fluids during either start up or shut down operations).

(vi) The owner or operator of the boiler must:

(A) Continuously monitor and record the carbon monoxide concentration and excess oxygen percentage in the stack gas while burning waste fluid; or

(B) If the boiler will burn <30,000 gallons of waste fluid per year, measure and record the carbon monoxide concentration and excess oxygen percentage in the stack gas at regular intervals of no longer than 60 minutes while burning waste fluid.

(vii) The primary fuel feed rate, waste fluid feed rate, and total quantities of both primary fuel and waste fluid fed to the boiler must be measured and recorded at regular intervals of no longer than 15 minutes while burning waste fluid.

(viii) The carbon monoxide concentration and the excess oxygen percentage must be checked at least once every hour that the waste is burned. If either measurement falls below the levels specified in either (a)(1)(ii) or (a)(1)(iii) of this section, the flow of waste to the boiler shall be stopped immediately.

(2) Prior to any person burning these liquids in the boiler, approval must be obtained from the EPA Regional Administrator for the EPA Region in which the boiler is located and any persons seeking such approval must submit to the EPA Regional Administrator a request containing at least the following information:

(i) The name and address of the owner or operator of the boiler and the address of the boiler.

(ii) The boiler rating in units of BTU/hour.

(iii) The carbon monoxide concentration and the excess oxygen percentage in the stack of the boiler when it is operated in a manner similar to the manner in which it will be operated when low concentration PCB liquid is burned.

(iv) The type of equipment, apparatus, and procedures to be used to control the feed of mineral oil dielectric fluid to the boiler and to monitor and record the carbon monoxide concentration and excess oxygen percentage in the stack.

(v) The type of waste to be burned (e.g., hydraulic fluid, contaminated fuel oil, heat transfer fluid, etc.).

(vi) The concentration of PCBs and of any other chlorinated hydrocarbon in the waste and the results of analyses using the ASTM International methods as follows: Carbon and hydrogen content using ASTM D3178–84, nitrogen content using ASTM E258–67 (Reapproved 1987), sulfur content using ASTM D2784–89, ASTM D1266–87, or ASTM D129–64 (Reapproved 1978), chlorine content using ASTM D808–87, water and sediment content using either ASTM D2709–88 or ASTM D1796–83 (Reapproved 1990), ash content using ASTM D482–87, calorific value using ASTM D240–87, carbon residue using either ASTM D2158–89 or ASTM D524–88, and flash point using ASTM D93–09 (all standards incorporated by reference in § 761.19).

(vii) The quantity of wastes estimated to be burned in a 30–day period.

(viii) An explanation of the procedures to be followed to ensure that burning the waste will not adversely affect the operation of the boiler such that combustion efficiency will decrease.

(3) On the basis of the information in paragraph (b)(2) of this section and any other available information, the Regional Administrator may, at his/her discretion, find that the alternate disposal method will not present an unreasonable risk of injury to health or the environment and approve the use of the boiler.

(4) When burning PCB wastes, the boiler must operate at a level of output no less than the output at which the measurements required under paragraph (b)(2)(iii) of this section were taken.

(5) Any person burning liquids in boilers approved as provided in paragraph (b)(3) of this section, must obtain the following information and retain the information for 5 years at the boiler location:

(i) The data required to be collected in paragraphs (b)(1)(vi) and (b)(1)(vii) of this section.

(ii) The quantity of low concentration PCB liquid burned in the boiler each month.

(iii) The analysis of the waste required by paragraph (b)(2)(vi) of this section taken once a month for each month during which low concentration PCB liquid is burned in the boiler.

[63 FR 35454, June 29, 1998, as amended at 77 FR 2464, Jan. 18, 2012]

§ 761.72 Scrap metal recovery ovens and smelters.

Any person may dispose of residual PCBs associated with PCB-Contaminated articles regulated for disposal under § 761.60(b), metal surfaces in PCB remediation waste regulated under § 761.61, or metal surfaces in PCB bulk product waste regulated under §§ 761.62(a)(6) and 761.79(c)(6), from which all free-flowing liquids have been removed:

(a) In a scrap metal recovery oven:

(1) The oven shall have at least two enclosed (i.e., negative draft, no fugitive emissions) interconnected chambers.

(2) The equipment with all free-flowing liquid removed shall first be placed in the primary chamber at room temperature.

(3) The primary chamber shall operate at a temperature between 537 °C and 650 °C for a minimum of 2½ hours and reach a minimum temperature of 650 °C (1,202 °F) once during each heating cycle or batch treatment of unheated, liquid-free equipment.

(4) Heated gases from the primary chamber must feed directly into the secondary chamber (i.e., afterburner) which must operate at a minimum temperature of 1,200 °C (2,192 °F) with at least a 3 percent excess oxygen and a retention time of 2.0 seconds with a minimum combustion efficiency of 99.9 percent according to the definition in § 761.70(a)(2).

(5) Heating of the primary chamber shall not commence until the secondary chamber has reached a temperature of 1,200 ±100 °C (2,192 ° ±180 °F).

(6) Continuous emissions monitors and recorders for carbon dioxide, carbon monoxide, and excess oxygen in the secondary chamber and continuous temperature recorders in the primary and secondary chambers shall be installed and operated while the primary and secondary chambers are in operation to assure that the two chambers are within the operating parameters in paragraphs (a)(3) through (a)(5) of this section.

(7) Emissions from the secondary chamber must be vented through an exhaust gas stack in accordance with either:

(i) State or local air regulations or permits, or

(ii) The standards in paragraph (a)(8) of this section.

(8) Exhaust gas stack emissions shall be for: particulates <0.015 grains/dry standard cubic foot, sulfur dioxide <35 parts per million by volume (ppmv), nitrogen oxide <150 ppmv, carbon monoxide <35 ppmv, and hydrogen chloride <35 ppmv.

(9) A measurement of the temperature in the secondary chamber at the time the primary chamber starts heating must be taken, recorded and retained at the facility for 3 years from the date each charge is introduced into the primary chamber.

(b) By smelting:

(1) The operating temperature of the hearth must be at least 1,000 °C at the time it is charged with any PCB-Contaminated non-porous surface.

(2) Each charge containing a PCB-Contaminated item must be added into molten metal or a hearth at ≥1,000 °C.

(3) Successive charges may not be introduced into the hearth in less than 15–minute intervals.

(4) The smelter must operate in compliance with any applicable emissions standards in part 60 of this chapter.

(5) The smelter must have an operational device which accurately measures directly or indirectly, the temperature in the hearth.

(6) Take, record and retain at the disposal facility for 3 years from the date each charge is introduced, a reading of

the temperature in the hearth at the time it is charged with a non-porous surface item.

(c)(1) Scrap metal recovery ovens and smelters must either have a final permit under RCRA (part 266, subpart H of this chapter and § 270.66 of this chapter) or be operating under a valid State air emissions permit which includes a standard for PCBs.

(2) Scrap metal recovery ovens and smelters disposing of PCBs must provide notification as disposers of PCBs, are not required to submit annual reports, and shall otherwise comply with all applicable provisions of subparts J and K of this part, as well as other applicable Federal, State, and local laws and regulations.

(3) In lieu of the requirements in paragraph (c)(1) of this section, upon written request by the owner or operator of a scrap metal recovery oven or smelter, the EPA Regional Administrator, for the Region where the oven or smelter is located, may make a finding in writing, based on a site-specific risk assessment, that the oven or smelter does not pose an unreasonable risk of injury to health or the environment because it is operating in compliance with the parameters and conditions listed in paragraph (a) or (b) of this section even though the oven or smelter does not have a RCRA or State air permit as required by paragraph (c)(1) of this section. The written request shall include a site-specific risk assessment.

(d) PCB liquids, other liquid waste qualifying as waste oils which may be used as provided for at § 761.20(e), or PCB remediation waste, other than PCB-Contaminated articles, may not be disposed of in a scrap metal recovery oven or smelter unless approved or otherwise allowed under subpart D of this part.

[63 FR 35455, June 29, 1998, as amended at 64 FR 33761, June 24, 1999]

§ 761.75 Chemical waste landfills.

This section applies to facilities used to dispose of PCBs in accordance with the part.

(a) *General.* A chemical waste landfill used for the disposal of PCBs and PCB Items shall be approved by the Agency Regional Administrator pursuant to paragraph (c) of this section. The landfill shall meet all of the requirements specified in paragraph (b) of this section, unless a waiver from these requirements is obtained pursuant to paragraph (c)(4) of this section. In addition, the landfill shall meet any other requirements that may be prescribed pursuant to paragraph (c)(3) of this section.

(b) *Technical requirements.* Requirements for chemical waste landfills used for the disposal of PCBs and PCB Items are as follows:

(1) *Soils.* The landfill site shall be located in thick, relatively impermeable formations such as large-area clay pans. Where this is not possible, the soil shall have a high clay and silt content with the following parameters:

(i) In-place soil thickness, 4 feet or compacted soil liner thickness, 3 feet;

(ii) Permeability (cm/sec), equal to or less than 1×10^{-7};

(iii) Percent soil passing No. 200 Sieve, >30;

(iv) Liquid Limit, >30; and

(v) Plasticity Index >15.

(2) *Synthetic membrane liners.* Synthetic membrane liners shall be used when, in the judgment of the Regional Administrator, the hydrologic or geologic conditions at the landfill require such a liner in order to provide at least a permeability equivalent to the soils in paragraph (b)(1) of this section. Whenever a synthetic liner is used at a landfill site, special precautions shall be taken to insure that its integrity is maintained and that it is chemically compatible with PCBs. Adequate soil underlining and soil cover shall be provided to prevent excessive stress on the liner and to prevent rupture of the liner. The liner must have a minimum thickness of 30 mils.

(3) *Hydrologic conditions.* The bottom of the landfill shall be above the historical high groundwater table as provided below. Floodplains, shorelands, and groundwater recharge areas shall be avoided. There shall be no hydraulic connection between the site and standing or flowing surface water. The site shall have monitoring wells and leachate collection. The bottom of the landfill liner system or natural in-place soil barrier shall be at least fifty feet from the historical high water table.

(4) *Flood protection.* (i) If the landfill site is below the 100-year floodwater elevation, the operator shall provide surface water diversion dikes around the perimeter of the landfill site with a minimum height equal to two feet above the 100-year floodwater elevation.

(ii) If the landfill site is above the 100-year floodwater elevation, the operators shall provide diversion structures capable of diverting all of the surface water runoff from a 24-hour, 25-year storm.

(5) *Topography.* The landfill site shall be located in an area of low to moderate relief to minimize erosion and to help prevent landslides or slumping.

(6) *Monitoring systems*—(i) *Water sampling.* (A) For all sites receiving PCBs, the ground and surface water from the disposal site area shall be sampled prior to commencing operations under an approval provided in paragraph (c) of this section for use as baseline data.

(B) Any surface watercourse designated by the Regional Administrator using the authority provided in paragraph (c)(3)(ii) of this section shall be sampled at least monthly when the landfill is being used for disposal operations.

(C) Any surface watercourse designated by the Regional Administrator using the authority provided in paragraph (c)(3)(ii) of this section shall be sampled for a time period specified by the Regional Administrator on a frequency of no less than once every six months after final closure of the disposal area.

(ii) *Groundwater monitor wells.* (A) If underlying earth materials are homogenous, impermeable, and uniformly sloping in one direction, only three sampling points shall be necessary. These three points shall be equally spaced on a line through the center of the disposal area and extending from the area of highest water table elevation to the area of the lowest water table elevation on the property.

(B) All monitor wells shall be cased and the annular space between the monitor zone (zone of saturation) and the surface shall be completely backfilled with Portland cement or an equivalent material and plugged with Portland cement to effectively prevent percolation of surface water into the well bore. The well opening at the surface shall have a removable cap to provide access and to prevent entrance of rainfall or stormwater runoff. The well shall be pumped to remove the volume of liquid initially contained in the well before obtaining a sample for analysis. The discharge shall be treated to meet applicable State or Federal discharge standards or recycled to the chemical waste landfill.

(iii) *Water analysis.* As a minimum, all samples shall be analyzed for the following parameters, and all data and records of the sampling and analysis shall be maintained as required in §761.180(d)(1). Sampling methods and analytical procedures for these parameters shall comply with those specified in 40 CFR part 136 as amended in 41 FR 52779 on December 1, 1976.

(A) PCBs.

(B) pH.

(C) Specific conductance.

(D) Chlorinated organics.

(7) *Leachate collection.* A leachate collection monitoring system shall be installed above the chemical waste landfill. Leachate collection systems shall be monitored monthly for quantity and physicochemical characteristics of leachate produced. The leachate should be either treated to acceptable limits for discharge in accordance with a State or Federal permit or disposed of by another State or Federally approved method. Water analysis shall be conducted as provided in paragraph (b)(6)(iii) of this section. Acceptable leachate monitoring/collection systems shall be any of the following designs, unless a waiver is obtained pursuant to paragraph (c)(4) of this section.

(i) *Simple leachate collection.* This system consists of a gravity flow drainfield installed above the waste disposal unit liner. This design is recommended for use when semi-solid or leachable solid wastes are placed in a lined pit excavated into a relatively thick, unsaturated, homogenous layer of low permeability soil.

(ii) *Compound leachate collection.* This system consists of a gravity flow drainfield installed above the waste disposal unit liner and above a secondary installed liner. This design is recommended for use when semi-liquid

or leachable solid wastes are placed in a lined pit excavated into relatively permeable soil.

(iii) *Suction lysimeters.* This system consists of a network of porous ceramic cups connected by hoses/tubing to a vacuum pump. The porous ceramic cups or suction lysimeters are installed along the sides and under the bottom of the waste disposal unit liner. This type of system works best when installed in a relatively permeable unsaturated soil immediately adjacent to the bottom and/or sides of the disposal facility.

(8) *Chemical waste landfill operations.* (i) PCBs and PCB Items shall be placed in a landfill in a manner that will prevent damage to containers or articles. Other wastes placed in the landfill that are not chemically compatible with PCBs and PCB Items including organic solvents shall be segregated from the PCBs throughout the waste handling and disposal process.

(ii) An operation plan shall be developed and submitted to the Regional Administrator for approval as required in paragraph (c) of this section. This plan shall include detailed explanations of the procedures to be used for recordkeeping, surface water handling procedures, excavation and backfilling, waste segregation burial coordinates, vehicle and equipment movement, use of roadways, leachate collection systems, sampling and monitoring procedures, monitoring wells, environmental emergency contingency plans, and security measures to protect against vandalism and unauthorized waste placements. EPA guidelines entitled ''Thermal Processing and Land Disposal of Solid Waste'' (39 FR 29337, Aug. 14, 1974) are a useful reference in preparation of this plan. If the facility is to be used to dispose of liquid wastes containing between 50 ppm and 500 ppm PCB, the operations plan must include procedures to determine that liquid PCBs to be disposed of at the landfill do not exceed 500 ppm PCB and measures to prevent the migration of PCBs from the landfill. Bulk liquids not exceeding 500 ppm PCBs may be disposed of provided such waste is pretreated and/or stabilized (e.g., chemically fixed, evaporated, mixed with dry inert absorbant) to reduce its liquid content or increase its solid content so that a non-flowing consistency is achieved to eliminate the presence of free liquids prior to final disposal in a landfill. PCB Container of liquid PCBs with a concentration between 50 and 500 ppm PCB may be disposed of if each container is surrounded by an amount of inert sorbant material capable of absorbing all of the liquid contents of the container.

(iii) Ignitable wastes shall not be disposed of in chemical waste landfills. Liquid ignitable wastes are wastes that have a flash point less than 60 °C (140 °F) as determined by the following method or an equivalent method: Flash point of liquids shall be determined by a Pensky-Martens Closed Cup Tester, using the protocol specified in ASTM D93–09, or the Setaflash Closed Tester using the protocol specified in ASTM D3278–89 (all standards incorporated by reference in § 761.19).

(iv) Records shall be maintained for all PCB disposal operations and shall include information on the PCB concentration in liquid wastes and the three dimensional burial coordinates for PCBs and PCB Items. Additional records shall be developed and maintained as required in § 761.180.

(9) *Supporting facilities.* (i) A six foot woven mesh fence, wall, or similar device shall be placed around the site to prevent unauthorized persons and animals from entering.

(ii) Roads shall be maintained to and within the site which are adequate to support the operation and maintenance of the site without causing safety or nuisance problems or hazardous conditions.

(iii) The site shall be operated and maintained in a manner to prevent safety problems or hazardous conditions resulting from spilled liquids and windblown materials.

(c) *Approval of chemical waste landfills.* Prior to the disposal of any PCBs and PCB Items in a chemical waste landfill, the owner or operator of the landfill shall receive written approval of the Agency Regional Administrator for the Region in which the landfill is located. The approval shall be obtained in the following manner:

(1) *Initial report.* The owner or operator shall submit to the Regional Administrator an initial report which contains:

(i) The location of the landfill;

(ii) A detailed description of the landfill including general site plans and design drawings;

(iii) An engineering report describing the manner is which the landfill complies with the requirements for chemical waste landfills specified in paragraph (b) of this section;

(iv) Sampling and monitoring equipment and facilities available;

(v) Expected waste volumes of PCBs;

(vi) General description of waste materials other than PCBs that are expected to be disposed of in the landfill;

(vii) Landfill operations plan as required in paragraph (b) of this section;

(viii) Any local, State, or Federal permits or approvals; and

(ix) Any schedules or plans for complying with the approval requirements of these regulations.

(2) *Other information.* In addition to the information contained in the report described in paragraph (c)(1) of this section, the Regional Administrator may require the owner or operator to submit any other information that the Regional Administrator finds to be reasonably necessary to determine whether a chemical waste landfill should be approved. Such other information shall be restricted to the types of information required in paragraphs (c)(1) (i) through (ix) of this section.

(3) *Contents of approval.* (i) Except as provided in paragraph (c)(4) of this section the Regional Administrator may not approve a chemical waste landfill for the disposal of PCBs and PCB Items, unless he finds that the landfill meets all of the requirements of paragraph (b) of this section.

(ii) In addition to the requirements of paragraph (b) of this section, the Regional Administrator may include in an approval any other requirements or provisions that the Regional Administrator finds are necessary to ensure that operation of the chemical waste landfill does not present an unreasonable risk of injury to health or the environment from PCBs. Such provisions may include a fixed period of time for which the approval is valid. The approval may also include a stipulation that the operator of the chemical waste landfill report to the Regional Administrator any instance when PCBs are detectable during monitoring activities conducted pursuant to paragraph (b)(6) of this section.

(4) *Waivers.* An owner or operator of a chemical waste landfill may submit evidence to the Regional Administrator that operation of the landfill will not present an unreasonable risk of injury to health or the environment from PCBs when one or more of the requirements of paragraph (b) of this section are not met. On the basis of such evidence and any other available information, the Regional Administrator may in his discretion find that one or more of the requirements of paragraph (b) of this section is not necessary to protect against such a risk and may waive the requirements in any approval for that landfill. Any finding and waiver under this paragraph will be stated in writing and included as part of the approval.

(5) *Persons approved.* Any approval will designate the persons who own and who are authorized to operate the chemical waste landfill, and will apply only to such persons, except as provided by paragraph (c)(7) of this section.

(6) *Final approval.* Approval of a chemical waste landfill will be in writing and will be signed by the Regional Administrator. The approval will state all requirements applicable to the approved landfill.

(7) *Transfer of property.* Any person who owns or operates an approved chemical waste landfill must notify EPA at least 30 days before transferring ownership in the property or transferring the right to conduct the chemical waste landfill operation. The transferor must also submit to EPA, at least 30 days before such transfer, a notarized affidavit signed by the transferee which states that the transferee will abide by the transferor's EPA chemical waste landfill approval. Within 30 days of receiving such notification and affidavit, EPA will issue an amended approval substituting the transferee's name for the transferor's name, or EPA may require the transferee to apply for a new chemical waste

landfill approval. In the latter case, the transferee must abide by the transferor's EPA approval until EPA issues the new approval to the transferee.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982, and amended at 48 FR 5730, Feb. 8, 1983; 49 FR 28191, July 10, 1984; 53 FR 12524, Apr. 15, 1988; 53 FR 21641, June 9, 1988; 57 FR 13323, Apr. 16, 1992; 63 FR 35456, June 29, 1998; 77 FR 2464, Jan. 18, 2012]

§ 761.77 Coordinated approval.

(a) *General requirements.* Notwithstanding any other provision of this part, the EPA Regional Administrator for the Region in which a PCB disposal or PCB commercial storage facility described in paragraphs (b) and (c) of this section is located may issue a TSCA PCB Coordinated Approval to the persons described in those paragraphs if the conditions listed in this section are met. A TSCA PCB Coordinated Approval will designate the persons who own and who are authorized to operate the facilities described in paragraphs (b) and (c) of this section and will apply only to such persons. All requirements, conditions, and limitations of any other permit or waste management document cited or described in paragraphs (b) and (c) of this section, as the technical or legal basis on which the TSCA PCB Coordinated Approval is issued, are conditions of the TSCA PCB Coordinated Approval.

(1) Persons seeking a TSCA PCB Coordinated Approval shall submit a request for approval by certified mail, to the EPA Regional Administrator for the Region in which the activity will take place. Persons seeking a TSCA PCB Coordinated Approval for a new PCB activity shall submit the request for approval at the same time they seek a permit, approval, or other action for a PCB waste management activity under any other Federal or State authority.

(i) The request for a TSCA PCB Coordinated Approval shall include a copy of the letter from EPA announcing or confirming the EPA identification number issued to the facility for conducting PCB activities; the name, organization, and telephone number of the person who is the contact point for the non-TSCA Federal or State waste management authority; a copy of the relevant permit or waste management document specified in paragraphs (b) and (c) of this section, including all requirements, conditions, and limitations, if the EPA Regional Administrator does not have a copy of the document, or a description of the waste management activities to be conducted if a permit or other relevant waste management document has not been issued; and a certification that the person who owns or operates the facility is aware of and will adhere to the TSCA PCB reporting and recordkeeping requirements at subparts J and K of this part.

(ii) The EPA Regional Administrator shall review the request for completeness, for compliance with the requirements of paragraphs (b) and (c) of this section, and to ensure that the PCB activity for which approval is requested will not present an unreasonable risk of injury to health or the environment. The EPA Regional Administrator shall either:

(A) Issue a written notice of deficiency explaining why the request for approval is deficient. If appropriate, the EPA Regional Administrator may either:

(*1*) Request additional information to cure the deficiency.

(*2*) Deny the request for a TSCA PCB Coordinated Approval.

(B) Issue a letter granting or denying the TSCA PCB Coordinated Approval. If the EPA Regional Administrator grants the TSCA PCB Coordinated Approval, he or she may acknowledge the non-TSCA approval meets the regulatory requirements under TSCA as written, or require additional conditions the EPA Regional Administrator has determined are necessary to prevent unreasonable risk of injury to health or the environment.

(C) If the EPA Regional Administrator denies a request for a Coordinated Approval under paragraphs (a)(1)(ii)(A) or (a)(1)(ii)(B) of this section, the person who requested the TSCA PCB Coordinated Approval may submit an application for a TSCA Disposal Approval.

(2) The EPA Regional Administrator may issue a notice of deficiency, revoke the TSCA PCB Coordinated Approval, require the person to whom the TSCA PCB Coordinated Approval was issued to submit an application for a TSCA PCB approval, or bring an enforcement action under TSCA if he or she determines that:

(i) Conditions of the approval relating to PCB waste management activities are not met.

(ii) The PCB waste management process is being operated in a manner which may result in an unreasonable risk of injury to health or the environment.

(iii) The non-TSCA approval expires, is revoked, is suspended, or otherwise ceases to be in full effect.

(3) Any person with a TSCA PCB Coordinated Approval must notify the EPA Regional Administrator in writing within 5 calendar days of changes relating to PCB waste requirements in the non-TSCA waste management document which serves as the basis for a TSCA PCB Coordinated Approval. Changes in the ownership of a commercial storage facility which holds a TSCA PCB Coordinated Approval shall be handled pursuant to § 761.65(j).

(b) Any person who owns or operates a facility that he or she intends to use to landfill PCB wastes; incinerate PCB wastes; dispose of PCB wastes using an alternative disposal method that is equivalent to disposal in an incinerator approved under § 761.70 or a high efficiency boiler operating in compliance with § 761.71; or stores PCB wastes may apply for a TSCA PCB Coordinated Approval. The EPA Regional Administrator may approve the request if the EPA Regional Administrator determines that the activity will not pose an unreasonable risk of injury to health or the environment and the person:

(1)(i) Has a waste management permit or other decision or enforcement document which exercises control over PCB wastes, issued by EPA or an authorized State Director for a State program that has been approved by EPA and is no less stringent in protection of health or the environment than the applicable TSCA requirements found in this part; or

(ii) Has a PCB waste management permit or other decision or enforcement document issued by a State Director pursuant to a State PCB waste management program no less stringent in protection of health or the environment than the applicable TSCA requirements found in this part; or

(iii) Is subject to a waste management permit or other decision or enforcement document which is applicable to the disposal of PCBs and which was issued through the promulgation of a regulation published in Title 40 of the Code of Federal Regulations.

(2) Complies with the terms and conditions of the permit or other decision or enforcement document described in paragraph (b)(1) of this section.

(3) Unless otherwise waived or modified in writing by the EPA Regional Administrator, complies with § 761.75(b); § 761.70(a)(1) through (a)(9), (b)(1) and (b)(2), and (c); or the PCB storage requirements at §§ 761.65(a), (c), and (d)(2), as appropriate.

(4) Complies with the reporting and recordkeeping requirements in subparts J and K of this part.

(c) A person conducting research and development (R&D) into PCB disposal methods (regardless of PCB concentration), or conducting PCB remediation activities may apply for a TSCA PCB Coordinated Approval. The EPA Regional Administrator may approve the request if the EPA Regional Administrator determines that the activity will not pose an unreasonable risk of injury to health or the environment and the person:

(1)(i) Has a permit or other decision and enforcement document issued or otherwise agreed to by EPA, or permit or other decision and enforcement document issued by an authorized State Director for a State program that has been approved by EPA, which exercises control over the management of PCB wastes, and that person is in compliance with all terms and conditions of that document; or

(ii) Has a permit, which exercises control over the management of PCB wastes, issued by a State Director pursuant to a State PCB disposal program no less stringent than the requirements in this part.

(2) Complies with the terms and conditions of that permit or other decision and enforcement document.

(3) Complies with the reporting and recordkeeping requirements in subparts J and K of this part.

[63 FR 35456, June 29, 1998]

§ 761.79 Decontamination standards and procedures.

(a) *Applicability*. This section establishes decontamination standards and procedures for removing PCBs, which are regulated for disposal, from water, organic liquids, non-porous surfaces (including scrap metal from disassembled electrical equipment), concrete, and non-porous surfaces covered with a porous surface, such as paint or coating on metal.

(1) Decontamination in accordance with this section does not require a disposal approval under subpart D of this part.

(2) Materials from which PCBs have been removed by decontamination in accordance with this section may be distributed in commerce in accordance with § 761.20(c)(5).

(3) Materials from which PCBs have been removed by decontamination in accordance with this section may be used or reused in accordance with § 761.30(u).

(4) Materials from which PCBs have been removed by decontamination in accordance with this section, not including decontamination waste and residuals under paragraph (g) of this section, are unregulated for disposal under subpart D of this part.

(5) Any person decontaminating porous surfaces other than concrete under paragraph (b)(4) of this section and non-porous surfaces covered with a porous surface, such as paint or coating on metal, under paragraph (b)(3) or (c)(6) of this section must obtain an alternative decontamination approval in accordance with paragraph (h) of this section.

(6) Any person engaging in decontamination under this section is responsible for determining and complying with all other applicable Federal, State, and local laws and regulations.

(b) *Decontamination standards*. Chopping (including wire chopping), distilling, filtering, oil/water separation, spraying, soaking, wiping, stripping of insulation, scraping, scarification or the use of abrasives or solvents may be used to remove or separate PCBs, to the following standards, from liquids, concrete, or non-porous surfaces.

(1) The decontamination standard for water containing PCBs is:

(i) Less than 200 µg/L (i.e., <200 ppb PCBs) for non-contact use in a closed system where there are no releases;

(ii) For water discharged to a treatment works (as defined in § 503.9(aa) of this chapter) or to navigable waters, <3 µg/L (approximately <3 ppb) or a PCB discharge limit included in a permit issued under section 307(b) or 402 of the Clean Water Act; or

(iii) Less than or equal to 0.5 µg/L (i.e., approximately ≤0.5 ppb PCBs) for unrestricted use.

(2) The decontamination standard for organic liquids and non-aqueous inorganic liquids containing PCBs is <2 milligrams per kilogram (i.e., <2 ppm PCBs).

(3) The decontamination standard for non-porous surfaces in contact with liquid and non-liquid PCBs is:

(i) For unrestricted use:

(A) For non-porous surfaces previously in contact with liquid PCBs at any concentration, where no free-flowing liquids are currently present, ≤10 micrograms PCBs per 100 square centimeters (≤10 µg/100 cm^2) as measured by a standard wipe test (§ 761.123) at locations selected in accordance with subpart P of this part.

(B) For non-porous surfaces in contact with non-liquid PCBs (including non-porous surfaces covered with a porous surface, such as paint or coating on metal), cleaning to Visual Standard No. 2, Near-White Blast Cleaned Surface Finish, of the National Association of Corrosion Engineers (NACE). A person shall verify compliance with standard No. 2 by visually inspecting all cleaned areas.

(ii) For disposal in a smelter operating in accordance with § 761.72(b):

(A) For non-porous surfaces previously in contact with liquid PCBs at any concentration, where no free-flowing liquids are currently present, <100 µg/100 cm^2 as measured by a standard

wipe test (§ 761.123) at locations selected in accordance with subpart P of this part.

(B) For non-porous surfaces in contact with non-liquid PCBs (including non-porous surfaces covered with a porous surface, such as paint or coating on metal), cleaning to Visual Standard No. 3, Commercial Blast Cleaned Surface Finish, of the National Association of Corrosion Engineers (NACE). A person shall verify compliance with standard No. 3 by visually inspecting all cleaned areas.

(4) The decontamination standard for concrete is ≤10 μg/100 cm^2 as measured by a standard wipe test (§ 761.123) if the decontamination procedure is commenced within 72 hours of the initial spill of PCBs to the concrete or portion thereof being decontaminated.

(c) *Self-implementing decontamination procedures.* The following self-implementing decontamination procedures are available as an alternative to the measurement-based decontamination methods specified in paragraph (b) of this section. Any person performing self-implementing decontamination must comply with one of the following procedures.

(1) Any person decontaminating a PCB Container must do so by flushing the internal surfaces of the container three times with a solvent containing <50 ppm PCBs. Each rinse shall use a volume of the flushing solvent equal to approximately 10 percent of the PCB Container capacity.

(2) Any person decontaminating movable equipment contaminated by PCBs, tools, and sampling equipment may do so by:

(i) Swabbing surfaces that have contacted PCBs with a solvent;

(ii) A double wash/rinse as defined in subpart S of this part; or

(iii) Another applicable decontamination procedure in this section.

(3) Any person decontaminating a non-porous surface in contact with free-flowing mineral oil dielectric fluid (MODEF) at levels ≤10,000 ppm PCBs must do so as follows:

(i) Drain the free-flowing MODEF and allow the residual surfaces to drain for an additional 15 hours.

(ii) Dispose of drained MODEF according to paragraph (g) of this section.

(iii) Soak the surfaces to be decontaminated in a sufficient amount of clean (containing <2 ppm PCBs) performance-based organic decontamination fluid (PODF) such that there is a minimum of 800 ml of PODF for each 100 cm^2 of contaminated or potentially contaminated surface for at least 15 hours at ≥20 °C.

(iv) Approved PODFs include:

(A) Kerosene.

(B) Diesel fuel.

(C) Terpene hydrocarbons.

(D) Mixtures of terpene hydrocarbons and terpene alcohols.

(v) Drain the PODF from the surfaces.

(vi) Dispose of the drained PODF in accordance with paragraph (g) of this section.

(4) Any person decontaminating a non-porous surface in contact with free-flowing MODEF containing >10,000 ppm PCB in MODEF or askarel PCB (up to 70 percent PCB in a mixture of trichlorobenzenes and tetrachlorobenzenes) must do so as follows:

(i) Drain the free-flowing MODEF or askarel and allow the residual surfaces to drain for an additional 15 hours.

(ii) Dispose of drained MODEF or askarel according to paragraph (g) of this section.

(iii) Soak the surfaces to be decontaminated in a sufficient amount of clean PODF (containing <2 ppm PCBs) such that there is a minimum of 800 ml of PODF for each 100 cm^2 of contaminated or potentially contaminated surface for at least 15 hours at ≥20 °C.

(iv) Approved PODFs include:

(A) Kerosene.

(B) Diesel fuel.

(C) Terpene hydrocarbons.

(D) Mixtures of terpene hydrocarbons and terpene alcohols.

(v) Drain the PODF from the surfaces.

(vi) Dispose of the drained PODF in accordance with paragraph (g) of this section.

(vii) Resoak the surfaces to be decontaminated, pursuant to paragraph (c)(3)(iii) of this section, in a sufficient amount of clean PODF (containing <2

ppm PCBs) such that there is a minimum of 800 ml of PODF for each 100 cm^2 of surface for at least 15 hours at ≥20 °C.

(viii) Drain the PODF from the surfaces.

(ix) Dispose of the drained PODF in accordance with paragraph (g) of this section.

(5) Any person decontaminating piping and air lines in an air compressor system must do so as follows:

(i) Before decontamination proceeds, disconnect or bypass the air compressors and air dryers from the piping and air lines and decontaminate the air compressors and air dryers separately in accordance with paragraphs (b), (c)(1) through (c)(4), or (c)(6) of this section. Dispose of filter media and desiccant in the air dyers based on their existing PCB concentration.

(ii) Test the connecting line and appurtenances of the system to assure that there is no leakage. Test by introducing air into the closed system at from 90 to 100 pounds per square inch (psi). Only if there is a pressure drop of <5 psi in 30 minutes may decontamination take place.

(iii) When there is no leakage, fill the piping and air lines with clean (containing <2 ppm PCBs) solvent. Solvents include PODF, aqueous potassium hydroxide at a pH between 9 and 12, or water containing 5 percent sodium hydroxide by weight.

(iv) Circulate the solvent to achieve turbulent flow through the piping and air lines in the air compressor system until the total volume of solvent circulated equals 10 times the total volume of the particular article being decontaminated, then drain the solvent. Calculate the total volume of solvent circulated by multiplying the pump rate by the time of pumping. Turbulent flow means a Reynolds number range from 20,000 to 43,000. Refill the system with clean solvent and repeat the circulation and drain process.

(6) Any person using thermal processes to decontaminate metal surfaces in contact with PCBs, as required by § 761.62(a)(6), must use one of the following options:

(i) Surfaces in contact with liquid and non-liquid PCBs at concentrations <500 ppm may be decontaminated in a scrap metal recovery oven or smelter for purposes of disposal in accordance with § 761.72.

(ii) Surfaces in contact with liquid or non-liquid PCBs at concentrations ≥500 ppm may be smelted in a smelter operating in accordance with § 761.72(b), but must first be decontaminated in accordance with § 761.72(a) or to a surface concentration of <100 µg/100 cm^2.

(d) *Decontamination solvents.* (1) Unless otherwise provided in paragraphs (c)(3) through (c)(5) of this section, the solubility of PCBs in any solvent used for purposes of decontamination under this section must be 5 percent or more by weight.

(2) The solvent may be reused for decontamination so long as its PCB concentration is <50 ppm.

(3) Solvent shall be disposed of under paragraph (g) of this section.

(4) Other than as allowed in paragraphs (c)(3) and (c)(4) of this section, solvents may be tested and validated for performance-based decontamination of non-porous surfaces contaminated with MODEF or other PCB liquids, in accordance with the self-implementing procedures found in subpart T of this part. Specific conditions for the performance-based testing from this validation are determined in the validation study.

(e) *Limitation of exposure and control of releases.* (1) Any person conducting decontamination activities under this section shall take necessary measures to protect against direct release of PCBs to the environment from the decontamination area.

(2) Persons participating in decontamination activities shall wear or use protective clothing or equipment to protect against dermal contact or inhalation of PCBs or materials containing PCBs.

(f) *Sampling and recordkeeping.* (1) Confirmatory sampling is required under paragraph (b) of this section. For liquids described in paragraphs (b)(1) and (b)(2) of this section, sample in accordance with §§ 761.269 and 761.272. For non-porous surfaces and concrete described in paragraphs (b)(3) and (b)(4) of this section, sample in accordance with subpart P of this part. A written record of such sampling must be established and maintained for 3 years from the

date of any decontamination under this section. The record must show sampling locations and analytical results and must be retained at the site of the decontamination or a copy of the record must be made available to EPA in a timely manner, if requested. In addition, recordkeeping is required in accordance with §761.180(a) for all wastes generated by a decontamination process and regulated for disposal under this subpart.

(2) Confirmatory sampling is not required for self-implementing decontamination procedures under paragraph (c) of this section. Any person using these procedures must retain a written record documenting compliance with the procedures for 3 years after completion of the decontamination procedures (e.g., video recordings, photographs).

(g) *Decontamination waste and residues.* Decontamination waste and residues shall be disposed of at their existing PCB concentration unless otherwise specified.

(1) Distillation bottoms or residues and filter media are regulated for disposal as PCB remediation waste.

(2) PCBs physically separated from regulated waste during decontamination (such as by chopping, shredding, scraping, abrading or oil/water separation, as opposed to solvent rinsing and soaking), other than wastes described in paragraph (g)(1) of this section, are regulated for disposal at their original concentration.

(3) Hydrocarbon solvent used or reused for decontamination under this section that contains <50 ppm PCB must be burned and marketed in accordance with the requirements for used oil in §761.20(e), disposed of in accordance with §761.60(a) or (e), or decontaminated pursuant to this section.

(4) Chlorinated solvent at any PCB concentration used for decontamination under this section shall be disposed of in an incinerator operating in compliance with §761.70, or decontaminated pursuant to this section.

(5) Solvents ≥50 ppm other than those described in paragraphs (g)(3) and (g)(4) of this section shall be disposed of in accordance with §761.60(a) or decontaminated pursuant to this section.

(6) Non-liquid cleaning materials and personal protective equipment waste at any concentration, including non-porous surfaces and other non-liquid materials such as rags, gloves, booties, other disposable personal protective equipment, and similar materials resulting from decontamination shall be disposed of in accordance with §761.61(a)(5)(v).

(h) *Alternative decontamination or sampling approval.* (1) Any person wishing to decontaminate material described in paragraph (a) of this section in a manner other than prescribed in paragraph (b) of this section must apply in writing to the Regional Administrator in the Region where the activity would take place, for decontamination activity occurring in a single EPA Region; or to the Director, Office of Resource Conservation and Recovery, for decontamination activity occurring in more than one EPA Region. Each application must describe the material to be decontaminated and the proposed decontamination method, and must demonstrate that the proposed method is capable of decontaminating the material to the applicable level set out in paragraphs (b)(1) through (b)(4) of this section.

(2) Any person wishing to decontaminate material described in paragraph (a) of this section using a self-implementing procedure other than prescribed in paragraph (c) of this section must apply in writing to the Regional Administrator in the Region where the activity would take place, for decontamination activity occurring in a single EPA Region; or to the Director, Office of Resource Conservation and Recovery, for decontamination activity occurring in more than one EPA Region. Each application must describe the material to be decontaminated and the proposed self-implementing decontamination method and must include a proposed validation study to confirm performance of the method.

(3) Any person wishing to sample decontaminated material in a manner other than prescribed in paragraph (f) of this section must apply in writing to the Regional Administrator in the Region where the activity would take place, for decontamination activity occurring in a single EPA Region; or to

the Director, Office of Resource Conservation and Recovery, for decontamination activity occurring in more than one EPA Region. Each application must contain a description of the material to be decontaminated, the nature and PCB concentration of the contaminating material (if known), the decontamination method, the proposed sampling procedure, and a justification for how the proposed sampling is equivalent to or more comprehensive than the sampling procedure required under paragraph (f) of this section.

(4) EPA may request additional information that it believes necessary to evaluate the application.

(5) EPA will issue a written decision on each application for risk-based decontamination or sampling. No person may conduct decontamination or sampling under this paragraph prior to obtaining written approval from EPA. EPA will approve an application if it finds that the proposed decontamination or sampling method will not pose an unreasonable risk of injury to health or the environment.

[63 FR 35457, June 29, 1998, as amended at 64 FR 33761, June 24, 1999; 72 FR 57240, Oct. 9, 2007; 74 FR 30233, June 25, 2009]

Subpart E—Exemptions

§ 761.80 Manufacturing, processing and distribution in commerce exemptions.

(a) The Administrator grants the following petitioner(s) an exemption for 1 year to process and distribute in commerce PCBs for use as a mounting medium in microscopy:

(1) McCrone Accessories Components, Division of Walter C. McCrone Associates, Inc., 2820 South Michigan Avenue, Chicago, IL. 60616.

(2) [Reserved]

(b) The Administrator grants the following petitioner(s) an exemption for 1 year to process and distribute in commerce PCBs for use as a mounting medium in microscopy, an immersion oil in low fluorescence microscopy and an optical liquid:

(1) R.P. Cargille Laboratories, Inc., 55 Commerce Road, Cedar Grove, N.J. 07009.

(2) [Reserved]

(c) The Administrator grants the following petitioner(s) an exemption for 1 year to export PCBs for use in small quantities for research and development:

(1) Accu-Standard, New Haven, CT. 06503.

(2) ManTech, Research Triangle Park, NC 27709.

(d) The Administrator grants the following petitioner(s) an exemption for 1 year to import (manufacture) into the United States, small quantities of existing PCB fluids from electrical equipment for analysis:

(1) Unison Transformer Services, Inc., Tarrytown, N.Y. 10591, provided each of the following conditions are met:

(i) The samples must be shipped in 5.0 ml or less, hermetically sealed vials.

(ii) The exemption is limited to no more than 250 total samples per year.

(iii) Unison makes quarterly inspections of its laboratories to ensure that proper safety procedures are being followed.

(iv) Unison annually notifies and describes to EPA its attempts to have samples analyzed abroad.

(2) [Reserved]

(e) The Administrator grants a class exemption to all research and development (R&D) facilities for a period of 1 year to manufacture or import PCBs for use solely in the manufacturer or importer's own research for the development of PCB disposal technologies. Each person that wishes to be part of the exemption must meet the following conditions:

(1) A petition for an exemption from the PCB prohibition on manufacturing PCBs must be received by EPA 60 days prior to engaging in these activities.

(2) Requests for renewal must be filed pursuant to § 750.11 of this chapter. EPA will deem any properly filed request for the renewal of the exemption by any member of the class as a renewal request for the entire class.

(3) The quantity of the PCBs manufactured annually must not exceed 500 grams by total weight of pure PCBs. Any person who wishes to manufacture or import more than 500 grams of PCBs in 1 year must receive written approval from the Director, National Program

Chemicals Division to exceed the limitations established by this provision. The Director, National Program Chemicals Division may grant approval without further rulemaking. Any increase granted will be in writing and will extend only for a maximum of the time remaining in a specific exemption year.

(4) The owner or operator of the facility must notify the EPA Regional Administrator in writing 30 days prior to the commencement of R&D activities that include the manufacture or import of PCBs under the exemption, unless the facility has obtained a PCB R&D approval from EPA pursuant to §761.60(e), §761.60(i)(2), §761.70(a), or §761.70(b) and the approval contains a provision allowing the manufacture of PCBs.

(5) Records are maintained of their PCB activities for a period of 3 years after ceasing operations. The records must include the sources and the annual amounts of PCBs received if imported and the type and annual amount of PCBs that were manufactured.

(6) All PCBs and materials containing PCBs, regardless of concentration, remaining from the disposal-related studies must be disposed of according to §761.60(j)(1)(vi), or decontaminated pursuant to §761.79, based on the original PCB concentration.

(f) The Administrator grants the following petitioner(s) an exemption for 1 year to manufacture PCBs for use in small quantities for research and development:

(1) California Bionuclear Corp., Sun Valley, CA 91352 (ME–13).

(2) Foxboro Co., North Haven, CT 06473 (ME–6).

(3) ULTRA-Scientific, Inc.,Hope, RI 02831 (ME–99.1).

(4) Midwest Research Institute, Kansas City, MO 64110 (ME–70.1).

(5) Pathfinder Laboratories, St. Louis, MO 63146 (A division of Sigma Aldridge Corporation, St. Louis, MO, 63178 (ME–76).

(6) Radian Corp., Austin, TX 78766 (ME–81.2).

(7) Wellington Sciences USA, College Station, TX 77840 (ME–104.1).

(8) Accu-Standard, 25 Science Park, New Haven, CT. 06503.

(g) The Administrator grants a class exemption to all processors and distributors of PCBs in small quantities for research and development provided that the following conditions are met:

(1) All processors and distributors must maintain records of their PCB activities for a period of 5 years.

(2) Any person or company which expects to process or distribute in commerce 100 grams (.22 lb) or more PCBs in 1 year must report to EPA identifying the sites of PCB activities and the quantity of PCBs to be processed or distributed in commerce.

(h) The Administrator grants the following petitioners an exemption for 1 year to process and distribute in commerce PCBs for analytical reference samples derived from actual waste materials:

(1) R.T. Corporation, Laramie, WY 82070.

(2) [Reserved]

(i) The Administrator grants a class exemption to all persons who manufacture, import, process, distribute in commerce, or export PCBs, or analytical reference samples derived from PCB waste material, provided the PCBs are manufactured, imported, processed, distributed in commerce, or exported solely for the purpose of R&D and the following conditions are met:

(1) Notification in the form of a petition for an exemption from the PCB prohibitions on manufacture, import, processing, distribution in commerce, or export is received by EPA 60 days prior to engaging in these activities.

(2) Requests for renewal are filed pursuant to §§750.11 and 750.31 of this chapter. EPA will deem any properly filed request for the renewal of the exemption by any member of the class as a renewal request for the entire class.

(3) The PCBs are packaged in one or more hermetically sealed containers of a volume of no more than 5.0 ml each. Analytical reference samples derived from PCB waste material may be packaged in a container larger than 5.0 ml when packaged pursuant to applicable DOT performance standards.

(4) The quantity of PCBs manufactured, imported, processed, distributed in commerce, or exported annually must not exceed 500 grams by total weight of pure PCBs. Any person who

expects to manufacture, import, process, distribute in commerce, or export more than 500 grams of PCBs in 1 year or to exceed the 5.0 ml packaging requirement must obtain a written approval from the Director, National Program Chemicals Division and must identify the sites of PCB activities and the quantity of PCBs to be manufactured, imported, processed, distributed in commerce, or exported. Each request must include a justification. The Director, National Program Chemicals Division, may grant approval without further rulemaking. Any increase granted will be in writing and will extend only for a maximum of the time remaining in a specific exemption year.

(5) All treated and untreated PCB regulated material and material coming into contact with regulated material must be stored and disposed of according to subpart D of this part, or decontaminated pursuant to §761.79.

(6) All PCB materials must be distributed in DOT-authorized packaging.

(7) Records are maintained of their PCB activities for a period of 3 years after ceasing operations. The records must include the sources and the annual amounts of PCBs received if imported, the annual amount of PCBs that were manufactured, the annual amount of PCBs that were processed and/or distributed in commerce (to include export), and the persons to whom the PCBs were shipped.

(j) The Administrator grants the United States Defense Logistics Agency's April 23, 2013 petition for an exemption for 1 year beginning on October 1, 2014, to import up to 1,014,222 pounds of PCBs and PCB Items stored or in use in Japan as identified in its petition for disposal.

(k)–(l) [Reserved]

(m) The Administrator grants the following petitioner(s) an exemption for 1 year to process and export small quantities of PCBs for research and development:

(1) Chem Service, Inc., West Chester, PA 19380 (PDE–41).

(2) Foxboro Co., North Haven, CT 06473 (ME–6).

(3) PolyScience Corp., Niles, IL 60648 (PDE–178).

(4) ULTRA-Scientific, Inc., Hope, RI 02831 (PDE–282.1).

(5) Supelco, Inc., Bellefonte, PA 16823–0048 (PDE–41.2).

(6) Radian Corp., Austin, TX 78766 (PDE–182.1).

(7) Restek Corporation, Bellefonte, PA

(n) The 1–year exemption granted to petitioners in paragraphs (a) through (c)(1), (d), (f), and (m)(1) through (m)(6) of this section shall be renewed automatically as long as there is no increase in the amount of PCBs to be processed and distributed, imported (manufactured), or exported, nor any change in the manner of processing and distributing, importing (manufacturing), or exporting of PCBs. If there is such a change, a new exemption petition must be submitted to EPA and it will be addressed through an exemption rulemaking. In such a case, the activities granted under the existing exemption may continue until the new petition is addressed by rulemaking, but must conform to the terms of the existing exemption approved by EPA. The 1–year exemption granted to petitioners in paragraphs (c)(2), (h) and (m)(7) of this section may be extended pursuant to 40 CFR 750.11(e) or 750.31(e).

(o) The 1–year class exemption granted to all processors and distributors of PCBs in small quantities for research and development in paragraph (g) of this section shall be renewed automatically unless information is submitted affecting EPA's conclusion that the class exemption, or the activities of any individual or company included in the exemption, will not pose an unreasonable risk of injury to health or the environment. EPA will evaluate the information, issue a proposed rule for public comment, and issue a final rule affecting the class exemption or individuals or companies included in the class exemption. Until EPA issues a final rule, individuals and companies included in the class exemption will be allowed to continue processing and distributing PCBs in small quantities for research and development.

[55 FR 38999, Sept. 24, 1990, as amended at 59 FR 16998, Apr. 11, 1994; 63 FR 35460, June 29, 1998; 68 FR 4941, Jan. 31, 2003; 72 FR 53158, Sept. 18, 2007; 79 FR 58270, Sept. 29, 2014]

Subpart F—Transboundary Shipments of PCBs for Disposal

SOURCE: 61 FR 11107, Mar. 18, 1996, unless otherwise noted.

§ 761.91 Applicability.

This subpart establishes requirements under section 6 of TSCA applicable to the transboundary shipments of PCBs and PCB Items into and out of the United States for disposal. Nothing in this subpart is intended to obviate or otherwise alter obligations applicable to imported or exported PCBs and PCB Items under foreign laws, international agreements or arrangements, other United States statutes and regulations, other sections of TSCA (e.g., sections 13 and 14), or laws of the various States of the United States. No provision of this section shall be construed to affect or limit the applicability of any requirement applicable to transporters of PCB waste under regulations issued by the U.S. Department of Transportation (DOT) and set forth at 49 CFR parts 171-180.

§ 761.93 Import for disposal.

(a) *General provisions.* No person may import PCBs or PCB Items for disposal without an exemption issued under the authority of TSCA section 6(e)(3).

(b) [Reserved]

[63 FR 35460, June 29, 1998]

§ 761.97 Export for disposal.

(a) General provisions. No person may export PCBs or PCB Items for disposal without an exemption, except that:

(1) PCBs and PCB Items at concentrations <50 ppm (or <10 μg PCB/100 cm^2 if no free-flowing liquids are present) may be exported for disposal.

(2) For the purposes of this section, PCBs and PCB Items of unknown concentrations shall be treated as if they contain ≥50 ppm.

(b) [Reserved]

[61 FR 11107, Mar. 18, 1996, as amended at 63 FR 35460, June 29, 1998]

§ 761.99 Other transboundary shipments.

For purposes of this subpart, the following transboundary shipments are not considered exports or imports:

(a) PCB waste generated in the United States, transported outside the Customs Territory of the United States (including any residuals resulting from cleanup of spills of such wastes in transit) through another country or its territorial waters, or through international waters, and returned to the United States for disposal.

(b) PCB waste in transit, including any residuals resulting from cleanup of spills during transit, through the United States (e.g., from Mexico to Canada, from Canada to Mexico).

(c) PCB waste transported from any State to any other State for disposal, regardless of whether the waste enters or leaves the customs territory of the United States, provided that the PCB waste or the PCBs from which the waste was derived were present in the United States on January 1, 1979, and have remained within the United States since that date.

[63 FR 35461, June 29, 1998, as amended at 66 FR 17478, Mar. 30, 2001]

Subpart G—PCB Spill Cleanup Policy

SOURCE: 52 FR 10705, Apr. 2, 1987, unless otherwise noted.

§ 761.120 Scope.

(a) *General.* This policy establishes criteria EPA will use to determine the adequacy of the cleanup of spills resulting from the release of materials containing PCBs at concentrations of 50 ppm or greater. The policy applies to spills which occur after May 4, 1987.

(1) Existing spills (spills which occurred prior to May 4, 1987, are excluded from the scope of this policy for two reasons:

(i) For old spills which have already been discovered, this policy is not intended to require additional cleanup where a party has already cleaned a spill in accordance with requirements imposed by EPA through its regional offices, nor is this policy intended to

interfere with ongoing litigation of enforcement actions which bring into issue PCB spills cleanup.

(ii) EPA recognizes that old spills which are discovered after the effective date of this policy will require site-by-site evaluation because of the likelihood that the site involves more pervasive PCB contamination than fresh spills and because old spills are generally more difficult to clean up than fresh spills (particularly on porous surfaces such as concrete). Therefore, spills which occurred before the effective date of this policy are to be decontaminated to requirements established at the discretion of EPA, usually through its regional offices.

(2) EPA expects most PCB spills subject to the TSCA PCB regulations to conform to the typical spill situations considered in developing this policy. This policy does, however, exclude from application of the final numerical cleanup standards certain spill situations from its scope: Spills directly into surface waters, drinking water, sewers, grazing lands, and vegetable gardens. These types of spills are subject to final cleanup standards to be established at the discretion of the regional office. These spills are, however, subject to the immediate notification requirements and measures to minimize further environmental contamination.

(3) For all other spills, EPA generally expects the decontamination standards of this policy to apply. Occasionally, some small percentage of spills covered by this policy may warrant more stringent cleanup requirements because of additional routes of exposure or significantly greater exposures than those assumed in developing the final cleanup standards of this policy. While the EPA regional offices have the authority to require additional cleanup in these circumstances, the Regional Administrator must first make a finding based on the specific facts of a spill that additional cleanup must occur to prevent unreasonable risk. In addition, before a final decision is made to require additional cleanup, the Regional Administrator must notify the Director, Office of Resource Conservation and Recovery of his/her finding and the basis for the finding.

(4) There may also be exceptional spill situations that requires less stringent cleanup or a different approach to cleanup because of factors associated with the particular spill. These factors may mitigate expected exposures and risks or make cleanup to these requirements impracticable.

(b) *Spills that may require more stringent cleanup levels.* For spills within the scope of this policy, EPA generally retains, under §761.135, the authority to require additional cleanup upon finding that, despite good faith efforts by the responsible party, the numerical decontamination levels in the policy have not been met. In addition, EPA foresees the possibility of exceptional spill situations in which site-specific risk factors may warrant additional cleanup to more stringent numerical decontamination levels than are required by the policy. In these situations, the Regional Administrator has the authority to require cleanup to levels lower than those included in this policy upon finding that further cleanup must occur to prevent unreasonable risk. The Regional Administrator will consult with the Director, Office of Resource Conservation and Recovery, prior to making such a finding.

(1) For example, site-specific characteristics, such as short depth to ground water, type of soil, or the presence of a shallow well, may pose exceptionally high potential for ground water contamination by PCBs remaining after cleanup to the standards specified in this policy. Spills that pose such a high degree of potential for ground water contamination have not been excluded from the policy under paragraph (d) of this section because the presence of such potential may not be readily apparent. EPA feels that automatically excluding such spills from the scope of the policy could result in the delay of cleanup—a particularly undesirable outcome if potential ground water contamination is, in fact, a significant concern.

(2) In those situations, the Regional Administrator may require cleanup in addition to that required under §761.125(b) and (c). However, the Regional Administrator must first make a finding, based on the specific facts of

a spill, that additional cleanup is necessary to prevent unreasonable risk. In addition, before making a final decision on additional cleanup, the Regional Administrator must notify the Director, Office of Resource Conservation and Recovery of his finding and the basis for the finding.

(c) *Flexibility to allow less stringent or alternative requirements.* EPA retains the flexibility to allow less stringent or alternative decontamination measures based upon site-specific considerations. EPA will exercise this flexibility if the responsible party demonstrates that cleanup to the numerical decontamination levels is clearly unwarranted because of risk-mitigating factors, that compliance with the procedural requirements or numerical standards in the policy is impracticable at a particular site, or that site-specific characteristics make the costs of cleanup prohibitive. The Regional Administrator will notify the Director, Office of Resource Conservation and Recovery of any decision and the basis for the decision to allow less stringent cleanup. The purpose of this notification is to enable the Director, Office of Resource Conservation and Recovery to ensure consistency of spill cleanup standards under special circumstances across the regions.

(d) *Excluded spills.* (1) Although the spill situations in paragraphs (d)(2) (i) through (vi) of this section are excluded from the automatic application of final decontamination standards under §761.125 (b) and (c), the general requirements under §761.125(a) do apply to these spills. In addition, all of these excluded situations require practicable, immediate actions to contain the area of contamination. While these situations may not always require more stringent cleanup measures, the Agency is excluding these scenarios because they will always involve significant factors that may not be adequately addressed by cleanup standards based upon typical spill characteristics.

(2) For the spill situations in paragraphs (d)(2)(i) through (vi) of this section, the responsible party shall decontaminate the spill in accordance with site-specific requirements established by the EPA regional offices.

(i) Spills that result in the direct contamination of surface waters (surface waters include, but are not limited to, ''waters of the United States'' as defined in part 122 of this chapter, ponds, lagoons, wetlands, and storage reservoirs).

(ii) Spills that result in the direct contamination of sewers or sewage treatment systems.

(iii) Spills that result in the direct contamination of any private or public drinking water sources or distribution systems.

(iv) Spills which migrate to and contaminate surface waters, sewers, or drinking water supplies before cleanup has been completed in accordance with this policy.

(v) Spills that contaminate animal grazing lands.

(vi) Spills that contaminate vegetable gradens.

(e) *Relationship of policy to other statutes.* (1) This policy does not affect cleanup standards or requirements for the reporting of spills imposed, or to be imposed, under other Federal statutory authorities, including but not limited to, the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), and the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act (SARA). Where more than one requirement applies, the stricter standard must be met.

(2) The Agency recognizes that the existence of this policy will inevitably result in attempts to apply the standards to situations within the scope of other statutory authorities. However, other statutes require the Agency to consider different or alternative factors in determining appropriate corrective actions. In addition, the types and magnitudes of exposures associated with sites requiring corrective action under other statutes often involve important differences from those expected of the typical, electrical equipment-type spills considered in developing this policy. Thus, cleanups under other statutes, such as RCRA corrective actions or remedial and response

actions under SARA may result in different outcomes.

[52 FR 10705, Apr. 2, 1987, as amended at 72 FR 57241, Oct. 9, 2007; 74 FR 30234, June 25, 2009]

§ 761.123 Definitions.

For purposes of this policy, certain words and phrases are used to denote specific materials, procedures, or circumstances. The following definitions are provided for purposes of clarity and are not to be taken as exhaustive lists of situations and materials covered by the policy.

Double wash/rinse means a minimum requirement to cleanse solid surfaces (both impervious and nonimpervious) two times with an appropriate solvent or other material in which PCBs are at least 5 percent soluble (by weight). A volume of PCB-free fluid sufficient to cover the contaminated surface completely must be used in each wash/rinse. The wash/rinse requirement does not mean the mere spreading of solvent or other fluid over the surface, nor does the requirement mean a once-over wipe with a soaked cloth. Precautions must be taken to contain any runoff resulting from the cleansing and to dispose properly of wastes generated during the cleansing.

High-concentration PCBs means PCBs that contain 500 ppm or greater PCBs, or those materials which EPA requires to be assumed to contain 500 ppm or greater PCBs in the absence of testing.

High-contact industrial surface means a surface in an industrial setting which is repeatedly touched, often for relatively long periods of time. Manned machinery and control panels are examples of high-contact industrial surfaces. High-contact industrial surfaces are generally of impervious solid material. Examples of low-contact industrial surfaces include ceilings, walls, floors, roofs, roadways and sidewalks in the industrial area, utility poles, unmanned machinery, concrete pads beneath electrical equipment, curbing, exterior structural building components, indoor vaults, and pipes.

High-contact residential/commercial surface means a surface in a residential/commercial area which is repeatedly touched, often for relatively long periods of time. Doors, wall areas below 6 feet in height, uncovered flooring, windowsills, fencing, bannisters, stairs, automobiles, and children's play areas such as outdoor patios and sidewalks are examples of high-contact residential/commercial surfaces. Examples of low-contact residential/commercial surfaces include interior ceilings, interior wall areas above 6 feet in height, roofs, asphalt roadways, concrete roadways, wooden utility poles, unmanned machinery, concrete pads beneath electrical equipment, curbing, exterior structural building components (e.g., aluminum/vinyl siding, cinder block, asphalt tiles), and pipes.

Impervious solid surfaces means solid surfaces which are nonporous and thus unlikely to absorb spilled PCBs within the short period of time required for cleanup of spills under this policy. Impervious solid surfaces include, but are not limited to, metals, glass, aluminum siding, and enameled or laminated surfaces.

Low-concentration PCBs means PCBs that are tested and found to contain less than 500 ppm PCBs, or those PCB-containing materials which EPA requires to be assumed to be at concentrations below 500 ppm (i.e., untested mineral oil dielectric fluid).

Nonimpervious solid surfaces means solid surfaces which are porous and are more likely to absorb spilled PCBs prior to completion of the cleanup requirements prescribed in this policy. Nonimpervious solid surfaces include, but are not limited to, wood, concrete, asphalt, and plasterboard.

Nonrestricted access areas means any area other than restricted access, outdoor electrical substations, and other restricted access locations, as defined in this section. In addition to residential/commercial areas, these areas include unrestricted access rural areas (areas of low density development and population where access is uncontrolled by either man-made barriers or naturally occurring barriers, such as rough terrain, mountains, or cliffs).

Other restricted access (nonsubstation) locations means areas other than electrical substations that are at least 0.1 kilometer (km) from a residential/commercial area and limited by man-made

barriers (e.g., fences and walls) to substantially limited by naturally occurring barriers such as mountains, cliffs, or rough terrain. These areas generally include industrial facilities and extremely remote rural locations. (Areas where access is restricted but are less than 0.1 km from a residential/commercial area are considered to be residential/commercial areas.)

Outdoor electrical substations means outdoor, fenced-off, and restricted access areas used in the transmission and/or distribution of electrical power Outdoor electrical substations restrict public access by being fenced or walled off as defined under §761.30(l)(1)(ii). For purposes of this TSCA policy, outdoor electrical substations are defined as being located at least 0.1 km from a residential/commercial area. Outdoor fenced-off and restricted access areas used in the transmission and/or distribution of electrical power which are located less than 0.1. km from a residential/commercial area are considered to be residential/commercial areas.

PCBs means polychlorinated biphenyls as defined under §761.3. As specified under §761.1(b), no requirements may be avoided through dilution of the PCB concentration.

Requirements and standards means:

(1) ''Requirements'' as used in this policy refers to both the procedural responses and numerical decontamination levels set forth in this policy as constituting adequate cleanup of PCBs.

(2) ''Standards'' refers to the numerical decontamination levels set forth in this policy.

Residential/commercial areas means those areas where people live or reside, or where people work in other than manufacturing or farming industries. Residential areas include housing and the property on which housing is located, as well as playgrounds, roadways, sidewalks, parks, and other similar areas within a residential community. Commercial areas are typically accessible to both members of the general public and employees and include public assembly properties, institutional properties, stores, office buildings, and transportation centers.

Responsible party means the owner of the PCB equipment, facility, or other source of PCBs or his/her designated agent (e.g., a facility manager or foreman).

Soil means all vegetation, soils and other ground media, including but not limited to, sand, grass, gravel, and oyster shells. It does not include concrete and asphalt.

Spill means both intentional and unintentional spills, leaks, and other uncontrolled discharges where the release results in any quantity of PCBs running off or about to run off the external surface of the equipment or other PCB source, as well as the contamination resulting from those releases. This policy applies to spills of 50 ppm or greater PCBs. The concentration of PCBs spilled is determined by the PCB concentration in the material spilled as opposed to the concentration of PCBs in the material onto which the PCBs were spilled. Where a spill of untested mineral oil occurs, the oil is presumed to contain greater than 50 ppm, but less than 500 ppm PCBs and is subject to the relevant requirements of this policy.

Spill area means the area of soil on which visible traces of the spill can be observed plus a buffer zone of 1 foot beyond the visible traces. Any surface or object (e.g., concrete sidewalk or automobile) within the visible traces area or on which visible traces of the spilled material are observed is included in the spill area. This area represents the minimum area assumed to be contaminated by PCBs in the absence of precleanup sampling data and is thus the minimum area which must be cleaned.

Spill boundaries means the actual area of contamination as determined by postcleanup verification sampling or by precleanup sampling to determine actual spill boundaries. EPA can require additional cleanup when necessary to decontaminate all areas within the spill boundaries to the levels required in this policy (e.g., additional cleanup will be required if postcleanup sampling indicates that the area decontaminated by the responsible party, such as the spill area as defined in this section, did not encompass the actual boundaries of PCB contamination).

Standard wipe test means, for spills of high-concentration PCBs on solid surfaces, a cleanup to numerical surface

standards and sampling by a standard wipe test to verify that the numerical standards have been met. This definition constitutes the minimum requirements for an appropriate wipe testing protocol. A standard-size template (10 centimeters (cm) × 10 cm) will be used to delineate the area of cleanup; the wiping medium will be a gauze pad or glass wool of known size which has been saturated with hexane. It is important that the wipe be performed very quickly after the hexane is exposed to air. EPA strongly recommends that the gauze (or glass wool) be prepared with hexane in the laboratory and that the wiping medium be stored in sealed glass vials until it is used for the wipe test. Further, EPA requires the collection and testing of field blanks and replicates.

[52 FR 10705, Apr. 2, 1987; 52 FR 23397, June 19, 1987]

§ 761.125 Requirements for PCB spill cleanup.

(a) *General.* Unless expressly limited, the reporting, disposal, and precleanup sampling requirements in paragraphs (a) (1) through (3) of this section apply to all spills of PCBs at concentrations of 50 ppm or greater which are subject to decontamination requirements under TSCA, including those spills listed under § 761.120(b) which are excluded from the cleanup standards at paragraphs (b) and (c) of this section.

(1) *Reporting requirements.* The reporting in paragraphs (a)(1) (i) through (iv) of this section is required in addition to applicable reporting requirements under the Clean Water Act (CWA) or the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA). For example, under the National Contingency Plan all spills involving 1 pound or more by weight of PCBs must currently be reported to the National Response Center (1-800-424-8802). The requirements in paragraphs (a)(1) (i) through (iv) of this section are designed to be consistent with existing reporting requirements to the extent possible so as to minimize reporting burdens on governments as well as the regulated community.

(i) Where a spill directly contaminates surface water, sewers, or drinking water supplies, as discussed under § 761.120(d), the responsible party shall notify the appropriate EPA regional office and obtain guidance for appropriate cleanup measures in the shortest possible time after discovery, but in no case later than 24 hours after discovery.

(ii) Where a spill directly contaminates grazing lands or vegetable gardens, as discussed under § 761.120(d), the responsible party shall notify the appropriate EPA regional office and proceed with the immediate requirements specified under paragraph (b) or (c) of this section, depending on the source of the spill, in the shortest possible time after discovery, but in no case later than 24 hours after discovery.

(iii) Where a spill exceeds 10 pounds of PCBs by weight and is not addressed in paragraph (a)(1) (i) or (ii) of this section, the responsible party will notify the appropriate EPA regional office and proceed to decontaminate the spill area in accordance with this TSCA policy in the shortest possible time after discovery, but in no case later than 24 hours after discovery.

(iv) Spills of 10 pounds or less, which are not addressed in paragraph (a)(1) (i) or (ii) of this section, must be cleaned up in accordance with this policy (in order to avoid EPA enforcement liability), but notification of EPA is not required.

(2) *Disposal of cleanup debris and materials.* All concentrated soils, solvents, rags, and other materials resulting from the cleanup of PCBs under this policy shall be properly stored, labeled, and disposed of in accordance with the provisions of subpart D of this part.

(3) *Determination of spill boundaries in the absence of visible traces.* For spills where there are insufficient visible traces yet there is evidence of a leak or spill, the boundaries of the spill are to be determined by using a statistically based sampling scheme.

(b) *Requirements for cleanup of low-concentration spills which involve less than 1 pound of PCBs by weight (less than 270 gallons of untested mineral oil)—* (1) *Decontamination requirements.* Spills of less than 270 gallons of untested mineral oil, low-concentration PCBs, as defined under § 761.123, which involve less than 1 pound of PCBs by weight (e.g., less than 270 gallons of untested

mineral oil containing less than 500 ppm PCBs) shall be cleaned in the following manner:

(i) Solid surfaces must be double washed/rinsed (as defined under §761.123); except that all indoor, residential surfaces other than vault areas must be cleaned to 10 micrograms per 100 square centimeters (10 μg/100 cm^2) by standard commercial wipe tests.

(ii) All soil within the spill area (i.e., visible traces of soil and a buffer of 1 lateral foot around the visible traces) must be excavated, and the ground be restored to its original configuration by back-filling with clean soil (i.e., containing less than 1 ppm PCBs).

(iii) Requirements of paragraphs (b)(1) (i) and (ii) of this section must be completed within 48 hours after the responsible party was notified or became aware of the spill.

(2) *Effect of emergency or adverse weather*. Completion of cleanup may be delayed beyond 48 hours in case of circumstances including but not limited to, civil emergency, adverse weather conditions, lack of access to the site, and emergency operating conditions. The occurrence of a spill on a weekend or overtime costs are not acceptable reasons to delay response. Completion of cleanup may be delayed only for the duration of the adverse conditions. If the adverse weather conditions, or time lapse due to other emergency, has left insufficient visible traces, the responsible party must use a statistically based sampling scheme to determine the spill boundaries as required under paragraph (a)(3) of this section.

(3) *Records and certification*. At the completion of cleanup, the responsible party shall document the cleanup with records and certification of decontamination. The records and certification must be maintained for a period of 5 years. The records and certification shall consist of the following:

(i) Identification of the source of the spill (e.g., type of equipment).

(ii) Estimated or actual date and time of the spill occurrence.

(iii) The date and time cleanup was completed or terminated (if cleanup was delayed by emergency or adverse weather: the nature and duration of the delay).

(iv) A brief description of the spill location.

(v) Precleanup sampling data used to establish the spill boundaries if required because of insufficient visible traces, and a brief description of the sampling methodology used to establish the spill boundaries.

(vi) A brief description of the solid surfaces cleaned and of the double wash/rinse method used.

(vii) Approximate depth of soil excavation and the amount of soil removed.

(viii) A certification statement signed by the responsible party stating that the cleanup requirements have been met and that the information contained in the record is true to the best of his/her knowledge.

(ix) While not required for compliance with this policy, the following information would be useful if maintained in the records:

(A) Additional pre- or post-cleanup sampling.

(B) The estimated cost of the cleanup by man-hours, dollars, or both.

(c) *Requirements for cleanup of high-concentration spills and low-concentration spills involving 1 pound or more PCBs by weight (270 gallons or more of untested mineral oil)*. Cleanup of low-concentration spills involving 1 lb or more PCBs by weight and of all spills of materials other than low-concentration materials shall be considered complete if all of the immediate requirements, cleanup standards, sampling, and recordkeeping requirements of paragraphs (c) (1) through (5) of this section are met.

(1) *Immediate requirements*. The four actions in paragraphs (c)(1) (i) through (iv) of this section must be taken as quickly as possible and within no more than 24 hours (or within 48 hours for PCB Transformers) after the responsible party was notified or became aware of the spill, except that actions described in paragraphs (c)(1) (ii) through (iv) of this section can be delayed beyond 24 hours if circumstances (e.g., civil emergency, hurricane, tornado, or other similar adverse weather conditions, lack of access due to physical impossibility, or emergency operating conditions) so require for the duration of the adverse conditions. The occurrence of a spill on a weekend or

overtime costs are not acceptable reasons to delay response. Owners of spilled PCBs who have delayed cleanup because of these types of circumstances must keep records documenting the fact that circumstances precluded rapid response.

(i) The responsible party shall notify the EPA regional office and the NRC as required by § 761.125(a)(1) or by other applicable statutes.

(ii) The responsible party shall effectively cordon off or otherwise delineate and restrict an area encompassing any visible traces plus a 3-foot buffer and place clearly visible signs advising persons to avoid the area to minimize the spread of contamination as well as the potential for human exposure.

(iii) The responsible party shall record and document the area of visible contamination, noting the extent of the visible trace areas and the center of the visible trace area. If there are no visible traces, the responsible party shall record this fact and contact the regional office of the EPA for guidance in completing statistical sampling of the spill area to establish spill boundaries.

(iv) The responsible party shall initiate cleanup of all visible traces of the fluid on hard surfaces and initiate removal of all visible traces of the spill on soil and other media, such as gravel, sand, oyster shells, etc.

(v) If there has been a delay in reaching the site and there are insufficient visible traces of PCBs remaining at the spill site, the responsible party must estimate (based on the amount of material missing from the equipment or container) the area of the spill and immediately cordon off the area of suspect contamination. The responsible party must then utilize a statistically based sampling scheme to identify the boundaries of the spill area as soon as practicable.

(vi) Although this policy requires certain immediate actions, as described in paragraphs (c)(1)(i) through (iv) of this section, EPA is not placing a time limit on completion of the cleanup effort since the time required for completion will vary from case to case. However, EPA expects that decontamination will be achieved promptly in all cases and will consider promptness of completion in determining whether the responsible party made good faith efforts to clean up in accordance with this policy.

(2) *Requirements for decontaminating spills in outdoor electrical substations.* Spills which occur in outdoor electrical substations, as defined under § 761.123, shall be decontaminated in accordance with paragraphs (c)(2) (i) and (ii) of this section. Conformance to the cleanup standards under paragraphs (c)(2) (i) and (ii) of this section shall be verified by post-cleanup sampling as specified under § 761.130. At such times as outdoor electrical substations are converted to another use, the spill site shall be cleaned up to the nonrestricted access requirements under paragraph (c)(4) of this section.

(i) Contaminated solid surfaces (both impervious and non-impervious) shall be cleaned to a PCB concentration of 100 micrograms (μg)/100 square centimeters (cm^2) (as measured by standard wipe tests).

(ii) At the option of the responsible party, soil contaminated by the spill will be cleaned either to 25 ppm PCBs by weight, or to 50 ppm PCBs by weight provided that a label or notice is visibly placed in the area. Upon demonstration by the responsible party that cleanup to 25 ppm or 50 ppm will jeopardize the integrity of the electrical equipment at the substation, the EPA regional office may establish an alternative cleanup method or level and place the responsible party on a reasonably timely schedule for completion of cleanup.

(3) *Requirements for decontaminating spills in other restricted access areas.* Spills which occur in restricted access locations other than outdoor electrical substations, as defined under § 761.123, shall be decontaminated in accordance with paragraphs (c)(3) (i) through (v) of this section. Conformance to the cleanup standards in paragraphs (c)(3) (i) through (v) of this section shall be verified by postcleanup sampling as specified under § 761.130. At such times as restricted access areas other than outdoor electrical substations are converted to another use, the spill site shall be cleaned up to the nonrestricted access area requirements of paragraph (c)(4) of this section.

(i) High-contact solid surfaces, as defined under § 761.163 shall be cleaned to 10 μg/100 cm^2 (as measured by standard wipe tests).

(ii) Low-contact, indoor, impervious solid surfaces will be decontaminated to 10 μg/100 cm^2.

(iii) At the option of the responsible party, low-contact, indoor, nonimpervious surfaces will be cleaned either to 10 μg/100 cm^2 or to 100 μg/100 cm^2 and encapsulated. The Regional Administrator, however, retains the authority to disallow the encapsulation option for a particular spill situation upon finding that the uncertainties associated with that option pose special concerns at that site. That is, the Regional Administrator would not permit encapsulation if he/she determined that if the encapsulation failed the failure would create an imminent hazard at the site.

(iv) Low-contact, outdoor surfaces (both impervious and nonimpervious) shall be cleaned to 100 μg/100 cm^2.

(v) Soil contaminated by the spill will be cleaned to 25 ppm PCBs by weight.

(4) *Requirements for decontaminating spills in nonrestricted access areas.* Spills which occur in nonrestricted access locations, as defined under § 761.123, shall be decontaminated in accordance with paragraphs (c)(4) (i) through (v) of this section. Conformance to the cleanup standards at paragraphs (c)(4) (i) through (v) of this section shall be verified by postcleanup sampling as specified under § 761.130.

(i) Furnishings, toys, and other easily replaceable household items shall be disposed of in accordance with the provisions of subpart D of this part and replaced by the responsible party.

(ii) Indoor solid surfaces and high-contact outdoor solid surfaces, defined as high contact residential/commercial surfaces under § 761.123, shall be cleaned to 10 μg/100 cm^2 (as measured by standard wipe tests).

(iii) Indoor vault areas and low-contact, outdoor, impervious solid surfaces shall be decontaminated to 10 μg/100 cm^2.

(iv) At the option of the responsible party, low-contact, outdoor, nonimpervious solid surfaces shall be either cleaned to 10 μg/100 cm^2 or cleaned to 100 μg/100 cm^2 and encapsulated. The Regional Administrator, however, retains the authority to disallow the encapsulation option for a particular spill situation upon finding that the uncertainties associated with that option pose special concerns at that site. That is, the Regional Administrator would not permit encapsulation if he/she determined that if the encapsulation failed the failure would create an imminent hazard at the site.

(v) Soil contaminated by the spill will be decontaminated to 10 ppm PCBs by weight provided that soil is excavated to a minimum depth of 10 inches. The excavated soil will be replaced with clean soil, i.e., containing less than 1 ppm PCBs, and the spill site will be restored (e.g., replacement of turf).

(5) *Records.* The responsible party shall document the cleanup with records of decontamination. The records must be maintained for a period of 5 years. The records and certification shall consist of the following:

(i) Identification of the source of the spill, e.g., type of equipment.

(ii) Estimated or actual date and time of the spill occurrence.

(iii) The date and time cleanup was completed or terminated (if cleanup was delayed by emergency or adverse weather: the nature and duration of the delay).

(iv) A brief description of the spill location and the nature of the materials contaminated. This information should include whether the spill occurred in an outdoor electrical substation, other restricted access location, or in a nonrestricted access area.

(v) Precleanup sampling data used to establish the spill boundaries if required because of insufficient visible traces and a brief description of the sampling methodology used to establish the spill boundaries.

(vi) A brief description of the solid surfaces cleaned.

(vii) Approximate depth of soil excavation and the amount of soil removed.

(viii) Postcleanup verification sampling data and, if not otherwise apparent from the documentation, a brief description of the sampling methodology and analytical technique used.

(ix) While not required for compliance with this policy, information on

the estimated cost of cleanup (by manhours, dollars, or both) would be useful if maintained in the records.

[52 FR 10705, Apr. 2, 1987, as amended at 53 FR 40884, Oct. 19, 1988; 63 FR 35461, June 29, 1998; 72 FR 57241, Oct. 9, 2007]

§ 761.130 Sampling requirements.

Postcleanup sampling is required to verify the level of cleanup under § 761.125(c) (2) through (4). The responsible party may use any statistically valid, reproducible, sampling scheme (either random samples or grid samples) provided that the requirements of paragraphs (a) and (b) of this section are satisfied.

(a) The sampling area is the greater of (1) an area equal to the area cleaned plus an additional 1-foot boundary, or (2) an area 20 percent larger than the original area of contamination.

(b) The sampling scheme must ensure 95 percent confidence against false positives.

(c) The number of samples must be sufficient to ensure that areas of contamination of a radius of 2 feet or more within the sampling area will be detected, except that the minimum number of samples is 3 and the maximum number of samples is 40.

(d) The sampling scheme must include calculation for expected variability due to analytical error.

(e) EPA recommends the use of a sampling scheme developed by the Midwest Research Institute (MRI) for use in enforcement inspections: ''Verification of PCB Spill Cleanup by Sampling and Analysis.'' Guidance for the use of this sampling scheme is available in the MRI report ''Field Manual for Grid Sampling of PCB Spill Sites to Verify Cleanup.'' Both the MRI sampling scheme and the guidance document are available on EPA's PCB Web site at *http://www.epa.gov/pcb*, or from the Program Management, Communications, and Analysis Office, Office of Resource Conservation and Recovery (5305P), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. The major advantage of this sampling scheme is that it is designed to characterize the degree of contamination within the entire sampling area with a high degree of confidence while using fewer samples than any other grid or random sampling scheme. This sampling scheme also allows some sites to be characterized on the basis of composite samples.

(f) EPA may, at its discretion, take samples from any spill site. If EPA's sampling indicates that the remaining concentration level exceeds the required level, EPA will require further cleanup. For this purpose, the numerical level of cleanup required for spills cleaned in accordance with § 761.125(b) is deemed to be the equivalent of numerical cleanup requirements required for cleanups under § 761.125(c) (2) through (4). Using its best engineering judgment, EPA may sample a statistically valid random or grid sampling technique, or both. When using engineering judgment or random ''grab'' samples, EPA will take into account that there are limits on the power of a grab sample to dispute statistically based sampling of the type required of the responsible party. EPA headquarters will provide guidance to the EPA regions on the degree of certainty associated with various grab sample results.

[52 FR 10705, Apr. 2, 1987, as amended at 60 FR 34465, July 3, 1995; 72 FR 57241, Oct. 9, 2007; 74 FR 30234, June 25, 2009]

§ 761.135 Effect of compliance with this policy and enforcement.

(a) Although a spill of material containing 50 ppm or greater PCBs is considered improper PCB disposal, this policy establishes requirements that EPA considers to be adequate cleanup of the spilled PCBs. Cleanup in accordance with this policy means compliance with the procedural as well as the numerical requirements of this policy. Compliance with this policy creates a presumption against both enforcement action for penalties and the need for further cleanup under TSCA. The Agency reserves the right, however, to initiate appropriate action to compel cleanup where, upon review of the records of cleanup or EPA sampling following cleanup, EPA finds that the decontamination levels in the policy have not been achieved. The Agency also reserves the right to seek penalties where the Agency believes that the responsible party has not made a good faith effort to comply with all

provisions of this policy, such as prompt notification of EPA of a spill, recordkeeping, etc.

(b) EPA's exercise of enforcement discretion does not preclude enforcement action under other provisions of TSCA or any other Federal statute. This includes, even in cases where the numerical decontamination levels set forth in this policy have been met, civil or criminal action for penalties where EPA believes the spill to have been the result of gross negligence or knowing violation.

Subparts H–I [Reserved]

Subpart J—General Records and Reports

§ 761.180 Records and monitoring.

This section contains recordkeeping and reporting requirements that apply to PCBs, PCB Items, and PCB storage and disposal facilities that are subject to the requirements of the part.

(a) *PCBs and PCB Items in service or projected for disposal.* Beginning February 5, 1990, each owner or operator of a facility, other than a commercial storer or a disposer of PCB waste, using or storing at any one time at least 45 kilograms (99.4 pounds) of PCBs contained in PCB Container(s), or one or more PCB Transformers, or 50 or more PCB Large High or Low Voltage Capacitors shall develop and maintain at the facility, or a central facility provided they are maintained at that facility, all annual records and the written annual document log of the disposition of PCBs and PCB Items. The written annual document log must be prepared for each facility by July 1 covering the previous calendar year (January through December). The annual document log shall be maintained for at least 3 years after the facility ceases using or storing PCBs and PCB Items in the quantities prescribed in this paragraph. Annual records (manifests and certificates of disposal) shall be maintained for the same period. The annual records and the annual document log shall be available for inspection at the facility where they are maintained by authorized representatives of EPA during normal business hours, and each owner or operator of a facility subject to these requirements shall know the location of these records. All records and annual documents required to be prepared and maintained by this section prior to February 5, 1990 shall continue to be maintained at the facility for the same time as the annual records and the annual document log. The annual document required for 1989 shall cover the period from January 1, 1989 to February 5, 1990.

(1) The annual records shall include the following:

(i) All signed manifests generated by the facility during the calendar year.

(ii) All Certificates of Disposal that have been received by the facility during the calendar year.

(iii) Records of inspections and cleanups performed in accordance with § 761.65(c)(5).

(2) The written annual document log shall include the following:

(i) The name, address, and EPA identification number of the facility covered by the annual document log and the calendar year covered by the annual document log.

(ii) The unique manifest number of every manifest generated by the facility during the calendar year, and from each manifest and for unmanifested waste that may be stored at the facility, the following information:

(A) For bulk PCB waste (*e.g.*, in a tanker or truck), its weight in kilograms, the first date it was removed from service for disposal, the date it was placed into transport for off-site storage or disposal, and the date of disposal, if known.

(B) The serial number (if available) or other means of identifying each PCB Article (*e.g.*, transformer or capacitor), the weight in kilograms of the PCB waste in each transformer or capacitor, the date it was removed from service for disposal, the date it was placed in transport for off-site storage or disposal, and the date of disposal, if known.

(C) A unique number identifying each PCB Container, a description of the contents of each PCB Container, such as liquid, soil, cleanup debris, etc., including the total weight of the material in kilograms in each PCB Container, the first date material placed in

each PCB Container was removed from service for disposal, and the date each PCB Container was placed in transport for off-site storage or disposal, and the date of disposal (if known).

(D) A unique number identifying each PCB Article Container, a description of the contents of each PCB Article Container, such as pipes, capacitors, electric motors, pumps, etc., including the total weight in kilograms of the content of each PCB Article Container, the first date a PCB Article placed in each PCB Article Container was removed from service for disposal, and the date the PCB Article Container was placed in transport for off-site storage or disposal, and the date of disposal (if known.)

(iii) The total number by specific type of PCB Articles and the total weight in kilograms of PCBs in PCB Articles, the total number of PCB Article Containers and total weight in kilograms of the contents of PCB Article Containers, the total number of PCB Containers and the total weight in kilograms of the contents of PCB Containers, and the total weight in kilograms of bulk PCB waste that was placed into storage for disposal or disposed during the calendar year.

(iv) The total number of PCB Transformers and total weight in kilograms of PCBs contained in the transformers remaining in service at the end of the calendar year.

(v) The total number of Large High or Low Voltage PCB Capacitors remaining in service at the end of the calendar year.

(vi) The total weight in kilograms of any PCBs and PCB Items in PCB Containers, including the identification of container contents, remaining in service at the facility at the end of the calendar year.

(vii) For any PCBs or PCB item received from or shipped to another facility owned or operated by the same generator, the information required under paragraph (a)(2)(ii)(A) through (a)(2)(ii)(D) of this section.

(viii) [Reserved]

(ix) Whenever a PCB Item, excluding small capacitors, with a concentration of ≥50 ppm is distributed in commerce for reuse pursuant to § 761.20(c)(1), the name, address, and telephone number of the person to whom the item was transferred, date of transfer, and the serial number of the item or the internal identification number, if a serial number is not available, must be recorded in the annual document log. The serial number or internal identification number shall be permanently marked on the equipment.

(3) [Reserved]

(4) For purposes of this paragraph, PCB Voltage Regulators shall be recorded as PCB Transformers.

(b) *Disposers and commercial storers of PCB waste.* Beginning February 5, 1990, each owner or operator of a facility (including high efficiency boiler operations) used for the commercial storage or disposal of PCBs and PCB Items shall maintain annual records on the disposition of all PCBs and PCB items at the facility and prepare and maintain a written annual document log that includes the information required by paragraphs (b)(2) of this section for PCBs and PCB Items that were handled as PCB waste at the facility. The written annual document log shall be prepared by July 1 for the previous calendar year (January through December). The written annual document log shall be maintained at each facility for at least 3 years after the facility is no longer used for the storage or disposal of PCBs and PCB Items except that, in the case of chemical waste landfills, the annual document log shall be maintained at least 20 years after the chemical waste landfill is no longer used for the disposal of PCBs and PCB Items. The annual records shall be maintained for the same period. The annual records and written annual document log shall be available at the facility for inspection by authorized representatives of the EPA. All records and annual documents required to be prepared and maintained by this section prior to February 5, 1990 shall continue to be maintained at the facility for the same time as the annual records and the annual document log. The annual document for 1989 shall cover the period from January 1, 1989 to February 5, 1990. From the written annual document log the owner or operator of a facility must prepare the annual report containing the information required by paragraphs (b)(3)(i) through (b)(3)(vi) of

this section for PCBs and PCB Items that were handled as PCB waste at the facility during the previous calendar year (January through December). The annual report must be submitted by July 15 of each year for the preceding calendar year. If the facility ceases commercial PCB storage or disposal operations, the owner or operator of the facility shall provide at least 60 days advance written notice to the Regional Administrator for the region in which the facility is located of the date the facility intends to begin closure. d

(1) The annual records shall include the following:

(i) All signed manifests generated or received at the facility during the calendar year.

(ii) All Certificates of Disposal that have been generated or received by the facility during the calendar year.

(iii) Records of inspections and cleanups performed in accordance with §761.65(c)(5).

(2) The written annual document log shall include the following:

(i) The name, address, and EPA identification number of the storage or disposal facility covered by the annual document log and the calendar year covered by the annual document log.

(ii) For each manifest generated or received by the facility during the calendar year, the unique manifest number and the name and address of the facility that generated the manifest and the following information:

(A) For bulk PCB waste (*e.g.*, in a tanker or truck), its weight in kilograms, the first date PCB waste placed in the tanker or truck was removed from service for disposal, the date it was received at the facility, the date it was placed in transport for off-site disposal (if applicable), and the date of disposal, (if known).

(B) The serial number or other means of identifying each PCB Article, not in a PCB Container or PCB Article Container, the weight in kilograms of the PCB waste in the PCB Article, the date it was removed from service for disposal, the date it was received at the facility, the date it was placed in transport for off-site disposal (if applicable), and the date of disposal (if known).

(C) The unique number assigned by the generator identifying each PCB Container, a description of the contents of each PCB Container, such as liquid, soil, cleanup debris, etc., including the total weight of the PCB waste in kilograms in each PCB Container, the first date PCB waste placed in each PCB Container was removed from service for disposal, the date it was received at the facility, the date each PCB Container was placed in transport for off-site storage or disposal (as applicable), and the date the PCB Container was disposed of (if known).

(D) The unique number assigned by the generator identifying each PCB Article Container, a description of the contents of each PCB Article Container, such as pipes, capacitors, electric motors, pumps, etc., including the total weight in kilograms of the PCB waste in each PCB Article Container, the first date a PCB Article placed in each PCB Article Container was removed from service for disposal, the date it was received at the facility, the date each PCB Article Container was placed in transport for off-site storage or disposal (as applicable), and the date the PCB Article Container was disposed of (if known).

(E) Disposers of PCB waste shall include the confirmed date of disposal for items in paragraphs (b)(2)(ii)(A) through (b)(2)(ii)(D) of this section.

(iii) For any PCB waste disposed at a facility that generated the PCB waste or any PCB waste that was not manifested to the facility, the information required under paragraph (b)(2)(ii)(A) through (b)(2)(ii)(E) of this section.

(3) The owner or operator of a PCB disposal facility (including an owner or operator who disposes of his/her own waste and does not receive or generate manifests) or a commercial storage facility shall submit an annual report, which briefly summarizes the records and annual document log required to be maintained and prepared under paragraphs (b)(1) and (b)(2) of this section to the EPA Regional Administrator of the Region in which the facility is located by July 15 of each year, beginning with July 15, 1991. The first annual report submitted on July 15, 1991, shall be for the period starting February 5, 1990, and ending December

31, 1990. The annual report shall contain no confidential business information. The annual report shall consist of the information listed in paragraphs (b)(3)(i) through (b)(3)(vi) of this section.

(i) The name, address, and EPA identification number of the facility covered by the annual report for the calendar year.

(ii) A list of the numbers of all signed manifests of PCB waste initiated or received by the facility during that year.

(iii) The total weight in kilograms of bulk PCB waste, PCB waste in PCB Transformers, PCB waste in PCB Large High or Low Voltage Capacitors, PCB waste in PCB Article Containers, and PCB waste in PCB Containers in storage at the facility at the beginning of the calendar year, received or generated at the facility, transferred to another facility, or disposed of at the facility during the calendar year. The information must be provided for each of these categories, as appropriate.

(iv) The total number of PCB Transformers, the total number of PCB Large High or Low Voltage Capacitors, the total number of PCB Article Containers, and the total number of PCB Containers in storage at the facility at the beginning of the calendar year, received or generated at the facility, transferred to another facility, or disposed of at the facility during the calendar year. The information must be provided for each of these categories, as appropriate.

(v) The total weight in kilograms of each of the following PCB categories: bulk PCB waste, PCB waste in PCB Transformers, PCB waste in PCB Large High or Low Voltage Capacitors, PCB waste in PCB Article Containers, and PCB waste in PCB Containers remaining in storage for disposal at the facility at the end of the calendar year.

(vi) The total number of PCB Transformers, the total number of PCB Large High or Low Voltage Capacitors, the total number of PCB Article Containers, and the total number of PCB Containers remaining in storage for disposal at the facility at the end of the calendar year.

(vii) The requirement to submit annual reports to the Regional Administrator continues until the submission of the annual report for the calendar year during which the facility ceases PCB storage or disposal operations. Storage operations have not ceased until all PCB waste, including any PCB waste generated during closure, has been removed from the facility.

(4) Whenever a commercial storer of PCB waste accepts PCBs or PCB Items at his storage facility and transfers the PCB waste off-site to another facility for storage or disposal, the commercial storer of PCB waste shall initiate a manifest under subpart K of this part for the transfer of PCBs or PCB Items to the next storage or disposal facility.

NOTE: Any requirements for weights in kilograms of PCBs may be calculated values if the internal volume of PCBs in containers and transformers is known and included in the reports, together with any assumptions on the density of the PCBs contained in the containers or tranformers. If the internal volume of PCBs is not known, a best estimate may be used.

(5) For purposes of this paragraph, PCB Voltage Regulators shall be recorded and reported as PCB Transformers.

(c) *Incineration facilities.* Each owner or operator of a PCB incinerator facility shall collect and maintain for a period of 5 years from the date of collection the following information, in addition to the information required in paragraph (b) of this section:

(1) When PCBs are being incinerated, the following continuous and short-interval data:

(i) Rate and quantity of PCBs fed to the combustion system as required in § 761.70(a)(3);

(ii) Temperature of the combustion process as required in § 761.70(a)(4); and

(iii) Stack emission product to include O_2, CO, and CO_2 as required in § 761.70(a)(7).

(2) When PCBs are being incinerated, data and records on the monitoring of stack emissions as required in § 761.70(a)(6).

(3) Total weight in kilograms of any solid residues generated by the incineration of PCBs and PCB Items during the calendar year, the total weight in kilograms of any solid residues disposed of by the facility in chemical waste landfills, and the total weight in kilograms of any solid residues remaining on the facility site.

(4) When PCBs and PCB Items are being incinerated, additional periodic data shall be collected and maintained as specified by the Regional Administrator pursuant to §761.70(d)(4).

(5) Upon any suspension of the operation of any incinerator pursuant to §761.70(a)(8), the owner or operator of such an incinerator shall prepare a document. The document shall, at a minimum, include the date and time of the suspension and an explanation of the circumstances causing the suspension of operation. The document shall be sent to the appropriate Regional Administrator within 30 days of any such suspension.

(d) *Chemical waste landfill facilities.* Each owner or operator of a PCB chemical waste landfill facility shall collect and maintain until at least 20 years after the chemical waste landfill is no longer used for the disposal of PCBs the following information in addition to the information required in paragraph (b) of this section:

(1) Any water analysis obtained in compliance with §761.75(b)(6)(iii); and

(2) Any operations records including burial coordinates of wastes obtained in compliance with §761.75(b)(8)(ii).

(e) *High efficiency boiler facilities.* Each owner or operator of a high efficiency boiler used for the disposal of liquids between 50 and 500 ppm PCB shall collect and maintain for a period of 5 years the following information, in addition to the information required in paragraph (b) of this section:

(1) For each month PCBs are burned in the boiler the carbon monoxide and excess oxygen data required in §761.71(a)(1)(viii) and §761.71(b)(1)(viii);

(2) The quantity of PCBs burned each month as required in §761.71(a)(1)(vii) and §761.71(b)(1)(vii); and

(3) For each month PCBs (other than mineral oil dielectric fluid) are burned, chemical analysis data of the waste as required in §761.71(b)(2)(vi).

(f) *Retention of special records by storage and disposal facilities.* In addition to the information required to be maintained under paragraphs (b), (c), (d) and (e) of this section, each owner or operator of a PCB storage or disposal facility (including high efficiency boiler operations) shall collect and maintain for the time period specified in paragraph (b) of this section the following data:

(1) All documents, correspondence, and data that have been provided to the owner or operator of the facility by any State or local government agency and that pertain to the storage or disposal of PCBs and PCB Items at the facility.

(2) All documents, correspondence, and data that have been provided by the owner or operator of the facility to any State or local government agency and that pertain to the storage or disposal of PCBs and PCB Items at the facility.

(3) Any applications and related correspondence sent by the owner or operator of the facility to any local, State, or Federal authorities in regard to waste water discharge permits, solid waste permits, building permits, or other permits or authorizations such as those required by §§761.70(d) and 761.75(c).

(g) *Reclassification records.* If you reclassify electrical equipment using the procedures in §761.30(a)(2)(v) or §761.30(h)(2)(v), you must keep records showing that you followed the required reclassification procedures. Where these procedures require testing, the records must include copies of pre- and post-reclassification PCB concentration measurements from a laboratory using quality control and quality assurance procedures. You must make these records available promptly to EPA or to any party possessing the equipment through sale, loan, lease, or for servicing. You must retain the records for at least 3 years after you sell or dispose of the equipment.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[44 FR 31542, May 31, 1979. Redesignated at 47 FR 19527, May 6, 1982, and further redesignated at 47 FR 37360, Aug. 25, 1982; 49 FR 28191, July 10, 1984; 53 FR 12524, Apr. 15, 1988; 54 FR 52750, Dec. 21, 1989; 55 FR 26205, June 27, 1990; 58 FR 34205, June 23, 1993; 63 FR 35461, June 29, 1998; 66 FR 17619, Apr. 2, 2001; 77 FR 54830, Sept. 6, 2012]

§ 761.185 Certification program and retention of records by importers and persons generating PCBs in excluded manufacturing processes.

(a) In addition to meeting the basic requirements of § 761.1(f) and the definition of excluded manufacturing processes at § 761.3, manufacturers with processes inadvertently generating PCBs and importers of products containing inadvertently generated PCBs must report to EPA any excluded manufacturing process or imports for which the concentration of PCBs in products leaving the manufacturing site or imported is greater than 2 micrograms per gram (2 μg/g, roughly 2 ppm) for any resolvable gas chromatographic peak. Such reports must be filed by October 1, 1984 or, if no processes or imports require reports at the time, within 90 days of having processes or imports for which such reports are required.

(b) Manufacturers required to report by paragraph (a) of this section must transmit a letter notifying EPA of the number, the type, and the location of excluded manufacturing processes in which PCBs are generated when the PCB level in products leaving any manufacturing site is greater than 2 μg/g for any resolvable gas chromatographic peak. Importers required to report by paragraph (a) of this section must transmit a letter notifying EPA of the concentration of PCBs in imported products when the PCB concentration of products being imported is greater than 2 μg/g for any resolvable gas chromatographic peak. Persons must also certify the following:

(1) Their compliance with all applicable requirements of § 761.1(f), including any applicable requirements for air and water releases and process waste disposal.

(2) Whether determinations of compliance are based on actual monitoring of PCB levels or on theoretical assessments.

(3) That such determinations of compliance are being maintained.

(4) If the determination of compliance is based on a theoretical assessment, the letter must also notify EPA of the estimated PCB concentration levels generated and released.

(c) Any person who reports pursuant to paragraph (a) of this section:

(1) Must have performed either a theoretical analysis or actual monitoring of PCB concentrations.

(2) Must maintain for a period of three years after ceasing process operations or importation, or for seven years, whichever is shorter, records containing the following information:

(i) *Theoretical analysis.* Manufacturers records must include: the reaction or reactions believed to be generating PCBs; the levels of PCBs generated; and the levels of PCBs released. Importers records must include: the reaction or reactions believed to be generating PCBs and the levels of PCBs generated; the basis for all estimations of PCB concentrations; and the name and qualifications of the person or persons performing the theoretical analysis; or

(ii) *Actual monitoring.* (A) The method of analysis.

(B) The results of the analysis, including data from the Quality Assurance Plan.

(C) Description of the sample matrix.

(D) The name of the analyst or analysts.

(E) The date and time of the analysis.

(F) Numbers for the lots from which the samples are taken.

(d) The certification required by paragraph (b) of this section must be signed by a responsible corporate officer. This certification must be maintained by each facility or importer for a period of three years after ceasing process operation or importation, or for seven years, whichever is shorter, and must be made available to EPA upon request. For the purpose of this section, a responsible corporate officer means:

(1) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation.

(2) The manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding $25,000,000 (in second quarter 1980 dollars), if authority to sign documents has been assigned or

delegated to the manager in accordance with corporate procedures.

(e) Any person signing a document under paragraph (d) of this section shall also make the following certification:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate information. Based on my inquiry of the person or persons directly responsible for gathering information, the information is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for falsifying information, including the possibility of fines and imprisonment for knowing violations.

Dated: _____

Signature: _____

(f) This report must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, ATTN: PCB Notification. This report must be submitted by October 1, 1984 or within 90 days of starting up processes or commencing importation of PCBs.

(g) This certification process must be repeated whenever process conditions are significantly modified to make the previous certification no longer valid.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[49 FR 28191, July 10, 1984; 49 FR 33019, Aug. 20, 1984, as amended at 53 FR 12524, Apr. 15, 1988; 58 FR 34205, June 23, 1993; 59 FR 33697, June 30, 1994; 60 FR 34465, July 3, 1995; 71 FR 33642, June 12, 2006]

§ 761.187 Reporting importers and by persons generating PCBs in excluded manufacturing processes.

In addition to meeting the basic requirements of §761.1(f) and the definition of excluded manufacturing process at §761.3, PCB-generating manufacturing processes or importers of PCB-containing products shall be considered ''excluded manufacturing processes'' only when the following conditions are met:

(a) Data are reported to the EPA by the owner/operator or importer concerning the total quantity of PCBs in product from excluded manufacturing processes leaving any manufacturing site in any calendar year when such quantity exceeds 0.0025 percent of that site's rated capacity for such manufacturing processes as of October 1, 1984; or the total quantity of PCBs imported in any calendar year when such quantity exceeds 0.0025 percent of the average total quantity of such product containing PCBs imported by such importer during the years 1978, 1979, 1980, 1981 and 1982.

(b) Data are reported to the EPA by the owner/operator concerning the total quantity of inadvertently generated PCBs released to the air from excluded manufacturing processes at any manufacturing site in any calendar year when such quantity exceeds 10 pounds.

(c) Data are reported to the EPA by the owner/operator concerning the total quantity of inadvertently generated PCBs released to water from excluded manufacturing processes from any manufacturing site in any calendar year when such quantity exceeds 10 pounds.

(d) These reports must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, ATTN: PCB Notification.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[49 FR 28192, July 10, 1984, as amended at 53 FR 12524, Apr. 15, 1988; 58 FR 34205, June 23, 1993; 59 FR 33697, June 30, 1994; 60 FR 34465, July 3, 1995; 71 FR 33642, June 12, 2006]

§ 761.193 Maintenance of monitoring records by persons who import, manufacture, process, distribute in commerce, or use chemicals containing inadvertently generated PCBs.

(a) Persons who import, manufacture, process, distribute in commerce, or use chemicals containing PCBs present as a result of inadvertent generation or recycling who perform any actual monitoring of PCB concentrations must maintain records of any such monitoring for a period of three years after a process ceases operation or importing ceases, or for seven years, whichever is shorter.

(b) Monitoring records maintained pursuant to paragraph (a) of this section must contain:

(1) The method of analysis.

(2) The results of the analysis, including data from the Quality Assurance Plan.

(3) Description of the sample matrix.

(4) The name of the analyst or analysts.

(5) The date and time of the analysis.

(6) Numbers for the lots from which the samples are taken.

(Sec. 6, Pub. L. 94–469, 90 Stat. 2020 (15 U.S.C. 2605)

[49 FR 28193, July 10, 1984, as amended at 58 FR 34205, June 23, 1993]

Subpart K—PCB Waste Disposal Records and Reports

SOURCE: 54 FR 52752, Dec. 21, 1989, unless otherwise noted.

§ 761.202 EPA identification numbers.

(a) *General.* Any generator, commercial storer, transporter, or disposer of PCB waste who is required to have an EPA identification number under this subpart must notify EPA of his/her PCB waste handling activities, using the notification procedures and form described in § 761.205. EPA will confirm the EPA identification number of facilities already assigned one, and will assign an EPA identification number to facilities that do not have one.

(b) *Prohibitions.* After June 4, 1990:

(1) A generator of PCB waste shall not:

(i) Process, store, dispose of, transport, or offer for transportation PCB waste without having received an EPA identification number from the Agency. A generator of PCB waste who is exempted from notification under § 761.205(c)(1) or who notifies EPA in a timely manner under § 761.205(c)(2)(i), but has not yet received a unique identification number, shall be regarded as having received from EPA the identification number ''40 CFR PART 761.''

(ii) Offer the PCB waste to transporters, disposers, or commercial storers of PCB waste who have not received an EPA identification number.

(2) A transporter of PCB waste shall not:

(i) Transport PCB waste without having received an EPA identification number from EPA.

(ii) Deliver PCB waste to transporters, disposers, or commercial storers of PCB waste that have not received an EPA identification number.

(3) A commercial storer of PCB waste shall not accept any PCB waste for storage without having received an EPA identification number from EPA.

(4) A disposer of PCB waste shall not accept any PCB waste for disposal without having received an EPA identification number from EPA. A disposer of PCB waste who owns more than one disposal facility or mobile treatment unit shall not accept waste unless the disposer has received an EPA identification number for each facility or mobile unit.

(c) *PCB waste handled prior to effective date of this subpart.* Generators (other than generators exempt from notification under § 761.205(c)(1)), commercial storers, transporters, and disposers of PCB waste who are required to have EPA identification numbers under this subpart, and who were engaged in PCB waste handling activities on or prior to February 5, 1990, are not subject to the prohibitions of paragraph (b) of this section if they have applied for an EPA identification number in accordance with the applicable notification procedures of § 761.205. Such persons shall use the EPA identification number ''40 CFR PART 761,'' or a number assigned to the persons by EPA or a State under RCRA, until EPA issues to such persons a specific identification number under § 761.205(a), (b), or (c).

(d) *PCB waste first handled after effective date of this subpart.* Generators (other than generators exempt from notification under § 761.205(c)(1)), commercial storers, transporters, and disposers of PCB waste who are required to have EPA identification numbers under this subpart, and who first engage in PCB waste activities after February 5, 1990, are subject to the prohibitions in paragraph (b) of this section.

§ 761.205 Notification of PCB waste activity (EPA Form 7710–53).

(a)(1) All commercial storers, transporters, and disposers of PCB waste

who were engaged in PCB waste handling activities on or prior to February 5, 1990 shall notify EPA of their PCB waste activities by filing EPA Form 7710–53 with EPA by no later than April 4, 1990. Upon receiving the notification form, EPA will assign an EPA identification number to each entity that notifies.

(2) All generators (other than generators exempt from notification under paragraph (c)(1) of this section), commercial storers, transporters, and disposers of PCB waste who first engage in PCB waste handling activities after February 5, 1990, shall notify EPA of their PCB waste activities by filing EPA Form 7710–53 with EPA prior to engaging in PCB waste handling activities.

(3) Any person required to notify EPA under this section shall file with EPA Form 7710–53. Copies of EPA Form 7710–53 are available on EPA's Web site at *http://www.epa.gov/pcb*, or from the Program Management, Communications, and Analysis Office, Office of Resource Conservation and Recovery (5305P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Descriptive information and instructions for filling in the form are included in paragraphs (a)(4)(i) through (vii) of this section.

(4) All of the following information shall be provided to EPA on Form 7710–53:

(i) The name of the facility, and the name of the owner or operator of the facility.

(ii) EPA identification number, if any, previously issued to the facility.

(iii) The facility's mailing address.

(iv) The location of the facility.

(v) The facility's installation contact and telephone number.

(vi) The type of PCB waste activity engaged in at the facility.

(vii) Signature of the signer of the certification statement, typed or printed name and official title of signer, and date signed.

(viii) EPA has determined that the information in paragraphs (a)(4)(i) through (a)(4)(vii) of this section shall not be treated as confidential business information. This information will be disclosed to the public without further notice to the submitter unless the submitter provides a written justification (submitted with the notification form) which demonstrates extraordinary reasons why the information should be entitled to confidential treatment.

(b) Generators (other than those generators exempt from notification under paragraph (c)(1) of this section), commercial storers, transporters, and disposers of PCB waste who have previously notified EPA or a State of hazardous waste activities under RCRA shall notify EPA of their PCB waste activities under this part by filing EPA Form 7710–53 with EPA by no later than April 4, 1990. The notification shall include the EPA identification number previously issued by EPA or the State and upon receipt of the notification, EPA shall verify and authorize the use of the previously issued identification number for PCB waste activities.

(c)(1) Generators of PCB waste need not notify EPA and receive unique EPA identification numbers under this section, unless their PCB waste activities are described in paragraph (c)(2) of this section. Generators exempted from notifying EPA under this paragraph shall use the generic identification number ''40 CFR PART 761'' on the manifests, records, and reports which they shall prepare under this subpart, unless such generators elect to use a unique EPA identification number previously assigned to them under RCRA by EPA or a State.

(2) Generators of PCB waste who use, own, service, or process PCBs or PCB Items shall notify EPA of their PCB waste activities only if they own or operate PCB storage facilities subject to the storage requirements of § 761.65 (b) or (c)(7). Such generators shall notify EPA in the following manner:

(i) Generators storing PCB waste subject to the storage requirements of § 761.65 (b) or (c)(7) shall notify EPA by filing EPA Form 7710–53 with EPA by no later than April 4, 1990.

(ii) Generators who desire to commence storage of PCB waste after February 5, 1990 shall notify EPA and receive an EPA identification number before they may commence storage of PCBs at their facilities established under § 761.65 (b) or (c)(7).

(iii) A separate notification shall be submitted to EPA for each PCB storage facility owned or operated by generators of PCB waste. Upon receiving these notifications, EPA will assign generators unique EPA identification numbers for each storage facility notifying EPA under this section.

(d) Persons required to notify under this section shall file EPA Form 7710–53 with EPA by mailing the form to the following address: Document Control Officer, Office of Resource Conservation and Recovery (5305P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(e) The requirements under this section to notify EPA and obtain EPA identification numbers shall in no case excuse compliance by any person subject to the 1-year limit on storage prior to disposal under § 761.65(a).

(f) When a facility has previously notified EPA of its PCB waste handling activities using EPA Form 7710-53 and those activities change, the facility must resubmit EPA Form 7710-53 to reflect those changes no later than 30 days from when a change is made. Examples of when a PCB waste handler must renotify the Agency include, but are not limited to the following: the company changes location of the facility; or the company had notified solely as engaging in a certain type of PCB waste handling activity and now wishes to engage in another PCB waste activity (e.g., previously only commercially stored PCB waste and now wishes to transport PCB waste).

[54 FR 52752, Dec. 21, 1989, as amended at 58 FR 15809, Mar. 24, 1993; 58 FR 34205, June 23, 1993; 59 FR 33697, June 30, 1994; 63 FR 35461, June 29, 1998; 72 FR 57241, Oct. 9, 2007; 74 FR 30234, June 25, 2009]

§ 761.207 The manifest—general requirements.

(a) A generator who transports, or offers for transport PCB waste for commercial off-site storage or off-site disposal, and commercial storage or disposal facility who offers for transport a rejected load of PCB waste, must prepare a manifest on EPA Form 8700–22, and, if necessary, a continuation sheet, according to the instructions included in the appendix of 40 CFR Part 262. The generator shall specify:

(1) For each bulk load of PCBs, the identity of the PCB waste, the earliest date of removal from service for disposal, and the weight in kilograms of the PCB waste. (Item 14—Special Handling Instructions box)

(2) For each PCB Article Container or PCB Container, the unique identifying number, type of PCB waste (e.g., soil, debris, small capacitors), earliest date of removal from service for disposal, and weight in kilograms of the PCB waste contained. (Item 14—Special Handling Instructions box)

(3) For each PCB Article not in a PCB Container or PCB Article Container, the serial number if available, or other identification if there is no serial number, the date of removal from service for disposal, and weight in kilograms of the PCB waste in each PCB Article. (Item 14—Special Handling Instructions box)

NOTE 1 TO PARAGRAPH (a): EPA Form 8700–22A is not required as the PCB manifest continuation sheet. In practice, form 8700–22A does not have adequate space to list required PCB-specific information for several PCB articles. However, if form 8700–22A fits the needs of the user community, the form is permissible.

NOTE 2 TO PARAGRAPH (a): PCB waste handlers should use the Part 262 appendix instructions as a guide, but should defer to the Part 761 manifest regulations whenever there is any difference between the Part 761 requirements and the instructions in the appendix to Part 262. The differences should be minimal.

NOTE 3 TO PARAGRAPH (a): PCBs are not regulated under RCRA, thus do not have a RCRA waste code. EPA does not require boxes 13 and 31 on forms 8700–22 and 8700–22A (if used), respectively, to be completed for shipments only containing PCB waste. However, some States track PCB wastes as State-regulated hazardous wastes, and assign State hazardous waste codes to these wastes. In such a case, the user should follow the State instructions for completing the waste code fields.

(b) A generator must designate on the manifest one facility which is approved to handle the PCB waste described on the manifest.

(c) A generator may also designate on the manifest one alternate facility which is approved to handle his PCB

waste in the event an emergency prevents delivery of the waste to the primary designated facility.

(d) If the transporter is unable to deliver the PCB waste to the designated facility or the alternate facility, the generator must either designate another facility or instruct the transporter to return the PCB waste.

(e) The requirements of this section apply only to PCB wastes as defined in §761.3. This includes PCB wastes with PCB concentrations below 50 ppm where the PCB concentration below 50 ppm was the result of dilution; these PCB wastes are required under §761.1(b) to be managed as if they contained PCB concentrations of 50 ppm and above. An example of such a PCB waste is spill cleanup material containing <50 ppm PCBs when the spill involved material containing PCBs at a concentration of ≥50 ppm. However, there is no manifest requirement for material currently below 50 ppm which derives from pre-April 18, 1978, spills of any concentration, pre-July 2, 1979, spills of <500 ppm PCBs, or materials decontaminated in accordance with §761.79.

(f) The requirements of this subpart do not apply to the transport of PCB wastes on a public or private right-of-way within or along the border of contiguous property under the control of the same person, even if such contiguous property is divided by a public or private right-of-way.

[77 FR 54830, Sept. 6, 2012, as amended at 80 FR 37995, July 2, 2015]

§ 761.208 Obtaining manifests.

(a)(1) A generator may use manifests printed by any source so long as the source of the printed form has received approval from EPA to print the manifest under 40 CFR 262.21 (c) and (e). A registered source may be a:

(i) State agency;

(ii) Commercial printer;

(iii) PCB waste generator, transporter or, designated facility; or

(iv) PCB waste broker or other preparer who prepares or arranges shipments of PCB waste for transportation.

(2) A generator must determine whether the generator state or the consignment state for a shipment regulates PCB waste as a State-regulated hazardous waste. Generators also must determine whether the consignment state or generator state requires the generator to submit any copies of the manifest to these states. In cases where the generator must supply copies to either the generator's state or the consignment state, the generator is responsible for supplying legible photocopies of the manifest to these states.

(b) [Reserved]

[77 FR 54831, Sept. 6, 2012]

§ 761.209 Number of copies of a manifest.

The manifest consists of at least the number of copies which will provide the generator, each transporter, and the owner or operator of the designated facility with one copy each for their records and another copy to be returned to the generator.

[77 FR 54831, Sept. 6, 2012]

§ 761.210 Use of the manifest—Generator requirements.

(a) The generator must:

(1) Sign the manifest certification by hand; and

(2) Obtain the handwritten signature of the initial transporter and date of acceptance on the manifest; and

(3) Retain one copy, in accordance with §761.214(a)(1).

(b) The generator must give the transporter the remaining copies of the manifest.

(c) For shipments of PCB waste within the United States solely by water (bulk shipments only), the generator must send three copies of the manifest dated and signed in accordance with this section to the owner or operator of the designated facility. Copies of the manifest are not required for each transporter.

(d) For rail shipments of PCB waste within the United States which originate at the site of generation, the generator must send at least three copies of the manifest dated and signed in accordance with this section to:

(1) The next non-rail transporter, if any; or

(2) The designated facility if transported solely by rail.

(e) For rejected shipments of PCB waste that are returned to the generator by the designated facility (following the procedures of § 761.215(f)), the generator must:

(1) Sign either:

(i) Item 20 of the new manifest if a new manifest is used for the returned shipment; or

(ii) Item 18c of the original manifest if the original manifest is used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of delivery of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the generator; and

(4) Retain at the generator's site a copy of each manifest for at least three years from the date of delivery.

[77 FR 54831, Sept. 6, 2012]

§ 761.211 Manifest system—Transporter requirements.

(a)(1) A transporter shall not accept PCB waste from a generator unless it is accompanied by a manifest signed by the generator in accordance with § 761.210(a)(1), except that a manifest is not required if any one of the following conditions exists:

(i) The shipment of PCB waste consists solely of PCB wastes with PCB concentrations below 50 ppm, unless the PCB concentration below 50 ppm was the result of dilution, in which case § 761.1(b) requires that the waste be managed as if it contained PCBs at the concentration prior to dilution.

(ii) The PCB waste is accepted by the transporter for transport only to a storage or disposal facility owned or operated by the generator of the PCB waste.

(2) [Reserved]

(b) Before transporting the PCB waste, the transporter must sign and date the manifest acknowledging acceptance of the PCB waste from the generator. The transporter must return a signed copy to the generator before leaving the generator's property.

(c) The transporter shall ensure that the manifest accompanies the PCB waste.

(d) A transporter who delivers PCB waste to another transporter or to the designated facility must:

(1) Obtain the date of delivery and the handwritten signature of that transporter or of the owner or operator of the designated facility on the manifest; and

(2) Retain one copy of the manifest in accordance with § 761.214; and

(3) Give the remaining copies of the manifest to the accepting transporter or designated facility.

(e) The requirements of paragraphs (c), (d) and (f) of this section do not apply to water (bulk shipment) transporters if:

(1) The PCB waste is delivered by water (bulk shipment) to the designated facility; and

(2) A shipping paper containing all the information required on the manifest (excluding EPA identification number, generator certification, and signatures) accompanies the PCB waste; and

(3) The delivering transporter obtains the date of delivery and handwritten signature of the owner or operator of the designated facility on either the manifest or the shipping paper; and

(4) The person delivering the PCB waste to the initial water (bulk shipment) transporter obtains the date of delivery and signature of the water (bulk shipment) transporter on the manifest and forwards it to the designated facility; and

(5) A copy of the shipping paper or manifest is retained by each water (bulk shipment) transporter in accordance with § 761.214.

(f) For shipments involving rail transportation, the requirements of paragraphs (c), (d) and (e) do not apply and the following requirements do apply:

(1) When accepting PCB waste from a non-rail transporter, the initial rail transporter must:

(i) Sign and date the manifest acknowledging acceptance of the PCB waste;

(ii) Return a signed copy of the manifest to the non-rail transporter;

(iii) Forward at least three copies of the manifest to:

(A) The next non-rail transporter, if any; or,

(B) The designated facility, if the shipment is delivered to that facility by rail;

(iv) Retain one copy of the manifest and rail shipping paper in accordance with § 761.214.

(2) Rail transporters must ensure that a shipping paper containing all the information required on the manifest (excluding the EPA identification numbers, generator certification, and signatures) accompanies the PCB waste at all times.

NOTE: Intermediate rail transporters are not required to sign either the manifest or shipping paper.

(3) When delivering PCB waste to the designated facility, a rail transporter must:

(i) Obtain the date of delivery and handwritten signature of the owner or operator of the designated facility on the manifest or the shipping paper (if the manifest has not been received by the facility); and

(ii) Retain a copy of the manifest or signed shipping paper in accordance with § 761.214.

(4) When delivering PCB waste to a non-rail transporter a rail transporter must:

(i) Obtain the date of delivery and the handwritten signature of the next non-rail transporter on the manifest; and

(ii) Retain a copy of the manifest in accordance with § 761.214.

(5) Before accepting PCB waste from a rail transporter, a non-rail transporter must sign and date the manifest and provide a copy to the rail transporter.

[77 FR 54832, Sept. 6, 2012]

§ 761.212 Transporter compliance with the manifest.

(a) The transporter must deliver the entire quantity of PCB waste which he has accepted from a generator or a transporter to:

(1) The designated facility listed on the manifest; or

(2) The alternate designated facility, if the PCB waste cannot be delivered to the designated facility because an emergency prevents delivery; or

(3) The next designated transporter.

(b)(1) If the PCB waste cannot be delivered in accordance with paragraph (a) of this section because of an emergency condition other than rejection of the waste by the designated facility, then the transporter must contact the generator for further directions and must revise the manifest according to the generator's instructions.

(2) If PCB waste is rejected by the designated facility while the transporter is on the facility's premises, then the transporter must obtain the following:

(i) For a partial load rejection, a copy of the original manifest that includes the facility's date and signature, and the Manifest Tracking Number of the new manifest that will accompany the shipment, and a description of the partial rejection in the discrepancy block of the original manifest. The transporter must retain a copy of this manifest in accordance with § 761.214, and give the remaining copies of the original manifest to the rejecting designated facility. If the transporter is forwarding the rejected part of the shipment to an alternate facility or returning it to the generator, the transporter must obtain a new manifest to accompany the shipment, and the new manifest must include all of the information required in 40 CFR 761.215(e)(1) through (6) or (f)(1) through (6).

(ii) For a full load rejection that will be taken back by the transporter, a copy of the original manifest that includes the rejecting facility's signature and date attesting to the rejection, the description of the rejection in the discrepancy block of the manifest, and the name, address, phone number, and Identification Number for the alternate facility or generator to whom the shipment must be delivered. The transporter must retain a copy of the manifest in accordance with § 761.214, and give a copy of the manifest containing this information to the rejecting designated facility. If the original manifest is not used, then the transporter must obtain a new manifest for the shipment and comply with 40 CFR 761.215(e)(1) through (6).

(iii) No provision of this section shall be construed to affect or limit the applicability of any requirement applicable to transporters of PCB waste under regulations issued by the Department

of Transportation (DOT) and set forth at 49 CFR Part 171.

[77 FR 54832, Sept. 6, 2012]

§ 761.213 Use of manifest—Commercial storage and disposal facility requirements.

(a)(1) If a commercial storage or disposal facility receives PCB waste accompanied by a manifest, the owner, operator or his/her agent must sign and date the manifest as indicated in paragraph (a)(2) of this section to certify that the PCB waste covered by the manifest was received, that the PCB waste was received except as noted in the discrepancy space of the manifest, or that the PCB waste was rejected as noted in the manifest discrepancy space.

(2) If a commercial storage or disposal facility receives an off-site shipment of PCB waste accompanied by a manifest, the owner or operator, or his agent, shall:

(i) Sign and date, by hand, each copy of the manifest;

(ii) Note any discrepancies (as defined in § 761.215(a)) on each copy of the manifest;

(iii) Immediately give the transporter at least one copy of the manifest;

(iv) Within 30 days of delivery, send a copy of the manifest to the generator; and

(v) Retain at the facility a copy of each manifest for at least three years from the date of delivery.

(b) If a commercial storage or disposal facility receives, from a rail or water (bulk shipment) transporter, PCB waste which is accompanied by a shipping paper containing all the information required on the manifest (excluding the EPA identification numbers, generator's certification, and signatures), the owner or operator, or his agent, must:

(1) Sign and date each copy of the manifest or shipping paper (if the manifest has not been received) to certify that the PCB waste covered by the manifest or shipping paper was received;

(2) Note any significant discrepancies (as defined in § 761.215(a)) in the manifest or shipping paper (if the manifest has not been received) on each copy of the manifest or shipping paper.

NOTE TO PARAGRAPH (b)(2): The Agency does not intend that the owner or operator of a facility whose procedures include waste analysis must perform that analysis before signing the shipping paper and giving it to the transporter. Section 761.215(a), however, requires reporting an unreconciled discrepancy discovered during later analysis.

(3) Immediately give the rail or water (bulk shipment) transporter at least one copy of the manifest or shipping paper (if the manifest has not been received);

(4) Within 30 days after the delivery, send a copy of the signed and dated manifest or a signed and dated copy of the shipping paper (if the manifest has not been received within 30 days after delivery) to the generator; and

NOTE TO PARAGRAPH (b)(4): Section 761.210(c) requires the generator to send three copies of the manifest to the facility when PCB waste is sent by rail or water (bulk shipment).]

(5) Retain at the facility a copy of the manifest and shipping paper (if signed in lieu of the manifest at the time of delivery) for at least three years from the date of delivery.

(c) Whenever an off-site shipment of PCB waste is initiated from a commercial storage or disposal facility, the owner or operator of the commercial storage or disposal facility shall comply with the manifest requirements that apply to generators of PCB waste (§ 761.207).

[77 FR 54833, Sept. 6, 2012]

§ 761.214 Retention of manifest records.

(a)(1) A generator must keep a copy of each manifest signed in accordance with § 761.210(a) for three years or until he receives a signed copy from the designated facility which received the PCB waste. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter. A generator subject to annual document requirements under § 761.180 shall retain copies of each manifest for the period required by § 761.180(a).

(2) A transporter of PCB waste must keep a copy of the manifest signed by

the generator, himself, and the next designated transporter or the owner or operator of the designated facility for a period of three years from the date the PCB waste was accepted by the initial transporter.

(b) For shipments delivered to the designated facility by water (bulk shipment), each water (bulk shipment) transporter must retain a copy of the shipping paper containing all the information required in §761.211(e)(2) for a period of three years from the date the PCB waste was accepted by the initial transporter.

(c) For shipments of PCB waste by rail within the United States:

(1) The initial rail transporter must keep a copy of the manifest and shipping paper with all the information required in §761.211(f)(2) for a period of three years from the date the PCB waste was accepted by the initial transporter; and

(2) The final rail transporter must keep a copy of the signed manifest (or the shipping paper if signed by the designated facility in lieu of the manifest) for a period of three years from the date the PCB waste was accepted by the initial transporter.

NOTE TO PARAGRAPH (c): Intermediate rail transporters are not required to keep records pursuant to these regulations.

(d) A generator must keep a copy of each Exception Report for a period of at least three years from the due date of the report.

(e) The periods of retention referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

[77 FR 54833, Sept. 6, 2012]

§761.215 Manifest discrepancies.

(a) Manifest discrepancies are:

(1) Significant differences (as defined by paragraph (b) of this section) between the quantity or type of PCB waste designated on the manifest or shipping paper, and the quantity and type of PCB waste a facility actually receives; or

(2) Rejected wastes, which may be a full or partial shipment of PCB waste that the designated facility cannot accept.

(b) Significant differences in quantity are: For bulk waste, variations greater than 10 percent in weight or variations greater than 10 percent in weight of PCB waste in containers; for batch waste, any variation in piece count, such as a discrepancy of one PCB Transformer or PCB Container or PCB Article Container in a truckload. Significant differences in type are obvious differences which can be discovered by inspection or waste analysis, such as the substitution of solids for liquids or the substitution of high concentration PCBs (above 500 ppm) with lower concentration materials.

(c) Upon discovering a significant difference in quantity or type, the owner or operator must attempt to reconcile the discrepancy with the waste generator or transporter (e.g., with telephone conversations). If the discrepancy is not resolved within 15 days after receiving the waste, the owner or operator must immediately submit to the Regional Administrator a letter describing the discrepancy and attempts to reconcile it, and a copy of the manifest or shipping paper at issue.

(d)(1) Upon rejecting the PCB waste, the facility must consult with the generator prior to forwarding the waste to another facility that can manage the waste. If it is impossible to locate an alternative facility that can receive the waste, the facility may return the rejected waste to the generator. The facility must send the waste to the alternative facility or to the generator within 60 days of the rejection identification.

(2) While the facility is making arrangements for forwarding rejected wastes to another facility under this section, it must ensure that either the delivering transporter retains custody of the waste, or, the facility must provide for secure, temporary custody of the waste, pending delivery of the waste to the first transporter designated on the manifest prepared under paragraph (e) or (f) of this section.

(e) Except as provided in paragraph (e)(7) of this section, for full or partial load rejections that are to be sent off-

site to an alternate facility, the facility is required to prepare a new manifest in accordance with §761.207(a) and the following instructions:

(1) Write the generator's U.S. EPA ID number in Item 1 of the new manifest. Write the generator's name and mailing address in Item 5 of the new manifest. If the mailing address is different from the generator's site address, then write the generator's site address in the designated space for Item 5.

(2) Write the name of the alternate designated facility and the facility's U.S. EPA ID number in the designated facility block (Item 8) of the new manifest.

(3) Copy the manifest tracking number found in Item 4 of the old manifest to the Special Handling and Additional Information Block of the new manifest, and indicate that the shipment is a rejected waste from the previous shipment.

(4) Copy the manifest tracking number found in Item 4 of the new manifest to the manifest reference number line in the Discrepancy Block of the old manifest (Item 18a).

(5) Write the DOT description for the rejected load in Item 9 (U.S. DOT Description) of the new manifest and write the container types, quantity, and volume(s) of waste.

(6) Sign the Generator's/Offeror's Certification to certify, as the offeror of the shipment, that the waste has been properly packaged, marked and labeled and is in proper condition for transportation, and mail a signed copy of the manifest to the generator identified in Item 5 of the new manifest.

(7) For full load rejections that are made while the transporter remains present at the facility, the facility may forward the rejected shipment to the alternate facility by completing Item 18b of the original manifest and supplying the information on the next destination facility in the Alternate Facility space. The facility must retain a copy of this manifest for its records, and then give the remaining copies of the manifest to the transporter to accompany the shipment. If the original manifest is not used, then the facility must use a new manifest and comply with paragraphs (e)(1), (2), (3), (4), (5), and (6) of this section.

(f) Except as provided in paragraph (f)(7) of this section, for rejected wastes that must be sent back to the generator, the facility is required to prepare a new manifest in accordance with §761.207(a) and the following instructions:

(1) Write the facility's U.S. EPA ID number in Item 1 of the new manifest. Write the facility's name and mailing address in Item 5 of the new manifest. If the mailing address is different from the facility's site address, then write the facility's site address in the designated space for Item 5 of the new manifest.

(2) Write the name of the initial generator and the generator's U.S. EPA ID number in the designated facility block (Item 8) of the new manifest.

(3) Copy the manifest tracking number found in Item 4 of the old manifest to the Special Handling and Additional Information Block of the new manifest, and indicate that the shipment is a rejected waste from the previous shipment.

(4) Copy the manifest tracking number found in Item 4 of the new manifest to the manifest reference number line in the Discrepancy Block of the old manifest (Item 18a).

(5) Write the DOT description for the rejected load in Item 9 (U.S. DOT Description) of the new manifest and write the container types, quantity, and volume(s) of waste.

(6) Sign the Generator's/Offeror's Certification to certify, as offeror of the shipment, that the waste has been properly packaged, marked and labeled and is in proper condition for transportation.

(7) For full load rejections that are made while the transporter remains at the facility, the facility may return the shipment to the generator with the original manifest by completing Item 18a and 18b of the manifest and supplying the generator's information in the Alternate Facility space. The facility must retain a copy for its records and then give the remaining copies of the manifest to the transporter to accompany the shipment. If the original manifest is not used, then the facility must use a new manifest and comply with paragraphs (f)(1), (2), (3), (4), (5), (6), and (8) of this section.

(8) For full or partial load rejections that are returned to the generator, the facility must also comply with the exception reporting requirements in §761.217(a).

(g) If a facility rejects a waste after it has signed, dated, and returned a copy of the manifest to the delivering transporter or to the generator, the facility must amend its copy of the manifest to indicate the rejected wastes in the discrepancy space of the amended manifest. The facility must also copy the manifest tracking number from Item 4 of the new manifest to the Discrepancy space of the amended manifest, and must re-sign and date the manifest to certify to the information as amended. The facility must retain the amended manifest for at least three years from the date of amendment, and must within 30 days, send a copy of the amended manifest to the transporter and generator that received copies prior to their being amended.

[77 FR 54833, Sept. 6, 2012]

§761.216 Unmanifested waste report.

(a) If a facility accepts for storage or disposal any PCB waste from an offsite source without an accompanying manifest, or without an accompanying shipping paper as described by §761.211(e), and the owner or operator of the commercial storage or disposal facility cannot contact the generator of the PCB waste, then he shall notify the Regional Administrator of the EPA region in which his facility is located of the unmanifested PCB waste so that the Regional Administrator can determine whether further actions are required before the owner or operator may store or dispose of the unmanifested PCB waste, and additionally the owner or operator must prepare and submit a letter to the Regional Administrator within 15 days after receiving the waste. The unmanifested waste report must contain the following information:

(1) The EPA identification number, name and address of the facility;

(2) The date the facility received the waste;

(3) The EPA identification number, name and address of the generator and the transporter, if available;

(4) A description and the quantity of each unmanifested PCB waste the facility received;

(5) The method of storage or disposal for each PCB waste;

(6) Signature of the owner or operator of the facility or his authorized representative; and,

(7) A brief explanation of why the waste was unmanifested, if known.

(8) The disposition made of the unmanifested waste by the commercial storage or disposal facility, including:

(i) If the waste was stored or disposed by that facility, was the generator identified and was a manifest subsequently supplied.

(ii) If the waste was sent back to the generator, why and when.

(b) [Reserved]

[77 FR 54834, Sept. 6, 2012]

§761.217 Exception reporting.

(a)(1) A generator of PCB waste, who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the waste was accepted by the initial transporter, shall immediately contact the transporter and/or the owner or operator of the designated facility to determine the status of the PCB waste.

(2) A generator of PCB waste subject to the manifesting requirements shall submit an Exception Report to the EPA Regional Administrator for the Region in which the generator is located if the generator has not received a copy of the manifest with the hand written signature of the owner or operator of the designated facility within 45 days of the date the waste was accepted by the initial transporter. The exception report shall be submitted to EPA no later than 45 days from the date on which the generator should have received the manifest. The Exception Report shall include the following:

(i) A legible copy of the manifest for which the generator does not have confirmation of delivery;

(ii) A cover letter signed by the generator or his authorized representative explaining the efforts taken to locate the PCB waste and the results of those efforts.

(b) For rejected shipments of PCB waste that are forwarded to an alternate facility by a designated facility using a new manifest (following the procedures of § 761.215(e)(1) through (6)), the generator must comply with the requirements of paragraph (a) of this section, as applicable, for the shipment forwarding the material from the designated facility to the alternate facility instead of for the shipment from the generator to the designated facility. For purposes of paragraph (a) of this section for a shipment forwarding such waste to an alternate facility by a designated facility:

(1) The copy of the manifest received by the generator must have the handwritten signature of the owner or operator of the alternate facility in place of the signature of the owner or operator of the designated facility, and

(2) The 35- and 45-day timeframes begin the date the waste was accepted by the initial transporter forwarding the PCB waste shipment from the designated facility to the alternate facility.

[77 FR 54835, Sept. 6, 2012]

§ 761.218 Certificate of disposal.

(a) For each shipment of manifested PCB waste that the owner or operator of a disposal facility accepts by signing the manifest, the owner or operator of the disposal facility shall prepare a Certificate of Disposal for the PCBs and PCB Items disposed of at the facility, which shall include:

(1) The identity of the disposal facility, by name, address, and EPA identification number.

(2) The identity of the PCB waste affected by the Certificate of Disposal including reference to the manifest number for the shipment.

(3) A statement certifying the fact of disposal of the identified PCB waste, including the date(s) of disposal, and identifying the disposal process used.

(4) A certification as defined in § 761.3.

(b) The owner or operator of the disposal facility shall send the Certificate of Disposal to the generator identified on the manifest which accompanied the shipment of PCB waste within 30 days of the date that disposal of each item of PCB waste identified on the manifest was completed unless the generator and the disposer contractually agree to another time frame.

(c) The disposal facility shall keep a copy of each Certificate of Disposal among the records that it retains under § 761.180(b).

(d)(1) Generators of PCB waste shall keep a copy of each Certificate of Disposal that they receive from disposers of PCB waste among the records they retain under § 761.180(a).

(2) Commercial storers of PCB waste shall keep a copy of each Certificate of Disposal that they receive from disposers of PCB waste among the records they retain under § 761.180(b).

[54 FR 52752, Dec. 21, 1984, as amended at 63 FR 35462, June 29, 1998]

§ 761.219 One-year exception reporting.

(a) A disposer of PCB waste shall submit a One-year Exception Report to the EPA Regional Administrator for the Region in which the disposal facility is located no later than 45 days from the end of the 1-year storage for disposal date when the following occurs:

(1) The disposal facility receives PCBs or PCB Items on a date more than 9 months from the date the PCBs or PCB Items were removed from service for disposal, as indicated on the manifest or continuation sheet; and

(2) Because of contractual commitments or other factors affecting the facility's disposal capacity, the disposer of PCB waste could not dispose of the affected PCBs or PCB Items within 1 year of the date of removal from service for disposal.

(b) A generator or commercial storer of PCB waste who manifests PCBs or PCB Items to a disposer of PCB waste shall submit a One-year Exception Report to the EPA Regional Administrator for the Region in which the generator or commercial storer is located no later than 45 days from the date the following occurs:

(1) The generator or commercial storer transferred the PCBs or PCB Items to the disposer of PCB waste on a date within 9 months from the date of removal from service for disposal of the

affected PCBs or PCB Items, as indicated on the manifest or continuation sheet; and

(2) The generator or commercial storer either has not received within 13 months from the date of removal from service for disposal a Certificate of Disposal confirming the disposal of the affected PCBs or PCB Items, or the generator or commercial storer receives a Certificate of Disposal confirming disposal of the affected PCBs or PCB Items on a date more than 1 year after the date of removal from service.

(c) The One-year Exception Report shall include:

(1) A legible copy of any manifest or other written communication relevant to the transfer and disposal of the affected PCBs or PCB Items.

(2) A cover letter signed by the submitter or an authorized representative explaining:

(i) The date(s) when the PCBs or PCB Items were removed from service for disposal.

(ii) The date(s) when the PCBs or PCB Items were received by the submitter of the report, if applicable.

(iii) The date(s) when the affected PCBs or PCB Items were transferred to a designated disposal facility.

(iv) The identity of the transporters, commercial storers, or disposers known to be involved with the transaction.

(v) The reason, if known, for the delay in bringing about the disposal of the affected PCBs or PCB Items within 1 year from the date of removal from service for disposal.

(d) PCB/radioactive waste that is exempt from the 1-year storage for disposal time limit pursuant to §761.65(a)(1) is also exempt from the exception reporting requirements of paragraphs (a), (b), and (c) of this section.

[77 FR 54835, Sept. 6, 2012]

Subpart L [Reserved]

Subpart M—Determining a PCB Concentration for Purposes of Abandonment or Disposal of Natural Gas Pipeline: Selecting Sample Sites, Collecting Surface Samples, and Analyzing Standard PCB Wipe Samples

SOURCE: 63 FR 35462, June 29, 1998, unless otherwise noted.

§ 761.240 Scope and definitions.

(a) Use these procedures to select surface sampling sites for natural gas pipe to determine its PCB surface concentration for abandonment-in-place or removal and disposal off-site in accordance with §761.60(b)(5).

(b) ''Pipe segment'' means a length of natural gas pipe that has been removed from the pipeline system to be disposed of or reused, and that is usually approximately 12.2 meters (40 feet) or shorter in length. Pipe segments are usually linear.

(c) ''Pipeline section'' means a length of natural gas pipe that has been cut or otherwise separated from the active pipeline, usually for purposes of abandonment, and that is usually longer than 12.2 meters in length. Pipeline sections may be branched.

§ 761.243 Standard wipe sample method and size.

(a) Collect a surface sample from a natural gas pipe segment or pipeline section using a standard wipe test as defined in §761.123. Detailed guidance for the entire wipe sampling process appears in the document entitled, ''Wipe Sampling and Double Wash/Rinse Cleanup as Recommended by the Environmental Protection Agency PCB Spill Cleanup Policy,'' dated June 23, 1987 and revised on April 18, 1991. This document is available on EPA's Web site at *http://www.epa.gov/pcb*, or from the Program Management, Communications, and Analysis Office, Office of Resource Conservation and Recovery (5305P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(b) Collect a surface sample from a minimum surface area of 100 cm^2 at each sampling site selected. The EPA

Regional Administrator may approve, in writing, requests to collect a sample from smaller surface areas, when <100 cm^2 of surface eligible for sampling is present; e.g., when sampling a small diameter pipe, a small valve, or a small regulator. When smaller surfaces are sampled, convert the measurement to the equivalent measurement for 100 cm^2 for purposes of comparison to standards based on 100 cm^2.

[63 FR 35462, June 29, 1998, as amended at 72 FR 57241, Oct. 9, 2007; 74 FR 30235, June 25, 2009]

§ 761.247 Sample site selection for pipe segment removal.

(a) *General.* (1) Select the pipe segments to be sampled by following the directions in paragraph (b) of this section.

(2) Locate the proper position along the length of the pipe segment that you have selected for sampling, by following the directions in paragraph (c) of this section.

(3) Select the proper sampling position around the circumference of the pipe segment that you have selected for sampling, by following the directions in paragraph (d) of this section.

(4) Prior to removing pipe from the ground or lifting the pipe from its location during former operations, mark the top side of the pipe.

(5) Do not sample if there are free-flowing liquids in the pipe segment. Free-flowing liquids must be removed prior to sampling.

(b) *Selecting pipe segments to sample.* Select the pipe segment(s) that you will sample from a length of pipe or group of pipe segments, as follows:

(1) Do not sample a pipe segment that is longer than 12.2 meters (40 feet). If a segment is longer than 12.2 meters in length, cut the segment so that all resulting segments are 12.2 meters or less in length.

(2) Determine which pipe segments to sample as follows:

(i) When a length of pipe having seven or fewer segments is removed for purposes of disposal, sample each pipe segment.

(ii) When removing a length of pipe having multiple contiguous segments less than 3 miles in total length, take samples from a total of seven segments.

(A) Sample the first and last segments removed.

(B) Select the five additional segments according to one of the two following procedures:

(*1*) Assign all segments a unique sequential number. Then select five numbers using a random number table or random number generator. If the random number generator or random number table produces either the first pipe segment, the last pipe segment, or any previously selected segment, select another random number until there are seven different numbers, each corresponding to a different pipe segment.

(*2*) Divide the total number of segments by six. Round the resulting quotient off to the nearest whole number. The resulting number is the interval between the segments you will sample. For example, cut a 2.9 mile length of pipeline into 383 segments of approximately 40 feet each. Sample the first (number 1) and last (number 383) segments. To determine which additional five segments to sample, divide the total number of segments, 383, by 6. Round up the resulting number in this example, 63.8, to the next whole number, 64. Add 64 to the number of each preceding pipe segment five separate times to select five additional pipe segments for sampling. In this example, the first pipe segment has the number 1, add 64 to 1 to select segment 65. Next, add 64 to 65 to select segment 129. Continue in this fashion to select all seven segments: 1, 65, 129, 193, 257, 321, and 383.

(iii) When removing a length of pipe having multiple contiguous segments more than 3 miles in total length for purposes of disposal, take samples of each segment that is ½ mile distant from the segment previously sampled. Sample a minimum of seven segments.

(c) *Selecting the sampling position—length.* Select the sampling position along the length of the pipe segment, as follows:

(1) Take samples at the end upstream of the former gas flow of each segment removed.

(2) If the pipe segment is cut with a torch or other high temperature heat source, take the sample at least 15 cm

(6 inches) inside the cut end of the pipe segment.

(3) If the pipe segment is cut with a saw or other mechanical device, take the sample at least 2 cm (1 inch) inside the end of the pipe segment.

(4) If the sample site location selected in the procedure at paragraph (c)(2) or (c)(3) of this section is a porous surface (for example, there is significant corrosion so that the wipe material will be shredded), then move the sample site further inside the pipe segment (away from the end of the pipe or pipe segment) until there is no such porous surface. For purposes of this subpart, natural gas pipe with a thin porous corrosion preventive coating is a non-porous surface.

(5) If there is not a non-porous surface accessible by paragraphs (c)(2) and (c)(3) of this section, use one of the following three options:

(i) Sample the downstream end of the pipe segment using the same sample site location procedure as for the upstream end.

(ii) Select another pipe segment using the random selection procedure described in paragraph (b) of this section.

(iii) If there is no other pipe segment in the population to be sampled and both ends of a pipe segment have porous surfaces at all possible sample collection sites, then assume that the pipe segment contains ≥50 ppm PCB but <500 ppm PCB.

(d) *Selecting the sample position—circumference.* Based on the mark on the top of the pipe segment made prior to removing pipe from the ground or lifting the pipe from its location during former operations, sample the inside center of the bottom of the pipe being sampled. Make sure the sample is centered on the bottom of the pipe segment; that is, sample an equal area on both sides of the middle of the bottom of the pipe segment for the entire length of the sample.

[63 FR 35462, June 29, 1998, as amended at 64 FR 33762, June 24, 1999]

§ 761.250 Sample site selection for pipeline section abandonment.

This procedure is for the sample site selection for a pipeline section to be abandoned, in accordance with § 761.60(b)(5)(i)(B).

(a) *General.* (1) Select sample collection sites in the pipeline section(s) by following the directions in paragraph (b) of this section.

(2) Select the proper sampling position along the pipe by following the directions in § 761.247 (c) and (d).

(3) Assure, by visual inspection, the absence of free-flowing liquids in the pipe by affirming no liquids at all liquid collection points and all ends of the pipeline section to be abandoned.

(b) *Selection sample collection sites.* At a minimum, sample all ends of all pipeline sections to be abandoned in place.

(1) If the pipeline section to be abandoned is between the pressure side of one compressor station and the suction side of the next compressor station downstream of the former gas flow, at a minimum, sample all ends of the abandoned pipe.

(2) If the pipeline section to be abandoned is longer than the distance between the pressure side of one compressor station and the suction side of the next compressor station downstream of the former gas flow, divide the pipeline section, for purposes of sampling, into smaller pipeline sections no longer than the distance from the pressure side of one compressor station to the suction side of the next compressor station downstream of the former gas flow. Consider each of the smaller sections to be a separate abandonment and sample each one, at a minimum, at all ends.

(3) Use the following procedure to locate representative sample collection sites in pipeline sections at points other than the suction and pressure side of compressor stations, or the ends of the pipeline section to be abandoned.

(i) First, assign a unique identifying sequential number to each kilometer or fraction of a kilometer length of pipe within the entire pipeline section.

(ii) Use a random number table or a random number generator to select each representative sample collection site from a complete list of the sequential identification numbers.

(iii) Samples may be collected by removing any covering soil, cutting the

pipe to gain access to the sampling location, and collecting the surface sample with the pipe in place, rather than completely removing the pipeline sections to collect the surface sample.

[63 FR 35462, June 29, 1998, as amended at 64 FR 33762, June 24, 1999]

§ 761.253 Chemical analysis.

(a) Extract PCBs from the standard wipe sample collection medium and clean-up the extracted PCBs in accordance with either Method 3500B/3540C or Method 3500B/3550B from EPA's SW-846, Test Methods for Evaluating Solid Waste, or a method validated under subpart Q of this part. Use Method 8082 from SW-846, or a method validated under subpart Q of this part, to analyze these extracts for PCBs.

(b) Report all PCB sample concentrations in µg/100 cm^2 (16 square inches) of surface sampled. If sampling an area smaller than 100 cm^2, report converted sample concentrations in accordance with § 761.243(b).

§ 761.257 Determining the regulatory status of sampled pipe.

(a) For purposes of removal for disposal of a pipe segment that has been sampled, the sample results for that segment determines its PCB surface concentration. Determine the PCB surface concentration of a segment which was not sampled as follows:

(1) If the unsampled pipe segment is between two pipe segments which have been sampled, assume that the unsampled segment has the same PCB surface concentration as the nearest sampled pipe segment.

(2) If an unsampled pipe segment is equidistant between two pipe segments which have been sampled, assume the PCB surface concentration of the unsampled segment to be the arithmetic mean of the PCB surface concentrations measured in the two equidistant, sampled, pipe segments.

(b) For purposes of abandonment of a pipeline section, assume that the PCB surface concentration for an entire pipeline section is the arithmetic mean of the PCB surface concentrations measured at the ends of the pipeline section. If additional representative samples were taken in a pipeline section, assume that the PCB surface concentration for the entire pipeline section is the arithmetic mean of the concentrations measured in all representative samples taken.

(c) For purposes of removal for disposal under § 761.60(b)(5)(ii)(A)(*1*) or abandonment under § 761.60(b)(5)(i)(B), if the surface PCB concentration of a pipe segment, determined by direct measurement or in accordance with paragraph (a) of this section, or of a pipeline section as determined in accordance with paragraph (b) of this section, is >10 µg/100 cm^2, but <100 µg/100 cm^2, then that segment or section is PCB-Contaminated.

Subpart N—Cleanup Site Characterization Sampling for PCB Remediation Waste in Accordance with § 761.61(a)(2)

SOURCE: 63 FR 35464, June 29, 1998, unless otherwise noted.

§ 761.260 Applicability.

This subpart provides a method for collecting new data for characterizing a PCB remediation waste cleanup site or for assessing the sufficiency of existing site characterization data, as required by § 761.61(a)(2).

§ 761.265 Sampling bulk PCB remediation waste and porous surfaces.

(a) Use a grid interval of 3 meters and the procedures in §§ 761.283 and 761.286 to sample bulk PCB remediation waste that is not in a container and porous surfaces.

(b) Use the following procedures to sample bulk PCB remediation waste that is in a single container.

(1) Use a core sampler to collect a minimum of one core sample for the entire depth of the waste at the center of the container. Collect a minimum of 50 cm^3 of waste for analysis.

(2) If more than one core sample is taken, thoroughly mix all samples into a composite sample. Take a subsample of a minimum of 50 cm^3 from the mixed composite for analysis.

(c) Use the following procedures to sample bulk PCB remediation waste that is in more than one container.

(1) Segregate the containers by type (for example, a 55-gallon drum and a

roll-off container are types of containers).

(2) For fewer than three containers of the same type, sample all containers.

(3) For more than three containers of the same type, list the containers and assign each container an unique sequential number. Use a random number generator or table to select a minimum of 10 percent of the containers from the list, or select three containers, whichever is the larger.

(4) Sample the selected container(s) according to paragraph (b) of this section.

§ 761.267 Sampling non-porous surfaces.

(a) Sample large, nearly flat, non-porous surfaces by dividing the surface into roughly square portions approximately 2 meters on each side. Follow the procedures in § 761.302(a).

(b) It is not necessary to sample small or irregularly shaped surfaces.

§ 761.269 Sampling liquid PCB remediation waste.

(a) If the liquid is single phase, collect and analyze one sample. There are no required procedures for collecting a sample.

(b) If the liquid is multi-phasic, separate the phases, and collect and analyze a sample from each liquid phase. There are no required procedures for collecting a sample from each single phase liquid.

(c) If the liquid has a non-liquid phase which is >0.5 percent by total weight of the waste, separate the non-liquid phase from the liquid phase and sample it separately as a non-liquid in accordance with § 761.265.

§ 761.272 Chemical extraction and analysis of samples.

Use either Method 3500B/3540C or Method 3500B/3550B from EPA's SW-846, Test Methods for Evaluating Solid Waste, or a method validated under subpart Q of this part, for chemical extraction of PCBs from individual and composite samples of PCB remediation waste. Use Method 8082 from SW-846, or a method validated under subpart Q of this part, to analyze these extracts for PCBs.

§ 761.274 Reporting PCB concentrations in samples.

(a) Report all sample concentrations for non-liquid PCBs on a dry weight basis as micrograms of PCBs per gram of sample (ppm by weight). Report surface sampling results as μg/100 cm^2. Divide 100 cm^2 by the surface area and multiply this quotient by the total number of micrograms of PCBs on the surface to obtain the equivalent measurement of micrograms per 100 cm^2.

(b) Report all sample concentrations for liquid PCBs on a wet weight basis as micrograms of PCBs per gram of sample (ppm by weight).

Subpart O—Sampling To Verify Completion of Self-Implementing Cleanup and On-Site Disposal of Bulk PCB Remediation Waste and Porous Surfaces in Accordance With § 761.61(a)(6)

SOURCE: 63 FR 35465, June 29, 1998, unless otherwise noted.

§ 761.280 Application and scope.

Follow the procedures in this subpart when sampling to verify completion of the cleanup for self-implementing, on-site disposal of bulk PCB remediation waste and porous surfaces consistent with the levels of § 761.61(a)(4)(i) and (iii). The objective of this subpart is not to search for new contamination. Confirmation of compliance with the cleanup levels in § 761.61(a)(4) is only verifiable for the area sampled in accordance with this subpart. Do not make conclusions or extrapolations about PCB concentrations outside of the area which has been cleaned up and verified based on the results of this verification sampling.

§ 761.283 Determination of the number of samples to collect and sample collection locations.

This section addresses how to determine the number of samples to collect and sample collection locations for bulk PCB remediation waste and porous surfaces destined to remain at a cleanup site after cleanup.

(a) *Minimum number of samples.* (1) At each separate cleanup site at a PCB remediation waste location, take a minimum of three samples for each type of bulk PCB remediation waste or porous surface at the cleanup site, regardless of the amount of each type of waste that is present. There is no upper limit to the number of samples required or allowed.

(2) This is an example of how to calculate the minimum number of required samples at a PCB remediation waste location. There are three distinct cleanup sites at this example location: a loading dock, a transformer storage lot, and a disposal pit. The minimum number of samples to take appears in parentheses after each type of waste for each cleanup site. The PCB remediation wastes present at the loading dock are concrete (three samples) and clay soil (three samples). The nonliquid PCB remediation wastes present at the transformer storage lot are oily soil (three samples), clay soil (three samples) and gravel (three samples). The PCB remediation wastes present at the disposal pit are sandy soil (three samples), clay soil (three samples), oily soil (three samples), industrial sludge (three samples), and gravel (three samples).

(b) *Selection of sample locations—general.* (1)(i) Use a square-based grid system to overlay the entire area to be sampled. Orient the grid axes on a magnetic north-south line centered in the area and an east-west axis perpendicular to the magnetic north-south axis also centered in the area.

(ii) If the site is recleaned based on the results of cleanup verification conducted in accordance with §761.61(a)(6), follow the procedures in paragraph (b) of this section for locating sampling points after the recleaning, but reorient the grid axes established in paragraph (b)(1)(i) of this section by moving the origin one meter in the direction of magnetic north and one meter in the direction east of magnetic north.

(2) Mark out a series of sampling points 1.5 meters apart oriented to the grid axes. The sampling points shall proceed in every direction to the extent sufficient to result in a two-dimensional grid completely overlaying the sampling area.

(3) Collect a sample at each point if the grid falls in the cleanup area. Analyze all samples either individually or according to the compositing schemes provided in the procedures at §761.289. So long as every sample collected at a grid point is analyzed as either an individual sample or as part of a composite sample, there are no other restrictions on how many samples are analyzed.

(c) *Selection of sample locations—small cleanup sites.* When a cleanup site is sufficiently small or irregularly shaped that a square grid with a grid interval of 1.5 meters will not result in a minimum of three sampling points for each type of bulk PCB remediation waste or porous surface at the cleanup site, there are two options.

(1) Use a smaller square grid interval and the procedures in paragraph (b) of this section.

(2) Use the following coordinate-based random sampling scheme. If the site is recleaned based on the results of cleanup verification conducted in accordance with §761.61(a)(6), follow the procedures in this section for locating sampling points after the recleaning, but select three new pairs of sampling coordinates.

(i) Beginning in the southwest corner (lower left when facing magnetic north) of the area to be sampled, measure in centimeters (or inches) the maximum magnetic north-south dimension of the area to be sampled. Next, beginning in the southwest corner, measure in centimeters (or inches) the maximum magnetic east-west dimension of the area to be sampled. Designate the north-south and east-west dimensions (describing the west and south boundaries, respectively, of the area to be sampled), as the reference axes of a square-based grid system.

(ii) Use a random number table or random number generator to select a pair of coordinates that will locate the sample within the area to be sampled. The first coordinate in the pair is the measurement on the north-south axis. The second coordinate in the pair is the measurement on the east-west axis. Collect the sample at the intersection of an east-west line drawn through the measured spot on the north-south axis, and a north-south line drawn through the measured spot on the east-west

axis. If the cleanup site is irregularly shaped and this intersection falls outside the cleanup site, select a new pair of sampling coordinates. Continue to select pairs of sampling coordinates until three are selected for each type of bulk PCB remediation waste or porous surface at the cleanup site.

(d) *Area of inference.* Analytical results for an individual sample point apply to the sample point and to an area of inference extending to four imaginary lines parallel to the grid axes and one half grid interval distant from the sample point in four different directions. The area of inference forms a square around the sample point. The sides of the square are parallel to the grid axes and one grid interval in length. The sample point is in the center of the square area of inference. The area of inference from a composite sample is the total of the areas of the individual samples included in the composite.

§ 761.286 Sample size and procedure for collecting a sample.

At each selected sampling location for bulk PCB remediation waste or porous surfaces, collect at least 20 milliliters of waste, or a portion of sufficient weight for the chemical analyst to measure the concentration of PCBs and still have sufficient analytical detection sensitivity to reproducibly measure PCBs at the levels designated in §761.61(a)(4). Use a core sampler having a diameter ≥2 cm and ≤3 cm. Collect waste to a maximum depth of 7.5 cms.

§ 761.289 Compositing samples.

Compositing is a method of combining several samples of a specific type of bulk PCB remediation waste or porous surface from nearby locations for a single chemical analysis. There are two procedures for compositing bulk PCB remediation waste samples. These procedures are based on the method for selecting sampling site locations in §761.283(b) and (c). The single chemical analysis of a composite sample results in an averaging of the concentrations of its component samples. The area of inference of a composite is determined by the area of inference of each of its component samples as described in §761.283(d). Compositing is not mandatory. However, if compositing is used, it must be performed in accordance with the following procedures.

(a) *Compositing in the field or in a laboratory.* Compositing may occur either in the field or in a laboratory. Prepare composite samples using equal volumes of each constituent or component sample. Composited samples must be from the same type of bulk PCB remediation waste or porous surface (see the example at §761.283(a)(2)). Mix composite samples thoroughly. From each well-mixed composite sample, take a portion of sufficient weight for the chemical analyst to measure the concentration of PCBs and still have sufficient analytical detection sensitivity to reproducibly measure PCBs at the levels designated in §761.61(a)(4).

(b)(1) *Compositing from samples collected at grid points in accordance with §761.283(b).* There are two kinds of composite sampling procedures depending on the original source of contamination of the site.

(i) The first procedure is for sites with multiple point sources of contamination (such as an old electrical equipment storage area, a scrap yard, or repair shop) or for unknown sources of contamination. Under this compositing scheme, composite a maximum of nine samples for each type of bulk PCB remediation waste or porous surface at the cleanup site. The maximum dimensions of the area enclosing a nine grid point composite is two grid intervals bounded by three collinear grid points (3.0 meters or approximately 10 feet long). Take all samples in the composite at the same depth. Assure that composite sample areas and individually analyzed samples completely overlay the cleanup site.

(ii) The second procedure is for a single point source of contamination, such as discharge into a large containment area (e.g., pit, waste lagoon, or evaporation pond), or a leak onto soil from a single drum or tank. Single point source contamination may be from a one-time or continuous contamination. Composites come from two stages: an initial compositing area centered in the area to be sampled, and subsequent compositing areas forming concentric square zones around the initial

compositing area. The center of the initial compositing area and each of the subsequent compositing areas is the origin of the grid axes.

(A) *Definition of the initial compositing area.* The initial compositing area is based on a square that contains nine grid points, is centered on the grid origin, and has sides two grid intervals long. The initial compositing area has the same center as this square and sides one half a grid interval more distant from the center than the square. The initial compositing area has sides three grid intervals long.

(B) *Definition of subsequent compositing areas.* Subsequent composite sampling areas are in concentric square zones one grid interval wide around the initial compositing area and around each successive subsequent compositing area. The inner boundary of the first subsequent compositing area is the outer boundary of the initial compositing area. The outer boundary of the first subsequent compositing area is centered on the grid origin, has sides one grid interval more distant from the grid origin than the inner boundary, and is two grid intervals longer on a side than the inner boundary. The inner boundary of each further subsequent compositing area is the outer boundary of the previous subsequent compositing area. The outer boundary of each further subsequent compositing area is centered on the grid origin, has sides one grid interval more distant from the grid origin than the inner boundary, and is two grid intervals longer on a side than the inner boundary.

(C) *Taking composite samples from the initial and subsequent compositing areas.* (*1*) Select composite sampling areas from the initial compositing area and subsequent compositing areas such that all grid points in the initial compositing area and subsequent compositing areas are part of a composite or individual sample.

(*2*) A person may include in a single composite sample a maximum of all nine grid points in the initial compositing area. The maximum number of grid points in a composite sample taken from a subsequent compositing area is eight. These eight grid points must be adjacent to one another in the subsequent compositing area, but need not be collinear.

(2) *Compositing from samples taken at grid points or pairs of coordinates in accordance with § 761.283(c).* Samples collected at small sites are based on selecting pairs of coordinates or using the sample site selection procedure for grid sampling with a smaller grid interval.

(i) *Samples collected from a grid having a smaller grid interval.* Use the procedure in paragraph (b)(1)(i) of this section to composite samples and determine the area of inference for composite samples.

(ii) *Samples collected from pairs of coordinates.* All three samples must be composited. The area of inference for the composite is the entire area sampled.

§ 761.292 Chemical extraction and analysis of individual samples and composite samples.

Use either Method 3500B/3540C or Method 3500B/3550B from EPA's SW-846, Test Methods for Evaluating Solid Waste, or a method validated under subpart Q of this part, for chemical extraction of PCBs from individual and composite samples of PCB remediation waste. Use Method 8082 from SW-846, or a method validated under subpart Q of this part, to analyze these extracts for PCBs.

§ 761.295 Reporting and recordkeeping of the PCB concentrations in samples.

(a) Report all sample concentrations for bulk PCB remediation waste and porous surfaces on a dry weight basis and as micrograms of PCBs per gram of sample (ppm by weight).

(b) Record and keep on file for 3 years the PCB concentration for each sample or composite sample.

§ 761.298 Decisions based on PCB concentration measurements resulting from sampling.

(a) For grid samples which are chemically analyzed individually, the PCB concentration applies to the area of inference as described in § 761.283(d).

(b) For grid samples analyzed as part of a composite sample, the PCB concentration applies to the area of inference of the composite sample as described in §761.283(d) (i.e., the area of inference is the total of the areas of the individual samples included in the composite).

(c) For coordinate pair samples analyzed as part of a composite sample, in accordance with §§761.283(c)(2) and 761.289(b)(2)(ii), the PCB concentration applies to the entire cleanup site.

Subpart P—Sampling Non-Porous Surfaces for Measurement-Based Use, Reuse, and On-Site or Off-Site Disposal Under §761.61(a)(6) and Decontamination Under §761.79(b)(3)

SOURCE: 63 FR 35467, June 29, 1998, unless otherwise noted.

§761.300 Applicability.

This subpart provides sample site selection procedures for large, nearly flat non-porous surfaces, and for small or irregularly shaped non-porous surfaces. This subpart also provides procedures for analyzing the samples and interpreting the results of the sampling. Any person verifying completion of self-implementing cleanup and on-site disposal of non-porous surfaces under §761.61(a)(6), or verifying that decontamination standards under §761.79(b)(3) are met, must use these procedures.

§761.302 Proportion of the total surface area to sample.

(a) *Large nearly flat surfaces.* Divide the entire surface into approximately 1 meter square portions and mark the portions so that they are clearly identified. Determine the sample location in each portion as directed in §761.304.

(1) For large nearly flat surfaces contaminated by a single source of PCBs with a uniform concentration, assign each 1 meter square surface a unique sequential number.

(i) For three or fewer 1 meter square areas, sample all of the areas.

(ii) For four or more 1 meter square areas, use a random number generator or table to select a minimum of 10 percent of the areas from the list, or to select three areas, whichever is more.

(2) For other large nearly flat surfaces, sample all of the one meter square areas.

(b) *Small or irregularly shaped surfaces.* For small surfaces having irregular contours, such as hand tools, natural gas pipeline valves, and most exterior surfaces of machine tools, sample the entire surface. Any person may select sampling locations for small, nearly flat surfaces in accordance with §761.308 with the exception that the maximum area in §761.308(a) is <1 meter square.

(c) *Preparation of surfaces.* Drain all free-flowing liquids from surfaces and brush off dust or loose grit.

§761.304 Determining sample location.

(a) For 1 square meter non-porous surface areas having the same size and shape, it is permissible to sample the same 10 cm by 10 cm location or position in each identical 1 square meter area. This location or position is determined in accordance with §761.306 or §761.308.

(b) If some 1 square meter surfaces for a larger non-porous surface area have different sizes and shapes, separately select the 10 cm by 10 cm sampling position for each different 1 square meter surface in accordance with §761.308.

(c) If non-porous surfaces have been cleaned and the cleaned surfaces do not meet the applicable standards or levels, surfaces may be recleaned and resampled. When resampling surfaces previously sampled to verify cleanup levels, use the sampling procedures in §§761.306 through 761.316 to resample the surfaces. If any sample site selected coincides with a previous sampling site, restart the sample selection process until all resampling sites are different from any previous sampling sites.

§761.306 Sampling 1 meter square surfaces by random selection of halves.

(a) Divide each 1 meter square portion where it is necessary to collect a surface wipe test sample into two equal (or as nearly equal as possible) halves. For example, divide the area into top

and bottom halves or left and right halves. Choose the top/bottom or left/right division that produces halves having as close to the shape of a circle as possible. For example, a square is closer to the shape of a circle than is a rectangle and a rectangle having a length to width ratio of 2:1 is closer to the shape of a circle than a rectangle having a length to width ratio of 3:1.

(b) Assign a unique identifier to each half and then select one of the halves for further sampling with a random number generator or other device (i.e., by flipping a coin).

(c) Continue selecting progressively smaller halves by dividing the previously selected half, in accordance with paragraphs (a) and (b) of this section, until the final selected half is larger than or equal to 100 cm^2 and smaller than 200 cm^2.

(d) Perform a standard PCB wipe test on the final selected halves from each 1 meter square portion.

(e) The following is an example of applying sampling by halves. Assume that the area to sample is a 1 meter square surface area (a square that has sides 1 meter long). Assign each half to one face of a coin. After flipping the coin, the half assigned to the face of the coin that is showing is the half selected.

(1) Selecting the first half:

(i) For a square shape the top/bottom halves have the same shape as the left/right halves when compared to a circle, i.e., regardless of which way the surface is divided, each half is 1 half meter wide by 1 meter long. Therefore, divide the area either top/bottom or left/right. For selecting the first half, this example will select from left/right halves.

(ii) A coin flip selects the left half. The dimensions of this selected surface area are 1 meter high and ½ meter wide.

(2) Selecting the second half:

(i) If the next selection of halves was left/right, the halves would be rectangles four times as long as they are wide (¼ meter wide and 1 meter high). Halves selected from top/bottom would be square (½ meter on a side). Therefore, select the next halves top/bottom, because the shape of the top/bottom halves (square) is closer to the shape of a circle than the shape of the left/right halves (long narrow rectangles).

(ii) A coin flip selects the top half. The dimensions of this selected surface area are ½ meter high and ½ meter wide.

(3) Selecting the third half:

(i) Just as for the selection of the first half, which divided the original square area, both the left/right and the top/bottom halves have the same shape when compared to a circle (both are rectangles having the same dimensions). Therefore, choose either left/right or top/bottom halves. This example will select from left/right halves.

(ii) A coin flip selects the right half. The dimensions of this selected surface are ¼ meter by ½ meter.

(4) Selecting the fourth half:

(i) If the next selection of halves was left/right, the halves would be rectangles four times as long as they are wide (⅛ meter wide and ½ meter high. Halves selected from top/bottom would be square (¼ meter on a side). Therefore, select the next halves top/bottom, because the shape of the top/bottom halves (square) are closer to the shape of a circle than the shape of the left/right halves (long narrow rectangles).

(ii) A coin flip selects the bottom half. The dimensions of this selected surface area are ¼ meter high and ¼ meter wide.

(5) Selecting the fifth half:

(i) Just as for the selection of the first and third halves, both the left/right and the top/bottom halves have the same shape when compared to a circle (both are rectangles having the same dimensions). Therefore, choose either left/right or top/bottom halves. This example will select from left/right halves.

(ii) A coin flip selects the right half. The dimensions of the selected surface are ⅛ meter by ¼ meter.

(6) Selecting the sixth half:

(i) If the next selection of halves was left/right, the halves would be rectangles four times as long as they are wide (1/16 meter wide and ¼ meter high. Halves selected from top/bottom would be square (⅛ meter on a side). Therefore, select the next halves top/bottom, because the shape of the top/bottom halves (square) are closer to the shape

of a circle than the shape of the left/right halves (long narrow rectangles).

(ii) A coin flip selects the top half. The dimensions of this selected surface are ⅛ meter high and ⅛ meter wide or 12.5 cm by 12.5 cm.

(7) Collect a standard wipe test sample in the sixth half. Since the dimensions of half of the sixth half would be 12.5 cm by 6.25 cm, the area (approximately 78 cm^2) would be less than the required 100 cm^2 minimum area for the standard wipe test. Therefore, no further sampling by halves is necessary. Take the standard wipe test samples of the entire selected sixth half.

§ 761.308 Sample selection by random number generation on any two-dimensional square grid.

(a) Divide the surface area of the non-porous surface into rectangular or square areas having a maximum area of 1 square meter and a minimum dimension of 10 centimeters.

(b) Measure the length and width, in centimeters, of each area created in paragraph (a) of this section. Round off the number of centimeters in the length and the width measurements to the nearest centimeter.

(c) For each 1 square meter area created in accordance with paragraph (a) of this section, select two random numbers: one each for the length and width borders measured in paragraph (b) of this section. An eligible random number can be from zero up to the total width, minus 10 centimeters.

(d) Locate the 10 centimeter by 10 centimeter sample.

(1) Orient the 1 square meter surface area so that, when you are facing the area, the length is left to right and the width is top to bottom. The origin, or reference point for measuring selected random numbers of centimeters to the sampling area, is on the lower left corner when facing the surface.

(2) Mark the random number selected for the length distance, in centimeters, from the origin to the right (at the bottom of the area away from the origin).

(3) From the marked length distance on the bottom of the area, move perpendicularly up from the bottom of the area into the area for the distance randomly selected for the width.

(4) Use the point determined in paragraph (d)(3) of this section as the lower left corner of the 10 centimeter by 10 centimeter sample.

§ 761.310 Collecting the sample.

Use the standard wipe test as defined in § 761.123 to sample one 10 centimeter by 10 centimeter square (100 cm^2) area to represent surface area PCB concentrations of each square meter or fraction of a square meter of a nearly flat, non-porous surface. For small surfaces, use the same procedure as for the standard wipe test, only sample the entire area, rather than 10 centimeter by 10 centimeter squares.

§ 761.312 Compositing of samples.

For a surface originally contaminated by a single source of PCBs with a uniform concentration, it is permissible to composite surface wipe test samples and to use the composite measurement to represent the PCB concentration of the entire surface. Composite samples consist of more than one sample gauze extracted and chemically analyzed together resulting in a single measurement. The composite measurement represents an arithmetic mean of the composited samples.

(a) *Compositing samples from surfaces to be used or reused.* For small or irregularly shaped surfaces or large nearly flat surfaces, if the surfaces are contaminated by a single source of PCBs with a uniform concentration, composite a maximum of three adjacent samples.

(b) *Compositing samples from surfaces to be disposed of off-site or on-site.* (1) For small or irregularly shaped surfaces, composite a maximum of three adjacent samples.

(2) For large nearly flat surfaces, composite a maximum of 10 adjacent samples.

§ 761.314 Chemical analysis of standard wipe test samples.

Perform the chemical analysis of standard wipe test samples in accordance with § 761.272. Report sample results in micrograms per 100 cm^2.

§ 761.316 Interpreting PCB concentration measurements resulting from this sampling scheme.

(a) For an individual sample taken from an approximately 1 meter square portion of the entire surface area and not composited with other samples, the status of the portion is based on the surface concentration measured in that sample. If the sample surface concentration is not equal to or lower than the cleanup level, by inference the entire 1 meter area, and not just the immediate area where the sample was taken, is not equal to or lower than the cleanup level.

(b) For areas represented by the measurement results from compositing more than one 10 centimeter by 10 centimeter sample, the measurement for the composite is the measurement for the entire area. For example, when there is a composite of 10 standard wipe test samples representing 9.5 square meters of surface area and the result of the analysis of the composite is 20 μg/100 cm^2, then the entire 9.5 square meters has a PCB surface concentration of 20 μg/100 cm^2, not just the area in the 10 cm by 10 cm sampled areas.

(c) For small surfaces having irregular contours, where the entire surface was sampled, measure the surface area. Divide 100 cm^2 by the surface area and multiply this quotient by the total number of micrograms of PCBs on the surface to obtain the equivalent measurement of micrograms per 100 cm^2.

Subpart Q—Self-Implementing Alternative Extraction and Chemical Analysis Procedures for Non-liquid PCB Remediation Waste Samples

SOURCE: 63 FR 35468, June 29, 1998, unless otherwise noted.

§ 761.320 Applicability.

This subpart describes self-implementing comparison testing requirements for chemical extraction and chemical analysis methods used as an alternative to the methods required in § 761.272 or § 761.292. Any person conducting comparison testing under this subpart must comply with the requirements of § 761.80(i), including notification. Use alternative methods only after successful completion of these comparison testing requirements and after documentation of the results of the testing.

§ 761.323 Sample preparation.

(a) The comparison study requires analysis of a minimum of 10 samples weighing at least 300 grams each. Samples of PCB remediation waste used in the comparison study must meet the following three requirements.

(1) The samples must either be taken from the PCB remediation waste at the cleanup site, or must be the same kind of material as that waste. For example, if the waste at the cleanup site is sandy soil, you must use the same kind of sandy soil in the comparison study. Do not use unrelated materials such as clay soil or dredged sediments in place of sandy soil.

(2) PCB remediation waste may contain interferences which confound or hamper sample extraction and chemical analysis. These interferences may be from chemicals or other attributes preexisting in the waste material, resulting from the PCB contamination source, or resulting from treatment to remove or destroy PCBs. Comparison study samples must also contain these interfering materials to demonstrate successful analysis in their presence. For example, a PCB remediation waste may have been co-disposed with chlorobenzene solvents or chlorinated pesticides. These chlorinated compounds would have to be present in the comparison study compounds at the same levels found, or at the highest levels expected to be found, in the PCB remediation waste. As another example, for PCB remediation waste which had been solvent washed with liquid amines to remove PCBs, comparison study samples would have to contain concentrations of these amines at the same levels found, or at the highest levels expected to be found, in the PCB remediation waste.

(b) Prior to initiating the comparison study, confirm the following PCB concentrations in the comparison study samples using the methods specified in § 761.292. All samples of non-liquid PCB

remediation waste must have PCB concentrations between 0.1 and 150 ppm.

(1) A minimum of three comparison study samples must have PCB concentrations above the cleanup level specified for the site in § 761.61(a)(4) and a minimum of three comparison study samples must have PCB concentrations below the specified cleanup level.

(2) At least one comparison study sample must have a PCB concentration ≥90 percent and ≤100 percent of the cleanup level.

(3) At least one comparison study sample must have a PCB concentration ≥100 percent and ≤110 percent of the cleanup level.

(c) If the comparison study samples do not have the concentrations or concentration ranges required by paragraph (b) of this section, for purposes of use in this chemical extraction and chemical analysis comparison study, a person may adjust PCB concentrations by dilution. Any excess material resulting from the preparation of these samples, which is not used as an analytical sample, is regulated as the PCB concentration in the component having the highest PCB concentration of the component materials in the sample.

§ 761.326 Conducting the comparison study.

Extract or analyze the comparison study samples using the alternative method. For an alternative extraction method or alternative analytical method to be comparable to the methods required in § 761.292, all of the following conditions must be met.

(a) All samples having PCB concentrations greater than or equal to the level of concern, as measured by the methods required in § 761.292, are found to be greater than or equal to the level of concern as measured by the alternative method (no false negatives).

(b) Only one sample which contains PCBs at a level less than the level of concern, as measured by the methods required in § 761.292, is found to have a PCB concentration greater than the level of concern as measured by the alternative method (false positive); and all other samples which contain PCBs at levels less than the level of concern, as measured by the methods required in § 761.292, are found by the alternative method to have PCBs less than the level of concern (there are no additional false positives).

Subpart R—Sampling Non-Liquid, Non-Metal PCB Bulk Product Waste for Purposes of Characterization for PCB Disposal in Accordance With § 761.62, and Sampling PCB Remediation Waste Destined for Off-Site Disposal, in Accordance With § 761.61

SOURCE: 63 FR 35469, June 29, 1998, unless otherwise noted.

§ 761.340 Applicability.

Use the procedures specified in this subpart to sample the following types of waste when it is necessary to analyze the waste to determine PCB concentration or leaching characteristics for storage or disposal.

(a) Existing accumulations of non-liquid, non-metal PCB bulk product waste.

(b) Non-liquid, non-metal PCB bulk product waste from processes that continuously generate new waste.

(c) Non-liquid PCB remediation waste from processes that continuously generate new waste, that will be sent off-site for disposal.

§ 761.345 Form of the waste to be sampled.

PCB bulk product waste and PCB remediation waste destined for off-site disposal must be in the form of either flattened or roughly conical piles. This subpart also contains a procedure for contemporaneous sampling of waste as it is being generated.

§ 761.346 Three levels of sampling.

To select a sample of the waste and prepare it for chemical extraction and analysis, there are three required levels of random sampling.

(a) First, select a single 19-liter (5 gallon) portion from a composite accumulated either contemporaneously with the generation of the waste or by sampling an existing pile of waste. Collection procedures for the first level of sampling from existing piles of waste

are in §761.347. Collection procedures for the first level of sampling from a contemporaneous generation of waste are in §761.348. Compositing requirements and requirements for the subsampling of composite samples to result in a single 19-liter sample are in §761.350. Send the 19-liter sample to the laboratory for the second and third levels of sampling, including particle size reduction for leach testing and drying as required by §761.1(b)(4).

(b) Second, at the laboratory, select one quarter of the 19-liter sample. Procedures the laboratory must use for this second level of sample selection appear in §761.353.

(c) Third, select a 100 gram subsample from the second level subsample. Procedures the laboratory must use for this third level of sample selection appear in §761.355.

§761.347 First level sampling—waste from existing piles.

(a) *General.* Sample piles that are either specifically configured for sampling (see paragraph (b) of this section) or that are of conical shape (see paragraph (c) of this section). If sampling from either of these shapes is not possible, conduct contemporaneous sampling, in accordance with the procedures in §761.348, or obtain the approval of the Regional Administrator for an alternate sampling plan in accordance with §761.62(c).

(b) *Specifically configured piles.* A specifically configured pile is a single flattened pile in the shape of a square or rectangle having no restrictions on length or width but restricted to 30 cm (1 foot) in depth. A square shaped pile facilitates sampling site selection for the first level sample. Select eight 19-liter samples from the pile and composite them into one 19-liter sample as follows:

(1) Divide the pile into quarters.

(2) Divide each of the quarter sections into quarters (i.e., into sixteenths of the original pile).

(3) Select two sixteenths from each of the four quarters, according to one of the two following options:

(i) Randomly select the two sixteenths from one quarter and sample the sixteenths occupying the same positions in each of the other three quarters.

(ii) Randomly select two sixteenths from each of the four quarters (i.e., perform a random selection four different times).

(4) At this point the eight selected sixteenths undergo further division and sample selection. Divide each of the eight selected sixteenths into four equal parts. Using a random number generator or random number table, select one of the four equal parts from each of the eight equal areas. If each of the four equal parts has a volume >76 liters when projected downwards 30 cm, continue to divide each selected area into four equal parts, and select one of the parts, until each selected area has a volume of <76 liters but ≥19 liters. When projected to a depth of 30 cm, a square having a 25 cm side or a circle having a diameter of approximately 28.5 cm equals a volume of approximately 19 liters. The volume of 76 liters is equal to the volume enclosed by a square having a side of 50 cm (or other shape having an area of 250 cm^2) projected to a depth of 30 cm.

(5) Take one sample of approximately 19 unsorted liters of waste from each of the eight selected areas. Place each sample into a separate 19-liter container, allowing only sufficient space at the top of the container to secure the lid.

(6) Composite the eight 19-liter samples in accordance with §761.350.

(c) *Conical-shaped piles.* If it is necessary to sample a pile which is too large to be spread on the site to a uniform thickness of 1 foot or 30 cm, or if there are too many piles to spread out in the space available, use the following procedure to sample the piles. This procedure assumes that the shape of the piles is analogous to a cone; that is, having a circular base with PCB bulk product waste or PCB remediation waste destined for off-site disposal stacked up uniformly to a peak that is a point centered above the center of the circular base. Collect eight 19-liter samples as follows:

(1) *Collecting samples from more than one pile.* If the PCB bulk product waste or PCB remediation waste consists of more than one pile or container, assign

each pile or container an integer number and then generate seven random integer numbers to select the piles from which you will collect samples. It is possible that this random selection procedure will result in selecting the same pile number more than once, even if seven or more piles are present. If so, sample the pile once and restart the sampling collection process to collect additional samples. Do not collect multiple samples from the same location in the pile.

(2) *Collecting samples from a single pile.* If only one pile or container is present, collect all eight samples from the same pile.

(3) *Setting up the sample site selection system from a pile.* Locate a sample in a pile by the use of three parameters: a particular radial direction, ''r,'' from the peak at the center of the pile to the outer edge at the base of the pile; a point, ''s,'' along that radial direction between the peak of the pile and the outer edge of the base of the pile; and a depth, ''t'', beneath point ''s.'' The top of the sample material will be below depth *t,* at point *s,* on radius *r.* Use a rod, dowel, stake, or broom handle as a marker. Nail or otherwise fasten to the top of the marker two pieces of string or cord of sufficient length and strength to reach from the top of the marker at the top of the pile to the farthest peripheral edge at the bottom of the pile, when the marker is positioned at the top or apex of the pile. Pound or push the marker into the top center (apex) of the pile, downward toward the center of the base. Insert the marker for at least 30 cm or one foot until the marker is rigidly standing on its own, even when the cord is pulled tight to the bottom peripheral edge of the pile. Ensure that the marker protrudes from the top of the pile sufficiently to allow the strings to move easily around the pile when they are pulled tight. Select the three parameters and the sampling location as follows:

(i) Determine the radial component (r) of the location for each sample.

(A) Tie to a stake or otherwise fasten one of the strings at ''b,'' the bottom of the pile, as a reference point for finding *r.*

(B) Measure the circumference ''c,'' the distance around the bottom of the pile. Determine *r* from *b* in one of two ways:

(*1*) Multiply *c* by a randomly generated fraction or percentage of one.

(*2*) Select a random number between one and the total number of centimeters in *c.*

(C) Locate *r* by starting at *b,* the place where the fixed string meets the base of the pile, and travel clockwise around the edge of the pile at the base for the distance you selected in paragraph (c)(3)(i)(B) of this section.

(D) Fasten the second string at the selected distance. The second string marks the first parameter *r.*

(ii) Determine the second parameter s of the location for each sample.

(A) Measure the distance, *l,* along the string, positioned in paragraph (c)(3)(i)(D) of this section, from the top to the bottom of the pile at the selected radial distance *r.* Determine the distance *s* from *l* in one of two ways:

(*1*) Multiply *l* by a randomly generated fraction or percentage of one.

(*2*) Select a random number between one and the total number of centimeters in *l.*

(B) Mark, for example by placing a piece of tape on the string positioned according to paragraph (c)(3)(i)(D) of this section, the distance *s,* up from the bottom of the pile on the string at *r.*

(iii) Determine the third and final parameter *t* of the location for each sample.

(A) Mark and number 1 cm intervals from one end of a rigid device, for example a rod, dowel, stake, or broom handle, for measuring the distance from the top of the pile to the bottom at the point *s* selected in paragraph (c)(3)(ii)(B) of this section. The marked and numbered device shall be of sufficient strength to be forced down through the maximum depth of the pile and sufficient length to measure the depth of the waste in the pile at any point.

(B) Take the measuring device, constructed according to paragraph (c)(3)(iii)(A) of this section, and at position s, push the end of the device marked with zero straight down into the pile until it reaches the bottom of the pile or ground level. The vertical

distance ''v'' is the number of centimeters from the surface of the pile at point s on the string to the bottom of the pile or ground level. Read the distance *v* on the measuring device at the surface of the pile. From the distance *v*, determine *t*, in one of two ways:

(*1*) Randomly generate a fraction of one and multiply the fraction times v.

(*2*) Select a random number between zero and the total number of centimeters of the vertical distance *v*.

(iv) Dig a hole straight down into the pile for *t* centimeters (inches) from the surface of the pile at *s*.

(v) At depth *t*, directly under the s mark on the string, outline the top of the sample container and collect (shovel) all waste under the outline in the following order of preference in paragraphs (c)(3)(v)(A) through (c)(3)(v)(C) of this section. It is possible that some of the eight sampling locations will not provide 19 liters of sample.

(A) For a depth of 30 cm.

(B) Until the container is full.

(C) Until the ground level is reached.

(d) *Compositing the samples.* Composite the eight 19-liter samples and subsample in accordance with §761.350. Send the subsample to a laboratory for further sampling as described in §§761.353 and 761.355 and for chemical extraction and analysis. If there is insufficient sample for a 19-liter sample from the composite sample composed of the eight iterations of sample site selection, according to the procedures in paragraphs (c)(3)(i) through (c)(3)(v) of this section, select additional sample sites, collect additional samples and composite the additional waste in the samples until a minimum of 19 liters is in the composite.

[63 FR 35469, June 29, 1998, as amended at 64 FR 33762, June 24, 1999]

§761.348 Contemporaneous sampling.

Contemporaneous sampling is possible when there is active generation of waste and it is possible to sample the waste stream as it is generated. Collect eight 19-liter samples as follows.

(a) Collect each sample by filling a 19-liter (5 gallon) container at a location where the PCB bulk product waste is released from the waste generator onto a pile or into a receptacle container before the waste reaches the pile or receptacle container.

(b) Determine a sample collection start time using a random number generator or a random number table to select a number between 1 and 60. Collect the first sample at the randomly selected time in minutes after start up of the waste output, or if the waste is currently being generated, after the random time is selected. For example, if the randomly selected time is 35, begin collection 35 minutes after the start up of waste generation. Similarly, if waste output is ongoing and the random start determination occurred at 8:35 a.m., collect the first sample at 9:10 a.m. (35 minutes after the random start determination).

(c) Collect seven more samples, one every 60 minutes after the initial sample is collected. If the waste output process stops, stop the 60–minute interval time clock. When the process restarts, restart the 60–minute interval time clock and complete the incomplete 60–minute interval.

(d) Composite the eight 19-liter samples and subsample in accordance with §761.350.

§761.350 Subsampling from composite samples.

(a) *Preparing the composite.* Composite the samples (eight from a flattened pile; eight or more from a conical pile; eight from waste that is continuously generated) and select a 19-liter subsample for shipment to the chemical extraction and analysis laboratory for further subsampling. There are two options for the preparation of the composite:

(1) *Option one.* Place all of the contents of all 19-liter samples that you collected into a 209 liter (55 gallon) drum or similar sized, cylinder-shaped container. Completely close the container, and roll it 10 or more complete revolutions to mix the contents.

(2) *Option two.* Add the 19-liter samples one at a time to a 209 liter (55 gallon) drum. Between the addition of each 19-liter sample, stir the composite using a broom handle or similar long, narrow, sturdy rod that reaches the bottom of the container. Stir the mixture for a minimum of 10 complete revolutions of the stirring instrument

around the container at a distance approximately half way between the outside and center of the container.

(b) *Selecting a 19-liter subsample from the composite.* Once the composite is mixed, pour the mixture of waste out on a plastic sheet and either divide it into 19-liter size piles or make one large pile.

(1) From 19-liter sized piles, use a random number generator or random number table to select one of the piles.

(2) From one large pile, flatten the pile to a depth of 30 cm and divide it into 4 quarters of equal size. Use a random number generator or random number table to select one quarter of the pile. Further divide the selected quarter pile into 19-liter portions and use a random number generator or random number table to select one 19-liter portion. A square having a 25 cm side or a circle having a diameter of approximately 28.5 cm when projected downwards 30 cm equals approximately 19 liters.

(c) *Transferring the sample to the analytical laboratory.* Place the selected 19-liter subsample in a container, approved for shipment of the sample, to the chemical extraction and analysis laboratory, for the next step in sample selection in accordance with §761.353.

§ 761.353 Second level of sample selection.

The second level of sample selection reduces the size of the 19-liter subsample that was collected according to either §761.347 or §761.348 and subsampled according to §761.350. The purpose of the sample size reduction is to limit the amount of time required to manually cut up larger particles of the waste to pass through a 9.5 millimeter (mm) screen.

(a) *Selecting a portion of the subsample for particle size reduction.* At the chemical extraction and analysis laboratory, pour the 19-liter subsample onto a plastic sheet or into a pan and divide the subsample into quarters. Use a random number generator or random number table to select one of these quarters.

(b) *Reduction of the particle size by the use of a 9.5 mm screen.* Collect the contents of the selected quarter of waste resulting from conducting the procedures in paragraph (a) of this section and shake the waste in a 9.5 mm screen. Separate the waste material which passes through the screen from the waste material which does not pass through the screen. Manually cut or otherwise reduce the size of all parts of the waste portion which did not pass through the 9.5 mm screen, such that each part of the waste shall pass through the 9.5 mm screen by shaking.

(c) Drying the reduced particle size waste. Dry all of the waste portion resulting from conducting the procedures in paragraph (b) of this section, from 10 to 15 hours in a drying oven at 100 °C. Allow the dried waste to cool to room temperature.

(d) *Mixing the dried waste.* Place all of the waste resulting from conducting the procedures in paragraph (c) of this section in a 19-liter pail or similarly sized, cylinder-shaped container. Mix the dried material according to one of the two following options:

(1) *First mixing option.* Completely close the container and roll the container a minimum of 10 complete revolutions to mix the contents.

(2) *Second mixing option.* Use a sturdy stirring rod, such as a broom handle or other device that reaches the bottom of the container, to stir the waste for a minimum of 10 complete revolutions around the container at a distance approximately half way between the outside and the center of the container.

§ 761.355 Third level of sample selection.

The third level of sample selection further reduces the size of the subsample to 100 grams which is suitable for the chemical extraction and analysis procedure.

(a) Divide the subsample resulting from conducting the procedures in §761.353 of this part into 100 gram portions.

(b) Use a random number generator or random number table to select one 100 gram size portion as a sample for a procedure used to simulate leachate generation.

(c) Dry the 100 gram sample, selected after conducting the procedure in paragraph (b) of this section, for 10 to 15 hours in a drying oven at 100 °C and cool it to the analytical laboratory

room temperature before analysis using a procedure used to simulate leachate generation. This sample was dried previously in the larger quantity sample at the second level of sampling (§ 761.353(c)) and is dried a second time here (in the third level of sample selection). This dried and cooled sample must weigh at least 50 grams.

(d) If the dried and cooled sample weighs <50 grams, select additional 100 gram portions of sample one at a time by repeating the directions in paragraph (b) and (c) of this section, and add each additional 100 gram portion of sample to the first 100 gram portion until at least 50 grams of dried material is in the sample to be analyzed using a procedure used to simulate leachate generation.

§ 761.356 Conducting a leach test.

No method is specified as a procedure used to simulate leachate generation.

§ 761.357 Reporting the results of the procedure used to simulate leachate generation.

Report the results of the procedure used to simulate leachate generation as micrograms PCBs per liter of extract from a 100 gram sample of dry bulk product waste. Divide 100 grams by the grams in the sample and multiply this quotient by the number of micrograms PCBs per liter of extract to obtain the equivalent measurement from a 100 gram sample.

§ 761.358 Determining the PCB concentration of samples of waste.

Use either Method 3500B/3540C or Method 3500B/3550B from EPA's SW-846, Test Methods for Evaluating Solid Waste, or a method validated under subpart Q of this part, for chemical extraction of PCBs from individual and composite samples of PCB bulk product waste. Use Method 8082 from SW-846, or a method validated under subpart Q of this part, to analyze these extracts for PCBs.

§ 761.359 Reporting the PCB concentrations in samples.

Report all sample concentrations as ppm by weight on a dry weight basis.

Subpart S—Double Wash/Rinse Method for Decontaminating Non-Porous Surfaces

SOURCE: 63 FR 35472, June 29, 1998, unless otherwise noted.

§ 761.360 Background.

The double wash/rinse procedure is used to quickly and effectively remove PCBs on surfaces. It is important to select and use the proper cleanup equipment, to conduct the procedure correctly so as not to redistribute PCBs, and to comply with disposal requirements for all cleanup materials.

§ 761.363 Applicability.

The double wash/rinse procedure includes two washing steps and two rinsing steps. The two washing and rinsing steps are slightly different depending on whether a contaminated surface was relatively clean before the spill (see § 761.372), or whether the surface was coated or covered with dust, dirt, grime, grease or another absorbent material (see § 761.375).

§ 761.366 Cleanup equipment.

(a) Use scrubbers and absorbent pads that are not dissolved by the solvents or cleaners used, and that do not shred, crumble, or leave visible fragments on the surface. Scrubbers and absorbent pads used to wash contaminated surfaces must not be reused. Scrubbers and absorbent pads for rinsing must not contain ≥2 ppm PCBs. Scrubbers and absorbent pads used in the second rinse of contaminated surfaces may be reused to wash contaminated surfaces.

(b) Capture and contain all solvents and cleaners for reuse, decontamination, or disposal. Clean organic solvents contain <2 ppm PCBs. Clean water contains <3 ppb PCBs.

§ 761.369 Pre-cleaning the surface.

If visible PCB-containing liquid is present on the surface to be cleaned, thoroughly wipe or mop the entire surface with absorbent paper or cloth until no liquid is visible on the surface.

§ 761.372 Specific requirements for relatively clean surfaces.

For surfaces that do not appear dusty or grimy before a spill, such as glass, automobile surfaces, newly-poured concrete, and desk tops, use the double wash/rinse procedures in this section.

(a) *First wash.* Cover the entire surface with organic solvent in which PCBs are soluble to at least 5 percent by weight. Contain and collect any runoff solvent for disposal. Scrub rough surfaces with a scrub brush or disposable scrubbing pad and solvent such that each 900 cm^2 (1 square foot) of the surface is always very wet for 1 minute. Wipe smooth surfaces with a solvent-soaked, disposable absorbent pad such that each 900 cm^2 (1 square foot) is wiped for 1 minute. Any surface <1 square foot shall also be wiped for 1 minute. Wipe, mop, and/or sorb the solvent onto absorbent material until no visible traces of the solvent remain.

(b) *First rinse.* Wet the surface with clean rinse solvent such that the entire surfaces is very wet for 1 minute. Drain and contain the solvent from the surface. Wipe the residual solvent off the drained surface using a clean, disposable absorbent pad until no liquid is visible on the surface.

(c) *Second wash.* Repeat the procedures in paragraph (a) of this section. The rinse solvent from the first rinse (paragraph (b) of this section) may be used.

(d) *Second rinse.* Repeat the procedures in paragraph (b) of this section.

§ 761.375 Specific requirements for surfaces coated or covered with dust, dirt, grime, grease, or another absorbent material.

(a) *First wash.* Cover the entire surface with concentrated or industrial strength detergent or non-ionic surfactant solution. Contain and collect all cleaning solutions for proper disposal. Scrub rough surfaces with a scrub brush or scrubbing pad, adding cleaning solution such that the surface is always very wet, such that each 900 cm^2 (1 square foot) is washed for 1 minute. Wipe smooth surfaces with a cleaning solution-soaked disposable absorbent pad such that each 900 cm^2 (1 square foot) is wiped for 1 minute. Wash any surface <1 square foot for 1 minute. Mop up or absorb the residual cleaner solution and suds with a clean, disposable, absorbent pad until the surface appears dry. This cleaning should remove any residual dirt, dust, grime, or other absorbent materials left on the surface during the first wash.

(b) *First rinse.* Rinse off the wash solution with 1 gallon of clean water per square foot and capture the rinse water. Mop up the wet surface with a clean, disposable, absorbent pad until the surface appears dry.

(c) *Second wash.* Follow the procedure in § 761.372(a).

(d) *Second rinse.* Follow the procedure in § 761.372(b).

§ 761.378 Decontamination, reuse, and disposal of solvents, cleaners, and equipment.

(a) *Decontamination.* Decontaminate solvents and non-porous surfaces on equipment in accordance with the standards and procedures in § 761.79(b) and (c).

(b) *Reuse.* A solvent may be reused so long as its PCB concentration is <50 ppm. Decontaminated equipment may be reused in accordance with § 761.30(u). Store solvents and equipment for reuse in accordance with § 761.35.

(c) *Disposal.* Dispose of all solvents, cleaners, and absorbent materials in accordance with § 761.79(g). Dispose of equipment in accordance with § 761.61(a)(5)(v)(A), or decontaminate in accordance with § 761.79(b) or (c). Store for disposal equipment, solvents, cleaners, and absorbent materials in accordance with § 761.65.

Subpart T—Comparison Study for Validating a New Performance-Based Decontamination Solvent Under § 761.79(d)(4)

SOURCE: 63 FR 35473, June 29, 1998, unless otherwise noted.

§ 761.380 Background.

This subpart provides self-implementing criteria for validating the conditions for use in performance-based decontamination of solvents other than those listed in § 761.79(c)(3) and (c)(4). Any person may use this subpart for validating either a chemical formulation or a product with a

trade name whether or not the constituents of the product are proprietary.

§ 761.383 Applicability.

Use the self-implementing decontamination procedure only on smooth, non-porous surfaces that were once in contact with liquid PCBs. Decontamination procedures under this subpart shall exactly parallel § 761.79(c)(3) and (c)(4), except that the procedures described in § 761.79(c)(3)(iii) and (c)(3)(iv) and (c)(4)(iii), (c)(4)(iv) and (c)(4)(vii) may be revised to contain parameters validated in accordance with this subpart.

§ 761.386 Required experimental conditions for the validation study and subsequent use during decontamination.

The following experimental conditions apply for any solvent:

(a) *Temperature and pressure.* Conduct the validation study and perform decontamination at room temperature (from ≥15 °C to ≤30 °C) and at atmospheric pressure.

(b) *Agitation.* Limit the movement in the solvent to the short-term movement from placing the contaminated surface into the soak solvent and from removing the surface from the soak solvent.

(c) *Time of soak.* Soak the surface for a minimum of 1 hour.

(d) *Surface conditions for the validation study.* Prior to beginning the validation study, ensure that there are no free-flowing liquids on surfaces and that surfaces are dry (i.e., there are no liquids visible without magnification). Also ensure that surfaces are virtually free from non-liquid residues, corrosion, and other defects which would prevent the solvent from freely circulating over the surface.

(e) *Confirmatory sampling for the validation study.* Select surface sample locations using representative sampling or a census. Sample a minimum area of 100 cm^2 on each individual surface in the validation study. Measure surface concentrations using the standard wipe test, as defined in § 761.123, from which a standard wipe sample is generated for chemical analysis. Guidance for wipe sampling appears in the document entitled ''Wipe Sampling and Double Wash/Rinse Cleanup as Recommended by the Environmental Protection Agency PCB Spill Cleanup Policy,'' available on EPA's Web site at *http://www.epa.gov/pcb*, or from the Program Management, Communications, and Analysis Office, Office of Resource Conservation and Recovery (5305P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(f) *Concentration of PCBs.* The method validated may be used only to decontaminate surfaces containing PCBs at concentrations on which the validation study was performed and lower concentrations.

[63 FR 35473, June 29, 1998, as amended at 72 FR 57241, Oct. 9, 2007; 74 FR 30235, June 25, 2009]

§ 761.389 Testing parameter requirements.

There are no restrictions on the variable testing parameters described in this section which may be used in the validation study. The conditions demonstrated in the validation study for these variables shall become the required conditions for decontamination using the solvent being validated and shall replace the comparable conditions in § 761.79(b)(3) through (b)(6). There are limited potential options for varying a single requirement in this section. If you change one of these variable requirements, change it only in the way listed in this section and do not change any other validated conditions. If you desire to change more than one of the requirements in this section, you must conduct a new study to validate the decontamination under the desired conditions.

(a) The study apparatus is not standardized. Critical components of the study are the PCB material (for example MODEF or some other spiking solution), the volume of the soaking solvent, and the area of the contaminated surface. The EPA study used beakers and shallow dishes as the experimental vessels to contain the surface and solvent during the soaking process. In order to minimize surface-to-volume ratios, it is convenient to utilize flat contaminated surfaces and shallow solvent containers. During the validation

study, use the same ratio of contaminated surface area to soak solvent volume as would be used during actual decontamination. It is also permissible to use a smaller surface area to soaking solvent volume than used in the validation study, so long as all other required parameters are used as validated in the confirmation required in §761.386 (a) through (f), and paragraphs (a) through (c) of this section. Do not use a larger surface-area-to-solvent-volumes ratio or different kind of solvent based on the results of the validation study.

(b) Except for the minimum soak time of 1 hour (as required in §761.386(c)), the length of soak time is not otherwise restricted in the validation study. The soak time used in the validation study, however, is a use requirement for subsequent decontamination using the solvent being validated. It is permissible to use longer soak times for decontamination than the soak time used in the validation study, if all other parameters required in §761.386, and paragraphs (a) and (c) of this section are used.

(c) There is no restriction on the kind of material containing PCBs to use to create the surface contamination for the validation study. There is also no restriction on the level of starting PCB surface concentration. It is permissible to use lower concentrations of PCB than the concentration used in the validation study, if all other parameters required in §761.386 (a) through (f), and paragraphs (a) through (c) of this section are used.

§761.392 Preparing validation study samples.

(a)(1) To validate a procedure to decontaminate a surface contaminated with a spill from liquid of a known concentration, contaminate (spike) the surface to be used in the validation study as follows:

(i) Use a spiking solution made of PCBs mixed with a solvent to contaminate clean surfaces. Clean surfaces are surfaces having PCB surface concentrations <1 μg/100 cm^2 before intentionally contaminating the surface.

(ii) Prior to contaminating a surface for the validation study, mark the surface sampling area to assure that it is completely covered with the spiking solution.

(iii) Deliver the spiking solution onto the surface, covering all of the sampling area. Contain any liquids which spill or flow off the surface. Allow the spiking solution to drip drain off into a container and then evaporate the spiking solution off the contaminated surface prior to beginning the validation study. Contaminate a minimum of eight surfaces for a complete validation study.

(iv) As a quality control step, test at least one contaminated surface to determine the PCB concentration to verify that there are measurable surface levels of PCBs resulting from the contamination before soaking the surface in the decontamination solvent. The surface levels of PCBs on the contaminated surfaces must be ≥20 μg/100 cm^2.

(2) To validate a procedure to decontaminate a specified surface concentrations of PCBs as measured by a standard wipe sample, contaminate a minimum of 10 surfaces. Contaminate all the surfaces identically following the procedures in paragraph (a)(1) of this section and measure the PCB surface concentrations of at least three of the surfaces using a standard wipe test to establish a surface concentration to be included in the standard operating procedure. The surface levels of PCBs on the contaminated surfaces must be ≥20 μg/100 cm^2.

(b) [Reserved]

§761.395 A validation study.

(a) Decontaminate the following prepared sample surfaces using the selected testing parameters and experimental conditions. Take a standard wipe sample of the decontaminated surface.

(1) At least one uncontaminated surface. The surface levels of PCBs on the uncontaminated surface must be <1 μg/100 cm^2.

(2) At least seven contaminated surfaces.

(b)(1) Use SW-846, Test Methods for Evaluating Solid Waste methods for sample extraction and chemical analysis as follows: Use Method 3500B/3540C or Method 3500B/3550B for the extraction and cleanup of the extract and

Method 8082 for the chemical analysis, or methods validated under subpart Q of this part.

(2) Report all validation study surface sample concentrations on the basis of micrograms of PCBs per 100 cm^2 of surface sampled.

(c) Following completion of the validation study, measurements from the contaminated surfaces must have an arithmetic mean of ≤10 μg/100 cm^2. If the arithmetic mean is >10 μg/100 cm^2, then the validation study failed and the solvent may not be used for decontamination under §761.79(d)(4) according to the parameters tested.

§761.398 Reporting and recordkeeping.

(a) Submit validation study results to the Director, Office of Resource Conservation and Recovery (5301P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, prior to the first use of a new solvent for alternate decontamination under §761.79(d)(4). The use of a new solvent is not TSCA Confidential Business Information (CBI). From time to time, EPA will confirm the use of validated new decontamination solvents and publish the new solvents and validated decontamination procedures in the FEDERAL REGISTER.

(b) Any person may begin to use solvent validated in accordance with this subpart at the time results are submitted to EPA.

(c) Record all testing parameters and experimental conditions from the successful validation study into a standard operating procedure (SOP) for reference whenever the decontamination procedure is used. Include in the SOP the identity of the soaking solvent, the length of time of the soak, and the ratio of the soak solvent to contaminated surface area during the soaking process. Also include in the SOP the maximum concentration of PCBs in the spilled material and the identity of the spilled material, and/or the measured maximum surface concentration of the contaminated surface used in the validation study. Record and keep the results of the validation study as an appendix to the SOP. Include in this appendix, the solvent used to make the spiking solution, the PCB concentration of the spiking solution used to contaminate the surfaces in the validation study, and all of the validation study testing parameters and experimental conditions.

[63 FR 35473, June 29, 1998, as amended at 72 FR 57241, Oct. 9, 2007; 74 FR 30235, June 25, 2009]

PART 763—ASBESTOS

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AUTHORITY: 15 U.S.C. 2605, 2607(c), 2643, and 2646.

Subparts A–D [Reserved]

Subpart E—Asbestos-Containing Materials in Schools

SOURCE: 52 FR 41846, Oct. 30, 1987, unless otherwise noted.

§ 763.80 Scope and purpose.

(a) This rule requires local education agencies to identify friable and nonfriable asbestos-containing material (ACM) in public and private elementary and secondary schools by visually inspecting school buildings for such materials, sampling such materials if they are not assumed to be ACM, and having samples analyzed by appropriate techniques referred to in this rule. The rule requires local education agencies to submit management plans to the Governor of their State by October 12, 1988, begin to implement the plans by July 9, 1989, and complete implementation of the plans in a timely fashion. In addition, local education agencies are required to use persons who have been accredited to conduct inspections, reinspections, develop management plans, or perform response actions. The rule also includes recordkeeping requirements. Local education agencies may contractually delegate their duties under this rule, but they remain responsible for the proper performance of those duties. Local education agencies are encouraged to consult with EPA Regional Asbestos Coordinators, or if applicable, a State's lead agency designated by the State Governor, for assistance in complying with this rule.

(b) Local education agencies must provide for the transportation and disposal of asbestos in accordance with EPA's ''Asbestos Waste Management Guidance.'' For convenience, applicable sections of this guidance are reprinted as appendix D of this subpart. There are regulations in place, however, that affect transportation and disposal of asbestos waste generated by this rule. The transportation of asbestos waste is covered by the Department of Transportation (49 CFR part 173, subpart J) and disposal is covered by the National Emissions Standards for Hazardous Air Pollutants (NESHAP) (40 CFR part 61, subpart M).

§ 763.83 Definitions.

For purposes of this subpart:

Act means the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601, *et seq*.

Accessible when referring to ACM means that the material is subject to disturbance by school building occupants or custodial or maintenance personnel in the course of their normal activities.

Accredited or *accreditation* when referring to a person or laboratory means that such person or laboratory is accredited in accordance with section 206 of Title II of the Act.

Air erosion means the passage of air over friable ACBM which may result in the release of asbestos fibers.

Asbestos means the asbestiform varieties of: Chrysotile (serpentine); crocidolite (riebeckite); amosite (cummingtonitegrunerite); anthophyllite; tremolite; and actinolite.

Asbestos-containing material (ACM) when referring to school buildings means any material or product which contains more than 1 percent asbestos.

Asbestos-containing building material (ACBM) means surfacing ACM, thermal system insulation ACM, or miscellaneous ACM that is found in or on interior structural members or other parts of a school building.

Asbestos debris means pieces of ACBM that can be identified by color, texture,

or composition, or means dust, if the dust is determined by an accredited inspector to be ACM.

Damaged friable miscellaneous ACM means friable miscellaneous ACM which has deteriorated or sustained physical injury such that the internal structure (cohesion) of the material is inadequate or, if applicable, which has delaminated such that its bond to the substrate (adhesion) is inadequate or which for any other reason lacks fiber cohesion or adhesion qualities. Such damage or deterioration may be illustrated by the separation of ACM into layers; separation of ACM from the substrate; flaking, blistering, or crumbling of the ACM surface; water damage; significant or repeated water stains, scrapes, gouges, mars or other signs of physical injury on the ACM. Asbestos debris originating from the ACBM in question may also indicate damage.

Damaged friable surfacing ACM means friable surfacing ACM which has deteriorated or sustained physical injury such that the internal structure (cohesion) of the material is inadequate or which has delaminated such that its bond to the substrate (adhesion) is inadequate, or which, for any other reason, lacks fiber cohesion or adhesion qualities. Such damage or deterioration may be illustrated by the separation of ACM into layers; separation of ACM from the substrate; flaking, blistering, or crumbling of the ACM surface; water damage; significant or repeated water stains, scrapes, gouges, mars or other signs of physical injury on the ACM. Asbestos debris originating from the ACBM in question may also indicate damage.

Damaged or significantly damaged thermal system insulation ACM means thermal system insulation ACM on pipes, boilers, tanks, ducts, and other thermal system insulation equipment where the insulation has lost its structural integrity, or its covering, in whole or in part, is crushed, waterstained, gouged, punctured, missing, or not intact such that it is not able to contain fibers. Damage may be further illustrated by occasional punctures, gouges or other signs of physical injury to ACM; occasional water damage on the protective coverings/jackets; or exposed ACM ends or joints. Asbestos debris originating from the ACBM in question may also indicate damage.

Encapsulation means the treatment of ACBM with a material that surrounds or embeds asbestos fibers in an adhesive matrix to prevent the release of fibers, as the encapsulant creates a membrane over the surface (bridging encapsulant) or penetrates the material and binds its components together (penetrating encapsulant).

Enclosure means an airtight, impermeable, permanent barrier around ACBM to prevent the release of asbestos fibers into the air.

Fiber release episode means any uncontrolled or unintentional disturbance of ACBM resulting in visible emission.

Friable when referring to material in a school building means that the material, when dry, may be crumbled, pulverized, or reduced to powder by hand pressure, and includes previously nonfriable material after such previously nonfriable material becomes damaged to the extent that when dry it may be crumbled, pulverized, or reduced to powder by hand pressure.

Functional space means a room, group of rooms, or homogeneous area (including crawl spaces or the space between a dropped ceiling and the floor or roof deck above), such as classroom(s), a cafeteria, gymnasium, hallway(s), designated by a person accredited to prepare management plans, design abatement projects, or conduct response actions.

High-efficiency particulate air (HEPA) refers to a filtering system capable of trapping and retaining at least 99.97 percent of all monodispersed particles 0.3 μm in diameter or larger.

Homogeneous area means an area of surfacing material, thermal system insulation material, or miscellaneous material that is uniform in color and texture.

Local education agency means:

(1) Any local educational agency as defined in section 198 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 3381).

(2) The owner of any nonpublic, nonprofit elementary, or secondary school building.

(3) The governing authority of any school operated under the defense dependent's education system provided for under the Defense Dependents' Education Act of 1978 (20 U.S.C. 921, *et seq.*).

Miscellaneous ACM means miscellaneous material that is ACM in a school building.

Miscellaneous material means interior building material on structural components, structural members or fixtures, such as floor and ceiling tiles, and does not include surfacing material or thermal system insulation.

Nonfriable means material in a school building which when dry may not be crumbled, pulverized, or reduced to powder by hand pressure.

Operations and maintenance program means a program of work practices to maintain friable ACBM in good condition, ensure clean up of asbestos fibers previously released, and prevent further release by minimizing and controlling friable ACBM disturbance or damage.

Potential damage means circumstances in which:

(1) Friable ACBM is in an area regularly used by building occupants, including maintenance personnel, in the course of their normal activities.

(2) There are indications that there is a reasonable likelihood that the material or its covering will become damaged, deteriorated, or delaminated due to factors such as changes in building use, changes in operations and maintenance practices, changes in occupancy, or recurrent damage.

Potential significant damage means circumstances in which:

(1) Friable ACBM is in an area regularly used by building occupants, including maintenance personnel, in the course of their normal activities.

(2) There are indications that there is a reasonable likelihood that the material or its covering will become significantly damaged, deteriorated, or delaminated due to factors such as changes in building use, changes in operations and maintenance practices, changes in occupancy, or recurrent damage.

(3) The material is subject to major or continuing disturbance, due to factors including, but not limited to, accessibility or, under certain circumstances, vibration or air erosion.

Preventive measures means actions taken to reduce disturbance of ACBM or otherwise eliminate the reasonable likelihood of the material's becoming damaged or significantly damaged.

Removal means the taking out or the stripping of substantially all ACBM from a damaged area, a functional space, or a homogeneous area in a school building.

Repair means returning damaged ACBM to an undamaged condition or to an intact state so as to prevent fiber release.

Response action means a method, including removal, encapsulation, enclosure, repair, operations and maintenance, that protects human health and the environment from friable ACBM.

Routine maintenance area means an area, such as a boiler room or mechanical room, that is not normally frequented by students and in which maintenance employees or contract workers regularly conduct maintenance activities.

School means any elementary or secondary school as defined in section 198 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 2854).

School building means:

(1) Any structure suitable for use as a classroom, including a school facility such as a laboratory, library, school eating facility, or facility used for the preparation of food.

(2) Any gymnasium or other facility which is specially designed for athletic or recreational activities for an academic course in physical education.

(3) Any other facility used for the instruction or housing of students or for the administration of educational or research programs.

(4) Any maintenance, storage, or utility facility, including any hallway, essential to the operation of any facility described in this definition of ''school building'' under paragraphs (1), (2), or (3).

(5) Any portico or covered exterior hallway or walkway.

(6) Any exterior portion of a mechanical system used to condition interior space.

Significantly damaged friable miscellaneous ACM means damaged friable miscellaneous ACM where the damage is extensive and severe.

Significantly damaged friable surfacing ACM means damaged friable surfacing ACM in a functional space where the damage is extensive and severe.

State means a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Northern Marianas, the Trust Territory of the Pacific Islands, and the Virgin Islands.

Surfacing ACM means surfacing material that is ACM.

Surfacing material means material in a school building that is sprayed-on, troweled-on, or otherwise applied to surfaces, such as acoustical plaster on ceilings and fireproofing materials on structural members, or other materials on surfaces for acoustical, fireproofing, or other purposes.

Thermal system insulation means material in a school building applied to pipes, fittings, boilers, breeching, tanks, ducts, or other interior structural components to prevent heat loss or gain, or water condensation, or for other purposes.

Thermal system insulation ACM means thermal system insulation that is ACM.

Vibration means the periodic motion of friable ACBM which may result in the release of asbestos fibers.

§ 763.84 General local education agency responsibilities.

Each local education agency shall:

(a) Ensure that the activities of any persons who perform inspections, reinspections, and periodic surveillance, develop and update management plans, and develop and implement response actions, including operations and maintenance, are carried out in accordance with subpart E of this part.

(b) Ensure that all custodial and maintenance employees are properly trained as required by this subpart E and other applicable Federal and/or State regulations (e.g., the Occupational Safety and Health Administration asbestos standard for construction, the EPA worker protection rule, or applicable State regulations).

(c) Ensure that workers and building occupants, or their legal guardians, are informed at least once each school year about inspections, response actions, and post-response action activities, including periodic reinspection and surveillance activities that are planned or in progress.

(d) Ensure that short-term workers (e.g., telephone repair workers, utility workers, or exterminators) who may come in contact with asbestos in a school are provided information regarding the locations of ACBM and suspected ACBM assumed to be ACM.

(e) Ensure that warning labels are posted in accordance with § 763.95.

(f) Ensure that management plans are available for inspection and notification of such availability has been provided as specified in the management plan under § 763.93(g).

(g)(1) Designate a person to ensure that requirements under this section are properly implemented.

(2) Ensure that the designated person receives adequate training to perform duties assigned under this section. Such training shall provide, as necessary, basic knowledge of:

(i) Health effects of asbestos.

(ii) Detection, identification, and assessment of ACM.

(iii) Options for controlling ACBM.

(iv) Asbestos management programs.

(v) Relevant Federal and State regulations concerning asbestos, including those in this subpart E and those of the Occupational Safety and Health Administration, U.S. Department of Labor, the U.S. Department of Transportation and the U.S. Environmental Protection Agency.

(h) Consider whether any conflict of interest may arise from the interrelationship among accredited personnel and whether that should influence the selection of accredited personnel to perform activities under this subpart.

§ 763.85 Inspection and reinspections.

(a) *Inspection.* (1) Except as provided in paragraph (a)(2) of this section, before October 12, 1988, local education agencies shall inspect each school

building that they lease, own, or otherwise use as a school building to identify all locations of friable and nonfriable ACBM.

(2) Any building leased or acquired on or after October 12, 1988, that is to be used as a school building shall be inspected as described under paragraphs (a) (3) and (4) of this section prior to use as a school building. In the event that emergency use of an uninspected building as a school building is necessitated, such buildings shall be inspected within 30 days after commencement of such use.

(3) Each inspection shall be made by an accredited inspector.

(4) For each area of a school building, except as excluded under §763.99, each person performing an inspection shall:

(i) Visually inspect the area to identify the locations of all suspected ACBM.

(ii) Touch all suspected ACBM to determine whether they are friable.

(iii) Identify all homogeneous areas of friable suspected ACBM and all homogeneous areas of nonfriable suspected ACBM.

(iv) Assume that some or all of the homogeneous areas are ACM, and, for each homogeneous area that is not assumed to be ACM, collect and submit for analysis bulk samples under §§763.86 and 763.87.

(v) Assess, under §763.88, friable material in areas where samples are collected, friable material in areas that are assumed to be ACBM, and friable ACBM identified during a previous inspection.

(vi) Record the following and submit to the person designated under §763.84 a copy of such record for inclusion in the management plan within 30 days of the inspection:

(A) An inspection report with the date of the inspection signed by each accredited person making the inspection, State of accreditation, and if applicable, his or her accreditation number.

(B) An inventory of the locations of the homogeneous areas where samples are collected, exact location where each bulk sample is collected, dates that samples are collected, homogeneous areas where friable suspected ACBM is assumed to be ACM, and homogeneous areas where nonfriable suspected ACBM is assumed to be ACM.

(C) A description of the manner used to determine sampling locations, the name and signature of each accredited inspector who collected the samples, State of accreditation, and, if applicable, his or her accreditation number.

(D) A list of whether the homogeneous areas identified under paragraph (a)(4)(vi)(B) of this section, are surfacing material, thermal system insulation, or miscellaneous material.

(E) Assessments made of friable material, the name and signature of each accredited inspector making the assessment, State of accreditation, and if applicable, his or her accreditation number.

(b) *Reinspection.* (1) At least once every 3 years after a management plan is in effect, each local education agency shall conduct a reinspection of all friable and nonfriable known or assumed ACBM in each school building that they lease, own, or otherwise use as a school building.

(2) Each inspection shall be made by an accredited inspector.

(3) For each area of a school building, each person performing a reinspection shall:

(i) Visually reinspect, and reassess, under §763.88, the condition of all friable known or assumed ACBM.

(ii) Visually inspect material that was previously considered nonfriable ACBM and touch the material to determine whether it has become friable since the last inspection or reinspection.

(iii) Identify any homogeneous areas with material that has become friable since the last inspection or reinspection.

(iv) For each homogeneous area of newly friable material that is already assumed to be ACBM, bulk samples may be collected and submitted for analysis in accordance with §§763.86 and 763.87.

(v) Assess, under §763.88, the condition of the newly friable material in areas where samples are collected, and newly friable materials in areas that are assumed to be ACBM.

(vi) Reassess, under §763.88, the condition of friable known or assumed ACBM previously identified.

(vii) Record the following and submit to the person designated under § 763.84 a copy of such record for inclusion in the management plan within 30 days of the reinspection:

(A) The date of the reinspection, the name and signature of the person making the reinspection, State of accreditation, and if applicable, his or her accreditation number, and any changes in the condition of known or assumed ACBM.

(B) The exact locations where samples are collected during the reinspection, a description of the manner used to determine sampling locations, the name and signature of each accredited inspector who collected the samples, State of accreditation, and, if applicable, his or her accreditation number.

(C) Any assessments or reassessments made of friable material, the name and signature of the accredited inspector making the assessments, State of accreditation, and if applicable, his or her accreditation number.

(c) *General.* Thermal system insulation that has retained its structural integrity and that has an undamaged protective jacket or wrap that prevents fiber release shall be treated as nonfriable and therefore is subject only to periodic surveillance and preventive measures as necessary.

§ 763.86 Sampling.

(a) *Surfacing material.* An accredited inspector shall collect, in a statistically random manner that is representative of the homogeneous area, bulk samples from each homogeneous area of friable surfacing material that is not assumed to be ACM, and shall collect the samples as follows:

(1) At least three bulk samples shall be collected from each homogeneous area that is 1,000 ft^2 or less, except as provided in § 763.87(c)(2).

(2) At least five bulk samples shall be collected from each homogeneous area that is greater than 1,000 ft^2 but less than or equal to 5,000 ft^2, except as provided in § 763.87(c)(2).

(3) At least seven bulk samples shall be collected from each homogeneous area that is greater than 5,000 ft^2, except as provided in § 763.87(c)(2).

(b) *Thermal system insulation.* (1) Except as provided in paragraphs (b) (2) through (4) of this section and § 763.87(c), an accredited inspector shall collect, in a randomly distributed manner, at least three bulk samples from each homogeneous area of thermal system insulation that is not assumed to be ACM.

(2) Collect at least one bulk sample from each homogeneous area of patched thermal system insulation that is not assumed to be ACM if the patched section is less than 6 linear or square feet.

(3) In a manner sufficient to determine whether the material is ACM or not ACM, collect bulk samples from each insulated mechanical system that is not assumed to be ACM where cement or plaster is used on fittings such as tees, elbows, or valves, except as provided under § 763.87(c)(2).

(4) Bulk samples are not required to be collected from any homogeneous area where the accredited inspector has determined that the thermal system insulation is fiberglass, foam glass, rubber, or other non-ACBM.

(c) *Miscellaneous material.* In a manner sufficient to determine whether material is ACM or not ACM, an accredited inspector shall collect bulk samples from each homogeneous area of friable miscellaneous material that is not assumed to be ACM.

(d) *Nonfriable suspected ACBM.* If any homogeneous area of nonfriable suspected ACBM is not assumed to be ACM, then an accredited inspector shall collect, in a manner sufficient to determine whether the material is ACM or not ACM, bulk samples from the homogeneous area of nonfriable suspected ACBM that is not assumed to be ACM.

§ 763.87 Analysis.

(a) Local education agencies shall have bulk samples, collected under § 763.86 and submitted for analysis, analyzed for asbestos using laboratories accredited by the National Bureau of Standards (NBS). Local education agencies shall use laboratories which have received interim accreditation for polarized light microscopy (PLM) analysis under the EPA Interim Asbestos

Bulk Sample Analysis Quality Assurance Program until the NBS PLM laboratory accreditation program for PLM is operational.

(b) Bulk samples shall not be composited for analysis and shall be analyzed for asbestos content by PLM, using the ''Interim Method for the Determination of Asbestos in Bulk Insulation Samples'' found at appendix E to subpart E of this part.

(c)(1) A homogeneous area is considered not to contain ACM only if the results of all samples required to be collected from the area show asbestos in amounts of 1 percent or less.

(2) A homogeneous area shall be determined to contain ACM based on a finding that the results of at least one sample collected from that area shows that asbestos is present in an amount greater than 1 percent.

(d) The name and address of each laboratory performing an analysis, the date of analysis, and the name and signature of the person performing the analysis shall be submitted to the person designated under §763.84 for inclusion into the management plan within 30 days of the analysis.

[52 FR 41846, Oct. 30, 1987, as amended at 60 FR 31922, June 19, 1995]

§763.88 Assessment.

(a)(1) For each inspection and reinspection conducted under §763.85 (a) and (c) and previous inspections specified under §763.99, the local education agency shall have an accredited inspector provide a written assessment of all friable known or assumed ACBM in the school building.

(2) Each accredited inspector providing a written assessment shall sign and date the assessment, provide his or her State of accreditation, and if applicable, accreditation number, and submit a copy of the assessment to the person designated under §763.84 for inclusion in the management plan within 30 days of the assessment.

(b) The inspector shall classify and give reasons in the written assessment for classifying the ACBM and suspected ACBM assumed to be ACM in the school building into one of the following categories:

(1) Damaged or significantly damaged thermal system insulation ACM.

(2) Damaged friable surfacing ACM.

(3) Significantly damaged friable surfacing ACM.

(4) Damaged or significantly damaged friable miscellaneous ACM.

(5) ACBM with potential for damage.

(6) ACBM with potential for significant damage.

(7) Any remaining friable ACBM or friable suspected ACBM.

(c) Assessment may include the following considerations:

(1) Location and the amount of the material, both in total quantity and as a percentage of the functional space.

(2) Condition of the material, specifying:

(i) Type of damage or significant damage (e.g., flaking, blistering, water damage, or other signs of physical damage).

(ii) Severity of damage (e.g., major flaking, severely torn jackets, as opposed to occasional flaking, minor tears to jackets).

(iii) Extent or spread of damage over large areas or large percentages of the homogeneous area.

(3) Whether the material is accessible.

(4) The material's potential for disturbance.

(5) Known or suspected causes of damage or significant damage (e.g., air erosion, vandalism, vibration, water).

(6) Preventive measures which might eliminate the reasonable likelihood of undamaged ACM from becoming significantly damaged.

(d) The local education agency shall select a person accredited to develop management plans to review the results of each inspection, reinspection, and assessment for the school building and to conduct any other necessary activities in order to recommend in writing to the local education agency appropriate response actions. The accredited person shall sign and date the recommendation, provide his or her State of accreditation, and, if applicable, provide his or her accreditation number, and submit a copy of the recommendation to the person designated under §763.84 for inclusion in the management plan.

§ 763.90 Response actions.

(a) The local education agency shall select and implement in a timely manner the appropriate response actions in this section consistent with the assessment conducted in § 763.88. The response actions selected shall be sufficient to protect human health and the environment. The local education agency may then select, from the response actions which protect human health and the environment, that action which is the least burdensome method. Nothing in this section shall be construed to prohibit removal of ACBM from a school building at any time, should removal be the preferred response action of the local education agency.

(b) If damaged or significantly damaged thermal system insulation ACM is present in a building, the local education agency shall:

(1) At least repair the damaged area.

(2) Remove the damaged material if it is not feasible, due to technological factors, to repair the damage.

(3) Maintain all thermal system insulation ACM and its covering in an intact state and undamaged condition.

(c)(1) If damaged friable surfacing ACM or damaged friable miscellaneous ACM is present in a building, the local education agency shall select from among the following response actions: encapsulation, enclosure, removal, or repair of the damaged material.

(2) In selecting the response action from among those which meet the definitional standards in § 763.83, the local education agency shall determine which of these response actions protects human health and the environment. For purposes of determining which of these response actions are the least burdensome, the local education agency may then consider local circumstances, including occupancy and use patterns within the school building, and its economic concerns, including short- and long-term costs.

(d) If significantly damaged friable surfacing ACM or significantly damaged friable miscellaneous ACM is present in a building the local education agency shall:

(1) Immediately isolate the functional space and restrict access, unless isolation is not necessary to protect human health and the environment.

(2) Remove the material in the functional space or, depending upon whether enclosure or encapsulation would be sufficient to protect human health and the environment, enclose or encapsulate.

(e) If any friable surfacing ACM, thermal system insulation ACM, or friable miscellaneous ACM that has potential for damage is present in a building, the local education agency shall at least implement an operations and maintenance (O&M) program, as described under § 763.91.

(f) If any friable surfacing ACM, thermal system insulation ACM, or friable miscellaneous ACM that has potential for significant damage is present in a building, the local education agency shall:

(1) Implement an O&M program, as described under § 763.91.

(2) Institute preventive measures appropriate to eliminate the reasonable likelihood that the ACM or its covering will become significantly damaged, deteriorated, or delaminated.

(3) Remove the material as soon as possible if appropriate preventive measures cannot be effectively implemented, or unless other response actions are determined to protect human health and the environment. Immediately isolate the area and restrict access if necessary to avoid an imminent and substantial endangerment to human health or the environment.

(g) Response actions including removal, encapsulation, enclosure, or repair, other than small-scale, short-duration repairs, shall be designed and conducted by persons accredited to design and conduct response actions.

(h) The requirements of this subpart E in no way supersede the worker protection and work practice requirements under 29 CFR 1926.58 (Occupational Safety and Health Administration (OSHA) asbestos worker protection standards for construction), 40 CFR part 763, subpart G (EPA asbestos worker protection standards for public employees), and 40 CFR part 61, subpart M (National Emission Standards for Hazardous Air Pollutants—Asbestos).

(i) Completion of response actions. (1) At the conclusion of any action to remove, encapsulate, or enclose ACBM or material assumed to be ACBM, a person designated by the local education agency shall visually inspect each functional space where such action was conducted to determine whether the action has been properly completed.

(2)(i) A person designated by the local education agency shall collect air samples using aggressive sampling as described in appendix A to this subpart E to monitor air for clearance after each removal, encapsulation, and enclosure project involving ACBM, except for projects that are of small-scale, short-duration.

(ii) Local education agencies shall have air samples collected under this section analyzed for asbestos using laboratories accredited by the National Bureau of Standards to conduct such analysis using transmission electron microscopy (TEM) or, under circumstances permitted in this section, laboratories enrolled in the American Industrial Hygiene Association Proficiency Analytical Testing Program for phase contrast microscopy (PCM).

(iii) Until the National Bureau of Standards TEM laboratory accreditation program is operational, local educational agencies shall use laboratories that use the protocol described in appendix A to subpart E of this part.

(3) Except as provided in paragraphs (i)(4), and (i)(5), of this section, an action to remove, encapsulate, or enclose ACBM shall be considered complete when the average concentration of asbestos of five air samples collected within the affected functional space and analyzed by the TEM method in appendix A of this subpart E, is not statistically significantly different, as determined by the Z-test calculation found in appendix A of this subpart E, from the average asbestos concentration of five air samples collected at the same time outside the affected functional space and analyzed in the same manner, and the average asbestos concentration of the three field blanks described in appendix A of this subpart E is below the filter background level, as defined in appendix A of this subpart E, of 70 structures per square millimeter (70 s/mm^2).

(4) An action may also be considered complete if the volume of air drawn for each of the five samples collected within the affected functional space is equal to or greater than 1,199 L of air for a 25 mm filter or equal to or greater than 2,799 L of air for a 37 mm filter, and the average concentration of asbestos as analyzed by the TEM method in appendix A of this subpart E, for the five air samples does not exceed the filter background level, as defined in appendix A, of 70 structures per square millimeter (70 s/mm^2). If the average concentration of asbestos of the five air samples within the affected functional space exceeds 70 s/mm^2, or if the volume of air in each of the samples is less than 1,199 L of air for a 25 mm filter or less than 2,799 L of air for a 37 mm filter, the action shall be considered complete only when the requirements of paragraph (i)(3) or (i)(5), of this section are met.

(5) At any time, a local education agency may analyze air monitoring samples collected for clearance purposes by phase contrast microscopy (PCM) to confirm completion of removal, encapsulation, or enclosure of ACBM that is greater than small-scale, short-duration and less than or equal to 160 square feet or 260 linear feet. The action shall be considered complete when the results of samples collected in the affected functional space and analyzed by phase contrast microscopy using the National Institute for Occupational Safety and Health (NIOSH) Method 7400 entitled ''Fibers'' published in the NIOSH Manual of Analytical Methods, 3rd Edition, Second Supplement, August 1987, show that the concentration of fibers for each of the five samples is less than or equal to a limit of quantitation for PCM (0.01 fibers per cubic centimeter (0.01 f/cm^3) of air). The method is available at the addresses in §700.17(b)(1) and (2) of this chapter. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The method is incorporated as

it exists on the effective date of this rule, and a notice of any change to the method will be published in the FEDERAL REGISTER.

(6) To determine the amount of ACBM affected under paragraph (i)(5) of this section, the local education agency shall add the total square or linear footage of ACBM within the containment barriers used to isolate the functional space for the action to remove, encapsulate, or enclose the ACBM. Contiguous portions of material subject to such action conducted concurrently or at approximately the same time within the same school building shall not be separated to qualify under paragraph (i)(5), of this section.

[52 FR 41846, Oct. 30, 1987, as amended at 53 FR 12525, Apr. 15, 1988; 60 FR 31922, June 19, 1995; 60 FR 34465, July 3, 1995; 69 FR 18803, Apr. 9, 2004; 77 FR 46292, Aug. 3, 2012]

§ 763.91 Operations and maintenance.

(a) *Applicability*. The local education agency shall implement an operations, maintenance, and repair (O&M) program under this section whenever any friable ACBM is present or assumed to be present in a building that it leases, owns, or otherwise uses as a school building. Any material identified as nonfriable ACBM or nonfriable assumed ACBM must be treated as friable ACBM for purposes of this section when the material is about to become friable as a result of activities performed in the school building.

(b) *Worker protection*. Local education agencies must comply with either the OSHA Asbestos Construction Standard at 29 CFR 1926.1101, or the Asbestos Worker Protection Rule at 40 CFR 763.120, whichever is applicable.

(c) *Cleaning*—(1) *Initial cleaning*. Unless the building has been cleaned using equivalent methods within the previous 6 months, all areas of a school building where friable ACBM, damaged or significantly damaged thermal system insulation ACM, or friable suspected ACBM assumed to be ACM are present shall be cleaned at least once after the completion of the inspection required by §763.85(a) and before the initiation of any response action, other than O&M activities or repair, according to the following procedures:

(i) HEPA-vacuum or steam-clean all carpets.

(ii) HEPA-vacuum or wet-clean all other floors and all other horizontal surfaces.

(iii) Dispose of all debris, filters, mopheads, and cloths in sealed, leak-tight containers.

(2) *Additional cleaning*. The accredited management planner shall make a written recommendation to the local education agency whether additional cleaning is needed, and if so, the methods and frequency of such cleaning.

(d) *Operations and maintenance activities*. The local education agency shall ensure that the procedures described below to protect building occupants shall be followed for any operations and maintenance activities disturbing friable ACBM:

(1) Restrict entry into the area by persons other than those necessary to perform the maintenance project, either by physically isolating the area or by scheduling.

(2) Post signs to prevent entry by unauthorized persons.

(3) Shut off or temporarily modify the air-handling system and restrict other sources of air movement.

(4) Use work practices or other controls, such as, wet methods, protective clothing, HEPA-vacuums, mini-enclosures, glove bags, as necessary to inhibit the spread of any released fibers.

(5) Clean all fixtures or other components in the immediate work area.

(6) Place the asbestos debris and other cleaning materials in a sealed, leak-tight container.

(e) *Maintenance activities other than small-scale, short-duration*. The response action for any maintenance activities disturbing friable ACBM, other than small-scale, short-duration maintenance activities, shall be designed by persons accredited to design response actions and conducted by persons accredited to conduct response actions.

(f) *Fiber release episodes*—(1) *Minor fiber release episode*. The local education agency shall ensure that the procedures described below are followed in the event of a minor fiber release episode (i.e., the falling or dislodging of 3 square or linear feet or less of friable ACBM): 5

(i) Thoroughly saturate the debris using wet methods.

(ii) Clean the area, as described in paragraph (e) of this section.

(iii) Place the asbestos debris in a sealed, leak-tight container.

(iv) Repair the area of damaged ACM with materials such as asbestos-free spackling, plaster, cement, or insulation, or seal with latex paint or an encapsulant, or immediately have the appropriate response action implemented as required by §763.90.

(2) *Major fiber release episode.* The local education agency shall ensure that the procedures described below are followed in the event of a major fiber release episode (i.e., the falling or dislodging of more than 3 square or linear feet of friable ACBM):

(i) Restrict entry into the area and post signs to prevent entry into the area by persons other than those necessary to perform the response action.

(ii) Shut off or temporarily modify the air-handling system to prevent the distribution of fibers to other areas in the building.

(iii) The response action for any major fiber release episode must be designed by persons accredited to design response actions and conducted by persons accredited to conduct response actions.

[52 FR 41846, Oct. 30, 1987, as amended at 65 FR 69216, Nov. 15, 2000]

§763.92 Training and periodic surveillance.

(a) *Training.* (1) The local education agency shall ensure, prior to the implementation of the O&M provisions of the management plan, that all members of its maintenance and custodial staff (custodians, electricians, heating/air conditioning engineers, plumbers, etc.) who may work in a building that contains ACBM receive awareness training of at least 2 hours, whether or not they are required to work with ACBM. New custodial and maintenance employees shall be trained within 60 days after commencement of employment. Training shall include, but not be limited to:

(i) Information regarding asbestos and its various uses and forms.

(ii) Information on the health effects associated with asbestos exposure.

(iii) Locations of ACBM identified throughout each school building in which they work.

(iv) Recognition of damage, deterioration, and delamination of ACBM.

(v) Name and telephone number of the person designated to carry out general local education agency responsibilities under §763.84 and the availability and location of the management plan.

(2) The local education agency shall ensure that all members of its maintenance and custodial staff who conduct any activities that will result in the disturbance of ACBM shall receive training described in paragraph (a)(1) of this section and 14 hours of additional training. Additional training shall include, but not be limited to:

(i) Descriptions of the proper methods of handling ACBM.

(ii) Information on the use of respiratory protection as contained in the EPA/NIOSH *Guide to Respiratory Protection for the Asbestos Abatement Industry*, September 1986 (EPA 560/OPPTS–86–001), available from the Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room E–543B, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 544–0551 and other personal protection measures.

(iii) The provisions of this section and §763.91, appendices A, C, and D of this subpart E of this part, EPA regulations contained in 40 CFR part 763, subpart G, and in 40 CFR part 61, subpart M, and OSHA regulations contained in 29 CFR 1926.58.

(iv) Hands-on training in the use of respiratory protection, other personal protection measures, and good work practices.

(3) Local education agency maintenance and custodial staff who have attended EPA-approved asbestos training or received equivalent training for O&M and periodic surveillance activities involving asbestos shall be considered trained for the purposes of this section.

(b) *Periodic surveillance.* (1) At least once every 6 months after a management plan is in effect, each local education agency shall conduct periodic

surveillance in each building that it leases, owns, or otherwise uses as a school building that contains ACBM or is assumed to contain ACBM.

(2) Each person performing periodic surveillance shall:

(i) Visually inspect all areas that are identified in the management plan as ACBM or assumed ACBM.

(ii) Record the date of the surveillance, his or her name, and any changes in the condition of the materials.

(iii) Submit to the person designated to carry out general local education agency responsibilities under § 763.84 a copy of such record for inclusion in the management plan.

[52 FR 41846, Oct. 30, 1987, as amended at 60 FR 34465, July 3, 1995; 65 FR 69216, Nov. 15, 2000]

§ 763.93 Management plans.

(a)(1) On or before October 12, 1988, each local education agency shall develop an asbestos management plan for each school, including all buildings that they lease, own, or otherwise use as school buildings, and submit the plan to an Agency designated by the Governor of the State in which the local education agency is located. The plan may be submitted in stages that cover a portion of the school buildings under the authority of the local education agency.

(2) If a building to be used as part of a school is leased or otherwise acquired after October 12, 1988, the local education agency shall include the new building in the management plan for the school prior to its use as a school building. The revised portions of the management plan shall be submitted to the Agency designated by the Governor.

(3) If a local education agency begins to use a building as a school after October 12, 1988, the local education agency shall submit a management plan for the school to the Agency designated by the Governor prior to its use as a school.

(b) On or before October 17, 1987, the Governor of each State shall notify local education agencies in the State regarding where to submit their management plans. States may establish administrative procedures for reviewing management plans. If the Governor does not disapprove a management plan within 90 days after receipt of the plan, the local education agency shall implement the plan.

(c) Each local education agency must begin implementation of its management plan on or before July 9, 1989, and complete implementation in a timely fashion.

(d) Each local education agency shall maintain and update its management plan to keep it current with ongoing operations and maintenance, periodic surveillance, inspection, reinspection, and response action activities. All provisions required to be included in the management plan under this section shall be retained as part of the management plan, as well as any information that has been revised to bring the plan up-to-date.

(e) The management plan shall be developed by an accredited management planner and shall include:

(1) A list of the name and address of each school building and whether the school building contains friable ACBM, nonfriable ACBM, and friable and nonfriable suspected ACBM assumed to be ACM.

(2) For each inspection conducted before the December 14, 1987:

(i) The date of the inspection.

(ii) A blueprint, diagram, or written description of each school building that identifies clearly each location and approximate square or linear footage of any homogeneous or sampling area where material was sampled for ACM, and, if possible, the exact locations where bulk samples were collected, and the dates of collection.

(iii) A copy of the analyses of any bulk samples, dates of analyses, and a copy of any other laboratory reports pertaining to the analyses.

(iv) A description of any response actions or preventive measures taken to reduce asbestos exposure, including if possible, the names and addresses of all contractors involved, start and completion dates of the work, and results of any air samples analyzed during and upon completion of the work.

(v) A description of assessments, required to be made under §763.88, of material that was identified before December 14, 1987, as friable ACBM or friable suspected ACBM assumed to be ACM, and the name and signature, State of accreditation, and if applicable, accreditation number of each accredited person making the assessments.

(3) For each inspection and reinspection conducted under §763.85:

(i) The date of the inspection or reinspection and the name and signature, State of accreditation and, if applicable, the accreditation number of each accredited inspector performing the inspection or reinspection.

(ii) A blueprint, diagram, or written description of each school building that identifies clearly each location and approximate square or linear footage of homogeneous areas where material was sampled for ACM, the exact location where each bulk sample was collected, date of collection, homogeneous areas where friable suspected ACBM is assumed to be ACM, and where nonfriable suspected ACBM is assumed to be ACM.

(iii) A description of the manner used to determine sampling locations, and the name and signature of each accredited inspector collecting samples, the State of accreditation, and if applicable, his or her accreditation number.

(iv) A copy of the analyses of any bulk samples collected and analyzed, the name and address of any laboratory that analyzed bulk samples, a statement that the laboratory meets the applicable requirements of §763.87(a) the date of analysis, and the name and signature of the person performing the analysis.

(v) A description of assessments, required to be made under §763.88, of all ACBM and suspected ACBM assumed to be ACM, and the name, signature, State of accreditation, and if applicable, accreditation number of each accredited person making the assessments.

(4) The name, address, and telephone number of the person designated under §763.84 to ensure that the duties of the local education agency are carried out, and the course name, and dates and hours of training taken by that person to carry out the duties.

(5) The recommendations made to the local education agency regarding response actions, under §763.88(d), the name, signature, State of accreditation of each person making the recommendations, and if applicable, his or her accreditation number.

(6) A detailed description of preventive measures and response actions to be taken, including methods to be used, for any friable ACBM, the locations where such measures and action will be taken, reasons for selecting the response action or preventive measure, and a schedule for beginning and completing each preventive measure and response action.

(7) With respect to the person or persons who inspected for ACBM and who will design or carry out response actions, except for operations and maintenance, with respect to the ACBM, one of the following statements:

(i) If the State has adopted a contractor accreditation program under section 206(b) of Title II of the Act, a statement that the person(s) is accredited under such plan.

(ii) A statement that the local education agency used (or will use) persons who have been accredited by another State which has adopted a contractor accreditation plan under section 206(b) of Title II of the Act or is accredited by an EPA-approved course under section 206(c) of Title II of the Act.

(8) A detailed description in the form of a blueprint, diagram, or in writing of any ACBM or suspected ACBM assumed to be ACM which remains in the school once response actions are undertaken pursuant to §763.90. This description shall be updated as response actions are completed.

(9) A plan for reinspection under §763.85, a plan for operations and maintenance activities under §763.91, and a plan for periodic surveillance under §763.92, a description of the recommendation made by the management planner regarding additional cleaning under §763.91(c)(2) as part of an operations and maintenance program, and the response of the local education agency to that recommendation.

(10) A description of steps taken to inform workers and building occupants, or their legal guardians, about

inspections, reinspections, response actions, and post-response action activities, including periodic reinspection and surveillance activities that are planned or in progress.

(11) An evaluation of the resources needed to complete response actions successfully and carry out reinspection, operations and maintenance activities, periodic surveillance and training.

(12) With respect to each consultant who contributed to the management plan, the name of the consultant and one of the following statements:

(i) If the State has adopted a contractor accreditation plan under section 206(b) of Title II of the Act, a statement that the consultant is accredited under such plan.

(ii) A statement that the contractor is accredited by another State which has adopted a contractor accreditation plan under section 206(b) of Title II of the Act, or is accredited by an EPA-approved course developed under section 206(c) of Title II of the Act.

(f) A local education agency may require each management plan to contain a statement signed by an accredited management plan developer that such person has prepared or assisted in the preparation of such plan or has reviewed such plan, and that such plan is in compliance with this subpart E. Such statement may not be signed by a person who, in addition to preparing or assisting in preparing the management plan, also implements (or will implement) the management plan.

(g)(1) Upon submission of a management plan to the Governor for review, a local education agency shall keep a copy of the plan in its administrative office. The management plans shall be available, without cost or restriction, for inspection by representatives of EPA and the State, the public, including teachers, other school personnel and their representatives, and parents. The local education agency may charge a reasonable cost to make copies of management plans.

(2) Each local education agency shall maintain in its administrative office a complete, updated copy of a management plan for each school under its administrative control or direction. The management plans shall be available, during normal business hours, without cost or restriction, for inspection by representatives of EPA and the State, the public, including teachers, other school personnel and their representatives, and parents. The local education agency may charge a reasonable cost to make copies of management plans.

(3) Each school shall maintain in its administrative office a complete, updated copy of the management plan for that school. Management plans shall be available for inspection, without cost or restriction, to workers before work begins in any area of a school building. The school shall make management plans available for inspection to representatives of EPA and the State, the public, including parents, teachers, and other school personnel and their representatives within 5 working days after receiving a request for inspection. The school may charge a reasonable cost to make copies of the management plan.

(4) Upon submission of its management plan to the Governor and at least once each school year, the local education agency shall notify in writing parent, teacher, and employee organizations of the availability of management plans and shall include in the management plan a description of the steps taken to notify such organizations, and a dated copy of the notification. In the absence of any such organizations for parents, teachers, or employees, the local education agency shall provide written notice to that relevant group of the availability of management plans and shall include in the management plan a description of the steps taken to notify such groups, and a dated copy of the notification.

(h) Records required under § 763.94 shall be made by local education agencies and maintained as part of the management plan.

(i) Each management plan must contain a true and correct statement, signed by the individual designated by the local education agency under § 763.84, which certifies that the general, local education agency responsibilities, as stipulated by § 763.84, have been met or will be met.

§ 763.94 Recordkeeping.

(a) Records required under this section shall be maintained in a centralized location in the administrative office of both the school and the local education agency as part of the management plan. For each homogeneous area where all ACBM has been removed, the local education agency shall ensure that such records are retained for 3 years after the next reinspection required under § 763.85(b)(1), or for an equivalent period.

(b) For each preventive measure and response action taken for friable and nonfriable ACBM and friable and nonfriable suspected ACBM assumed to be ACM, the local education agency shall provide:

(1) A detailed written description of the measure or action, including methods used, the location where the measure or action was taken, reasons for selecting the measure or action, start and completion dates of the work, names and addresses of all contractors involved, and if applicable, their State of accreditation, and accreditation numbers, and if ACBM is removed, the name and location of storage or disposal site of the ACM.

(2) The name and signature of any person collecting any air sample required to be collected at the completion of certain response actions specified by § 763.90(i), the locations where samples were collected, date of collection, the name and address of the laboratory analyzing the samples, the date of analysis, the results of the analysis, the method of analysis, the name and signature of the person performing the analysis, and a statement that the laboratory meets the applicable requirements of § 763.90(i)(2)(ii).

(c) For each person required to be trained under § 763.92(a) (1) and (2), the local education agency shall provide the person's name and job title, the date that training was completed by that person, the location of the training, and the number of hours completed in such training.

(d) For each time that periodic surveillance under § 763.92(b) is performed, the local education agency shall record the name of each person performing the surveillance, the date of the surveillance, and any changes in the conditions of the materials.

(e) For each time that cleaning under § 763.91(c) is performed, the local education agency shall record the name of each person performing the cleaning, the date of such cleaning, the locations cleaned, and the methods used to perform such cleaning.

(f) For each time that operations and maintenance activities under § 763.91(d) are performed, the local education agency shall record the name of each person performing the activity, the start and completion dates of the activity, the locations where such activity occurred, a description of the activity including preventive measures used, and if ACBM is removed, the name and location of storage or disposal site of the ACM.

(g) For each time that major asbestos activity under § 763.91(e) is performed, the local education agency shall provide the name and signature, State of accreditation, and if applicable, the accreditation number of each person performing the activity, the start and completion dates of the activity, the locations where such activity occurred, a description of the activity including preventive measures used, and if ACBM is removed, the name and location of storage or disposal site of the ACM.

(h) For each fiber release episode under § 763.91(f), the local education agency shall provide the date and location of the episode, the method of repair, preventive measures or response action taken, the name of each person performing the work, and if ACBM is removed, the name and location of storage or disposal site of the ACM.

(Approved by the Office of Management and Budget under control number 2070–0091)

§ 763.95 Warning labels.

(a) The local education agency shall attach a warning label immediately adjacent to any friable and nonfriable ACBM and suspected ACBM assumed to be ACM located in routine maintenance areas (such as boiler rooms) at each school building. This shall include:

(1) Friable ACBM that was responded to by a means other than removal.

(2) ACBM for which no response action was carried out.

(b) All labels shall be prominently displayed in readily visible locations and shall remain posted until the ACBM that is labeled is removed.

(c) The warning label shall read, in print which is readily visible because of large size or bright color, as follows:

CAUTION: ASBESTOS. HAZARDOUS. DO NOT DISTURB WITHOUT PROPER TRAINING AND EQUIPMENT.

§ 763.97 Compliance and enforcement.

(a) *Compliance with Title II of the Act.* (1) Section 207(a) of Title II of the Act (15 U.S.C. 2647) makes it unlawful for any local education agency to:

(i) Fail to conduct inspections pursuant to section 203(b) of Title II of the Act, including failure to follow procedures and failure to use accredited personnel and laboratories.

(ii) Knowingly submit false information to the Governor regarding any inspection pursuant to regulations under section 203(i) of Title II of the Act.

(iii) Fail to develop a management plan pursuant to regulations under section 203(i) of Title II of the Act.

(2) Section 207(a) of Title II of the Act (15 U.S.C. 2647) also provides that any local education agency which violates any provision of section 207 shall be liable for a civil penalty of not more than $5,000 for each day during which the violation continues. For the purposes of this subpart, a ''violation'' means a failure to comply with respect to a single school building.

(b) *Compliance with Title I of the Act.* (1) Section 15(1)(D) of Title I of the Act (15 U.S.C. 2614) makes it unlawful for any person to fail or refuse to comply with any requirement of Title II or any rule promulgated or order issued under Title II. Therefore, any person who violates any requirement of this subpart is in violation of section 15 of Title I of the Act.

(2) Section 15(3) of Title I of the Act (15 U.S.C. 2614) makes it unlawful for any person to fail or refuse to establish or maintain records, submit reports, notices or other information, or permit access to or copying of records, as required by this Act or a rule thereunder.

(3) Section 15(4) (15 U.S.C. 2614) of Title I of the Act makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11 of Title I of the Act.

(4) Section 16(a) of Title I of the Act (15 U.S.C. 2615) provides that any person who violates any provision of section 15 of Title I of the Act shall be liable to the United States for a civil penalty in an amount not to exceed $25,000 for each such violation. Each day such a violation continues shall, for purposes of this paragraph, constitute a separate violation of section 15. A local education agency is not liable for any civil penalty under Title I of the Act for failing or refusing to comply with any rule promulgated or order issued under Title II of the Act.

(c) *Criminal penalties.* If any violation committed by any person (including a local education agency) is knowing or willful, criminal penalties may be assessed under section 16(b) of Title I of the Act.

(d) *Injunctive relief.* The Agency may obtain injunctive relief under section 208(b) of Title II of the Act to respond to a hazard which poses an imminent and substantial endangerment to human health or the environment or section 17 (15 U.S.C. 2616) of Title I of the Act to restrain any violation of section 15 of Title I of the Act or to compel the taking of any action required by or under Title I of the Act.

(e) *Citizen complaints.* Any citizen who wishes to file a complaint pursuant to section 207(d) of Title II of the Act should direct the complaint to the Governor of the State or the EPA Asbestos Ombudsman, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The citizen complaint should be in writing and identified as a citizen complaint pursuant to section 207(d) of Title II of TSCA. The EPA Asbestos Ombudsman or the Governor shall investigate and respond to the complaint within a reasonable period of time if the allegations provide a reasonable basis to believe that a violation of the Act has occurred.

(f) *Inspections.* EPA may conduct inspections and review management plans under section 11 of Title I of the Act (15 U.S.C. 2610) to ensure compliance.

§ 763.98 Waiver; delegation to State.

(a) *General.* (1) Upon request from a state Governor and after notice and comment and an opportunity for a public hearing in accordance with paragraphs (b) and (c) of this section, EPA may waive some or all of the requirements of this subpart E if the state has established and is implementing or intends to implement a program of asbestos inspection and management that contains requirements that are at least as stringent as the requirements of this subpart. In addition, if the state chooses to receive electronic documents, the state program must include, at a minimum, the requirements of 40 CFR part 3—(Electronic reporting).

(2) A waiver from any requirement of this subpart E shall apply only to the specific provision for which a waiver has been granted under this section. All requirements of this subpart E shall apply until a waiver is granted under this section.

(b) *Request.* Each request by a Governor to waive any requirement of this subpart E shall be sent with three complete copies of the request to the Regional Administrator for the EPA Region in which the State is located and shall include:

(1) A copy of the State provisions or proposed provisions relating to its program of asbestos inspection and management in schools for which the request is made.

(2)(i) The name of the State agency that is or will be responsible for administering and enforcing the requirements for which a waiver is requested, the names and job titles of responsible officials in that agency, and phone numbers where the officials can be contacted.

(ii) In the event that more than one agency is or will be responsible for administering and enforcing the requirements for which a waiver is requested, a description of the functions to be performed by each agency, how the program will be coordinated by the lead agency to ensure consistency and effective administration in the asbestos inspection and management program within the State, the names and job titles of responsible officials in the agencies, and phone numbers where the officials can be contacted. The lead agency will serve as the central contact point for the EPA.

(3) Detailed reasons, supporting papers, and the rationale for concluding that the state's asbestos inspection and management program provisions for which the request is made are at least as stringent as the requirements of subpart E of this part, and that, if the state chooses to receive electronic documents, the state program includes, at a minimum, the requirements of 40 CFR part 3—(Electronic reporting).

(4) A discussion of any special situations, problems, and needs pertaining to the waiver request accompanied by an explanation of how the State intends to handle them.

(5) A statement of the resources that the State intends to devote to the administration and enforcement of the provisions relating to the waiver request.

(6) Copies of any specific or enabling State laws (enacted and pending enactment) and regulations (promulgated and pending promulgation) relating to the request, including provisions for assessing criminal and/or civil penalties.

(7) Assurance from the Governor, the Attorney General, or the legal counsel of the lead agency that the lead agency or other cooperating agencies have the legal authority necessary to carry out the requirements relating to the request.

(c) *General notice—hearing.* (1) Within 30 days after receipt of a request for a waiver, EPA will determine the completeness of the request. If EPA does not request further information within the 30-day period, the request will be deemed complete.

(2) Within 30 days after EPA determines that a request is complete, EPA will issue for publication in the FEDERAL REGISTER a notice that announces receipt of the request, describes the information submitted under paragraph (b) of this section, and solicits written comment from interested members of the public. Comments must be submitted within 60 days.

(3) If, during the comment period, EPA receives a written objection to a Governor's request and a request for a public hearing detailing specific objections to the granting of a waiver, EPA

will schedule a public hearing to be held in the affected State after the close of the comment period and will announce the public hearing date in the FEDERAL REGISTER before the date of the hearing. Each comment shall include the name and address of the person submitting the comment.

(d) *Criteria.* EPA may waive some or all of the requirements of subpart E of this part if:

(1) The State's lead agency and other cooperating agencies have the legal authority necessary to carry out the provisions of asbestos inspection and management in schools relating to the waiver request.

(2) The State's program of asbestos inspection and management in schools relating to the waiver request and implementation of the program are or will be at least as stringent as the requirements of this subpart E.

(3) The state has an enforcement mechanism to allow it to implement the program described in the waiver request and any electronic reporting requirements are at least as stringent as 40 CFR part 3—(Electronic reporting).

(4) The lead agency and any cooperating agencies have or will have qualified personnel to carry out the provisions relating to the waiver request.

(5) The State will devote adequate resources to the administration and enforcement of the asbestos inspection and management provisions relating to the waiver request.

(6) When specified by EPA, the State gives satisfactory assurances that necessary steps, including specific actions it proposes to take and a time schedule for their accomplishment, will be taken within a reasonable time to conform with applicable criteria under paragraphs (d) (2) through (4) of this section.

(e) *Decision.* EPA will issue for publication in the FEDERAL REGISTER a notice announcing its decision to grant or deny, in whole or in part, a Governor's request for a waiver from some or all of the requirements of this subpart E within 30 days after the close of the comment period or within 30 days following a public hearing, whichever is applicable. The notice will include the Agency's reasons and rationale for granting or denying the Governor's request. The 30-day period may be extended if mutually agreed upon by EPA and the State.

(f) *Modifications.* When any substantial change is made in the administration or enforcement of a State program for which a waiver was granted under this section, a responsible official in the lead agency shall submit such changes to EPA.

(g) *Reports.* The lead agency in each State that has been granted a waiver by EPA from any requirement of subpart E of this part shall submit a report to the Regional Administrator for the Region in which the State is located at least once every 12 months to include the following information:

(1) A summary of the State's implementation and enforcement activities during the last reporting period relating to provisions waived under this section, including enforcement actions taken.

(2) Any changes in the administration or enforcement of the State program implemented during the last reporting period.

(3) Other reports as may be required by EPA to carry out effective oversight of any requirement of this subpart E that was waived under this section.

(h) *Oversight.* EPA may periodically evaluate the adequacy of a State's implementation and enforcement of and resources devoted to carrying out requirements relating to the waiver. This evaluation may include, but is not limited to, site visits to local education agencies without prior notice to the State.

(i) *Informal conference.* (1) EPA may request that an informal conference be held between appropriate State and EPA officials when EPA has reason to believe that a State has failed to:

(i) Substantially comply with the terms of any provision that was waived under this section.

(ii) Meet the criteria under paragraph (d) of this section, including the failure to carry out enforcement activities or act on violations of the State program.

(2) EPA will:

(i) Specify to the State those aspects of the State's program believed to be inadequate.

(ii) Specify to the State the facts that underlie the belief of inadequacy.

(3) If EPA finds, on the basis of information submitted by the State at the conference, that deficiencies did not exist or were corrected by the State, no further action is required.

(4) Where EPA finds that deficiencies in the State program exist, a plan to correct the deficiencies shall be negotiated between the State and EPA. The plan shall detail the deficiencies found in the State program, specify the steps the State has taken or will take to remedy the deficiencies, and establish a schedule for each remedial action to be initiated.

(j) *Rescission.* (1) If the State fails to meet with EPA or fails to correct deficiencies raised at the informal conference, EPA will deliver to the Governor of the State and a responsible official in the lead agency a written notice of its intent to rescind, in whole or part, the waiver.

(2) EPA will issue for publication in the FEDERAL REGISTER a notice that announces the rescission of the waiver, describes those aspects of the State's program determined to be inadequate, and specifies the facts that underlie the findings of inadequacy.

[52 FR 41846, Oct. 30, 1987, as amended at 70 FR 59889, Oct. 13, 2005]

§ 763.99 Exclusions.

(a) A local education agency shall not be required to perform an inspection under § 763.85(a) in any sampling area as defined in 40 CFR 763.103 or homogeneous area of a school building where:

(1) An accredited inspector has determined that, based on sampling records, friable ACBM was identified in that homogeneous or sampling area during an inspection conducted before December 14, 1987. The inspector shall sign and date a statement to that effect with his or her State of accreditation and if applicable, accreditation number and, within 30 days after such determination, submit a copy of the statement to the person designated under § 763.84 for inclusion in the management plan. However, an accredited inspector shall assess the friable ACBM under § 763.88.

(2) An accredited inspector has determined that, based on sampling records, nonfriable ACBM was identified in that homogeneous or sampling area during an inspection conducted before December 14, 1987. The inspector shall sign and date a statement to that effect with his or her State of accreditation and if applicable, accreditation number and, within 30 days after such determination, submit a copy of the statement to the person designated under § 763.84 for inclusion in the management plan. However, an accredited inspector shall identify whether material that was nonfriable has become friable since that previous inspection and shall assess the newly-friable ACBM under § 763.88.

(3) Based on sampling records and inspection records, an accredited inspector has determined that no ACBM is present in the homogeneous or sampling area and the records show that the area was sampled, before December 14, 1987 in substantial compliance with § 763.85(a), which for purposes of this section means in a random manner and with a sufficient number of samples to reasonably ensure that the area is not ACBM.

(i) The accredited inspector shall sign and date a statement, with his or her State of accreditation and if applicable, accreditation number that the homogeneous or sampling area determined not to be ACBM was sampled in substantial compliance with § 763.85(a).

(ii) Within 30 days after the inspector's determination, the local education agency shall submit a copy of the inspector's statement to the EPA Regional Office and shall include the statement in the management plan for that school.

(4) The lead agency responsible for asbestos inspection in a State that has been granted a waiver from § 763.85(a) has determined that, based on sampling records and inspection records, no ACBM is present in the homogeneous or sampling area and the records show that the area was sampled before December 14, 1987, in substantial compliance with § 763.85(a). Such determination shall be included in the management plan for that school.

(5) An accredited inspector has determined that, based on records of an inspection conducted before December 14, 1987, suspected ACBM identified in that

homogeneous or sampling area is assumed to be ACM. The inspector shall sign and date a statement to that effect, with his or her State of accreditation and if applicable, accreditation number and, within 30 days of such determination, submit a copy of the statement to the person designated under §763.84 for inclusion in the management plan. However, an accredited inspector shall identify whether material that was nonfriable suspected ACBM assumed to be ACM has become friable since the previous inspection and shall assess the newly friable material and previously identified friable suspected ACBM assumed to be ACM under §763.88.

(6) Based on inspection records and contractor and clearance records, an accredited inspector has determined that no ACBM is present in the homogeneous or sampling area where asbestos removal operations have been conducted before December 14, 1987, and shall sign and date a statement to that effect and include his or her State of accreditation and, if applicable, accreditation number. The local education agency shall submit a copy of the statement to the EPA Regional Office and shall include the statement in the management plan for that school.

(7) An architect or project engineer responsible for the construction of a new school building built after October 12, 1988, or an accredited inspector signs a statement that no ACBM was specified as a building material in any construction document for the building, or, to the best of his or her knowledge, no ACBM was used as a building material in the building. The local education agency shall submit a copy of the signed statement of the architect, project engineer, or accredited inspector to the EPA Regional Office and shall include the statement in the management plan for that school.

(b) The exclusion, under paragraphs (a) (1) through (4) of this section, from conducting the inspection under §763.85(a) shall apply only to homogeneous or sampling areas of a school building that were inspected and sampled before October 17, 1987. The local education agency shall conduct an inspection under §763.85(a) of all areas inspected before October 17, 1987, that were not sampled or were not assumed to be ACM.

(c) If ACBM is subsequently found in a homogeneous or sampling area of a local education agency that had been identified as receiving an exclusion by an accredited inspector under paragraphs (a) (3), (4), (5) of this section, or an architect, project engineer or accredited inspector under paragraph (a)(7) of this section, the local education agency shall have 180 days following the date of identification of ACBM to comply with this subpart E.

APPENDIX A TO SUBPART E OF PART 763—INTERIM TRANSMISSION ELECTRON MICROSCOPY ANALYTICAL METHODS—MANDATORY AND NON-MANDATORY—AND MANDATORY SECTION TO DETERMINE COMPLETION OF RESPONSE ACTIONS

I. Introduction

The following appendix contains three units. The first unit is the mandatory transmission electron microscopy (TEM) method which all laboratories must follow; it is the minimum requirement for analysis of air samples for asbestos by TEM. The mandatory method contains the essential elements of the TEM method. The second unit contains the complete non-mandatory method. The non-mandatory method supplements the mandatory method by including additional steps to improve the analysis. EPA recommends that the non-mandatory method be employed for analyzing air filters; however, the laboratory may choose to employ the mandatory method. The non-mandatory method contains the same minimum requirements as are outlined in the mandatory method. Hence, laboratories may choose either of the two methods for analyzing air samples by TEM.

The final unit of this Appendix A to subpart E defines the steps which must be taken to determine completion of response actions. This unit is mandatory.

II. Mandatory Transmission Electron Microscopy Method

A. Definitions of Terms

1. *Analytical sensitivity*—Airborne asbestos concentration represented by each fiber counted under the electron microscope. It is determined by the air volume collected and the proportion of the filter examined. This method requires that the analytical sensitivity be no greater than 0.005 structures/cm^3.

2. *Asbestiform*—A specific type of mineral fibrosity in which the fibers and fibrils possess high tensile strength and flexibility.

3. *Aspect ratio*—A ratio of the length to the width of a particle. Minimum aspect ratio as defined by this method is equal to or greater than 5:1.

4. *Bundle*—A structure composed of three or more fibers in a parallel arrangement with each fiber closer than one fiber diameter.

5. *Clean area*—A controlled environment which is maintained and monitored to assure a low probability of asbestos contamination to materials in that space. Clean areas used in this method have HEPA filtered air under positive pressure and are capable of sustained operation with an open laboratory blank which on subsequent analysis has an average of less than 18 structures/mm^2 in an area of 0.057 mm^2 (nominally 10 200-mesh grid openings) and a maximum of 53 structures/mm^2 for any single preparation for that same area.

6. *Cluster*—A structure with fibers in a random arrangement such that all fibers are intermixed and no single fiber is isolated from the group. Groupings must have more than two intersections.

7. *ED*—Electron diffraction.

8. *EDXA*—Energy dispersive X-ray analysis.

9. *Fiber*—A structure greater than or equal to 0.5 μm in length with an aspect ratio (length to width) of 5:1 or greater and having substantially parallel sides.

10. *Grid*—An open structure for mounting on the sample to aid in its examination in the TEM. The term is used here to denote a 200-mesh copper lattice approximately 3 mm in diameter.

11. *Intersection*—Nonparallel touching or crossing of fibers, with the projection having an aspect ratio of 5:1 or greater.

12. *Laboratory sample coordinator*—That person responsible for the conduct of sample handling and the certification of the testing procedures.

13. *Filter background level*—The concentration of structures per square millimeter of filter that is considered indistinguishable from the concentration measured on a blank (filters through which no air has been drawn). For this method the filter background level is defined as 70 structures/mm^2.

14. *Matrix*—Fiber or fibers with one end free and the other end embedded in or hidden by a particulate. The exposed fiber must meet the fiber definition.

15. *NSD*—No structure detected.

16. *Operator*—A person responsible for the TEM instrumental analysis of the sample.

17. *PCM*—Phase contrast microscopy.

18. *SAED*—Selected area electron diffraction.

19. *SEM*—Scanning electron microscope.

20. *STEM*—Scanning transmission electron microscope.

21. *Structure*—a microscopic bundle, cluster, fiber, or matrix which may contain asbestos.

22. *S/cm^3*—Structures per cubic centimeter.

23. *S/mm^2*—Structures per square millimeter.

24. *TEM*—Transmission electron microscope.

B. Sampling

1. The sampling agency must have written quality control procedures and documents which verify compliance.

2. Sampling operations must be performed by qualified individuals completely independent of the abatement contractor to avoid possible conflict of interest (References 1, 2, 3, and 5 of Unit II.J.).

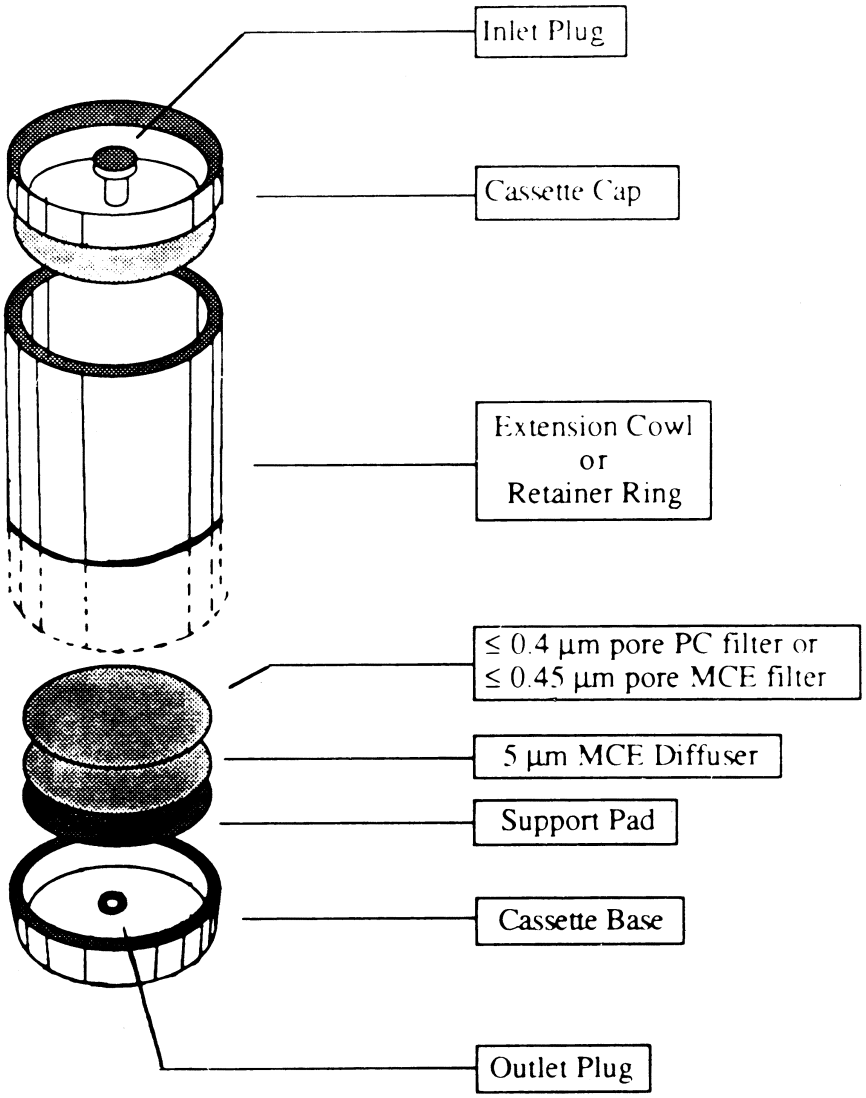
3. Sampling for airborne asbestos following an abatement action must use commercially available cassettes.

4. Prescreen the loaded cassette collection filters to assure that they do not contain concentrations of asbestos which may interfere with the analysis of the sample. A filter blank average of less than 18 s/mm^2 in an area of 0.057 mm^2 (nominally 10 200-mesh grid openings) and a single preparation with a maximum of 53 s/mm^2 for that same area is acceptable for this method.

5. Use sample collection filters which are either polycarbonate having a pore size less than or equal to 0.4 μm or mixed cellulose ester having a pore size less than or equal to 0.45 μm.

6. Place these filters in series with a 5.0 μm backup filter (to serve as a diffuser) and a support pad. See the following Figure 1:

FIGURE I--SAMPLING CASSETTE CONFIGURATION



7. Reloading of used cassettes is not permitted.

8. Orient the cassette downward at approximately 45 degrees from the horizontal.

9. Maintain a log of all pertinent sampling information.

10. Calibrate sampling pumps and their flow indicators over the range of their intended use with a recognized standard. Assemble the sampling system with a representative filter (not the filter which will be used in sampling) before and after the sampling operation.

11. Record all calibration information.

12. Ensure that the mechanical vibrations from the pump will be minimized to prevent transferral of vibration to the cassette.

13. Ensure that a continuous smooth flow of negative pressure is delivered by the pump by damping out any pump action fluctuations if necessary.

14. The final plastic barrier around the abatement area remains in place for the sampling period.

15. After the area has passed a thorough visual inspection, use aggressive sampling conditions to dislodge any remaining dust. (See suggested protocol in Unit III.B.7.d.)

16. Select an appropriate flow rate equal to or greater than 1 liter per minute (L/min) or less than 10 L/min for 25 mm cassettes. Larger filters may be operated at proportionally higher flow rates.

17. A minimum of 13 samples are to be collected for each testing site consisting of the following:

a. A minimum of five samples per abatement area.

b. A minimum of five samples per ambient area positioned at locations representative of the air entering the abatement site.

c. Two field blanks are to be taken by removing the cap for not more than 30 seconds and replacing it at the time of sampling before sampling is initiated at the following places:

i. Near the entrance to each abatement area.

ii. At one of the ambient sites. (DO NOT leave the field blanks open during the sampling period.)

d. A sealed blank is to be carried with each sample set. This representative cassette is not to be opened in the field.

18. Perform a leak check of the sampling system at each indoor and outdoor sampling site by activating the pump with the closed sampling cassette in line. Any flow indicates a leak which must be eliminated before initiating the sampling operation.

19. The following Table I specifies volume ranges to be used:

TABLE 1--NUMBER OF 200 MESH EM GRID OPENINGS ($0.0057\ MM^2$) THAT NEED TO BE ANALYZED TO MAINTAIN SENSITIVITY OF 0.005 STRUCTURES/CC BASED ON VOLUME AND EFFECTIVE FILTER AREA

	Effective Filter Area 385 sq mm		Effective Filter Area 855 sq mm	
	Volume (liters)	# of grid openings	Volume (liters)	# of grid openings
	560	*24*	*1,250*	*24*
	600	23	1,300	23
	700	19	1,400	21
	800	17	1,600	19
	900	15	1,800	17
	1,000	14	2,000	15
	1,100	12	2,200	14
	1,200	**11**	2,400	13
	1,300	**10**	2,600	12
Recommended Volume Range	**1,400**	**10**	**2,800**	**11**
	1,500	**9**	**3,000**	**10**
	1,600	**8**	**3,200**	**9**
	1,700	**8**	**3,400**	**9**
	1,800	**8**	**3,600**	**8**
	1,900	7	**3,800**	**8**
	2,000	7	**4,000**	**8**
	2,100	6	4,200	7
	2,200	6	4,400	7
	2,300	6	4,600	7
	2,400	6	4,800	6
	2,500	5	5,000	6
	2,600	5	5,200	6
	2,700	5	5,400	6
	2,800	5	5,600	5
	2,900	5	5,800	5
	3,000	5	6,000	5
	3,100	4	6,200	5
	3,200	4	6,400	5
	3,300	4	6,600	5
	3,400	4	6,800	4
	3,500	4	7,000	4
	3,600	4	7,200	4
	3,700	4	7,400	4
	3,800	4	7,600	4

Recommended Volume Range

Note minimum volumes required:
25 mm : 560 liters
37 mm : 1250 liters

Filter diameter of 25 mm = effective area of 385 sq mm
Filter diameter of 37 mm = effective area of 855 sq mm

20. Ensure that the sampler is turned upright before interrupting the pump flow.

21. Check that all samples are clearly labeled and that all pertinent information has been enclosed before transfer of the samples to the laboratory.

22. Ensure that the samples are stored in a secure and representative location.

23. Do not change containers if portions of these filters are taken for other purposes.

24. A summary of Sample Data Quality Objectives is shown in the following Table II:

TABLE II--SUMMARY OF SAMPLING AGENCY DATA QUALITY OBJECTIVES

This table summarizes the data quality objectives from the performance of this method in terms of precision, accuracy, completeness, representativeness, and comparability. These objectives are assured by the periodic control checks and reference checks listed here and described in the text of the method.

Unit Operation	QC Check	Frequency	Conformance Expectation
Sampling materials	Sealed blank	1 per I/O site	95%
Sample procedures	Field blanks	2 per I/O site	95%
	Pump calibration	Before and after each field series	90%
Sample custody	Review of chain-of-custody record	Each sample	95% complete
Sample shipment	Review of sending report	Each sample	95% complete

C. Sample Shipment

Ship bulk samples to the analytical laboratory in a separate container from air samples.

D. Sample Receiving

1. Designate one individual as sample coordinator at the laboratory. While that individual will normally be available to receive samples, the coordinator may train and supervise others in receiving procedures for those times when he/she is not available.

2. Bulk samples and air samples delivered to the analytical laboratory in the same container shall be rejected.

E. Sample Preparation

1. All sample preparation and analysis shall be performed by a laboratory independent of the abatement contractor.

2. Wet-wipe the exterior of the cassettes to minimize contamination possibilities before taking them into the clean room facility.

3. Perform sample preparation in a well-equipped clean facility.

NOTE: The clean area is required to have the following minimum characteristics. The area or hood must be capable of maintaining a positive pressure with make-up air being HEPA-filtered. The cumulative analytical blank concentration must average less than 18 s/mm^2 in an area of 0.057 mm^2 (nominally 10 200-mesh grid openings) and a single preparation with a maximum of 53 s/mm^2 for that same area.

4. Preparation areas for air samples must not only be separated from preparation areas for bulk samples, but they must be prepared in separate rooms.

5. Direct preparation techniques are required. The object is to produce an intact film containing the particulates of the filter surface which is sufficiently clear for TEM analysis.

a. TEM Grid Opening Area measurement must be done as follows:

i. The filter portion being used for sample preparation must have the surface collapsed using an acetone vapor technique.

ii. Measure 20 grid openings on each of 20 random 200-mesh copper grids by placing a grid on a glass and examining it under the PCM. Use a calibrated graticule to measure the average field diameters. From the data, calculate the field area for an average grid opening.

iii. Measurements can also be made on the TEM at a properly calibrated low magnification or on an optical microscope at a magnification of approximately 400X by using an eyepiece fitted with a scale that has been calibrated against a stage micrometer. Optical microscopy utilizing manual or automated procedures may be used providing instrument calibration can be verified.

b. TEM specimen preparation from polycarbonate (PC) filters. Procedures as described in Unit III.G. or other equivalent methods may be used.

c. TEM specimen preparation from mixed cellulose ester (MCE) filters.

i. Filter portion being used for sample preparation must have the surface collapsed using an acetone vapor technique or the Burdette procedure (Ref. 7 of Unit II.J.)

ii. Plasma etching of the collapsed filter is required. The microscope slide to which the collapsed filter pieces are attached is placed in a plasma asher. Because plasma ashers vary greatly in their performance, both from unit to unit and between different positions in the asher chamber, it is difficult to specify the conditions that should be used. Insufficient etching will result in a failure to expose embedded filters, and too much etching may result in loss of particulate from the surface. As an interim measure, it is recommended that the time for ashing of a

known weight of a collapsed filter be established and that the etching rate be calculated in terms of micrometers per second. The actual etching time used for the particulate asher and operating conditions will then be set such that a 1–2 μm (10 percent) layer of collapsed surface will be removed.

iii. Procedures as described in Unit III. or other equivalent methods may be used to prepare samples.

F. TEM Method

1. An 80–120 kV TEM capable of performing electron diffraction with a fluorescent screen inscribed with calibrated gradations is required. If the TEM is equipped with EDXA it must either have a STEM attachment or be capable of producing a spot less than 250 nm in diameter at crossover. The microscope shall be calibrated routinely for magnification and camera constant.

2. *Determination of Camera Constant and ED Pattern Analysis.* The camera length of the TEM in ED operating mode must be calibrated before ED patterns on unknown samples are observed. This can be achieved by using a carbon-coated grid on which a thin film of gold has been sputtered or evaporated. A thin film of gold is evaporated on the specimen TEM grid to obtain zone-axis ED patterns superimposed with a ring pattern from the polycrystalline gold film. In practice, it is desirable to optimize the thickness of the gold film so that only one or two sharp rings are obtained on the superimposed ED pattern. Thicker gold film would normally give multiple gold rings, but it will tend to mask weaker diffraction spots from the unknown fibrous particulate. Since the unknown d-spacings of most interest in asbestos analysis are those which lie closest to the transmitted beam, multiple gold rings are unnecessary on zone-axis ED patterns. An average camera constant using multiple gold rings can be determined. The camera constant is one-half the diameter of the rings times the interplanar spacing of the ring being measured.

3. *Magnification Calibration.* The magnification calibration must be done at the fluorescent screen. The TEM must be calibrated at the grid opening magnification (if used) and also at the magnification used for fiber counting. This is performed with a cross grating replica (e.g., one containing 2,160 lines/mm). Define a field of view on the fluorescent screen either by markings or physical boundaries. The field of view must be measurable or previously inscribed with a scale or concentric circles (all scales should be metric). A logbook must be maintained, and the dates of calibration and the values obtained must be recorded. The frequency of calibration depends on the past history of the particular microscope. After any maintenance of the microscope that involved adjustment of the power supplied to the lenses or the high-voltage system or the mechanical disassembly of the electron optical column apart from filament exchange, the magnification must be recalibrated. Before the TEM calibration is performed, the analyst must ensure that the cross grating replica is placed at the same distance from the objective lens as the specimens are. For instruments that incorporate a eucentric tilting specimen stage, all specimens and the cross grating replica must be placed at the eucentric position.

4. While not required on every microscope in the laboratory, the laboratory must have either one microscope equipped with energy dispersive X-ray analysis or access to an equivalent system on a TEM in another laboratory.

5. Microscope settings: 80–120 kV, grid assessment 250–1,000X, then 15,000–20,000X screen magnification for analysis.

6. Approximately one-half (0.5) of the predetermined sample area to be analyzed shall be performed on one sample grid preparation and the remaining half on a second sample grid preparation.

7. Individual grid openings with greater than 5 percent openings (holes) or covered with greater than 25 percent particulate matter or obviously having nonuniform loading must not be analyzed.

8. Reject the grid if:

a. Less than 50 percent of the grid openings covered by the replica are intact.

b. The replica is doubled or folded.

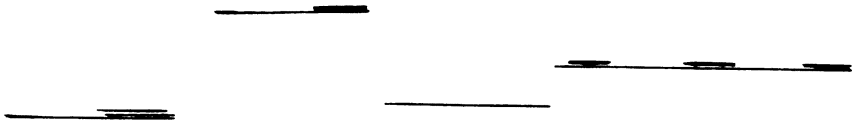
c. The replica is too dark because of incomplete dissolution of the filter.

9. *Recording Rules.*

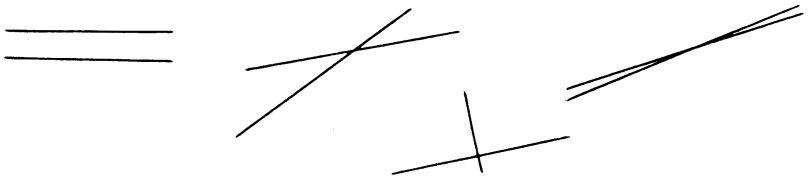
a. Any continuous grouping of particles in which an asbestos fiber with an aspect ratio greater than or equal to 5:1 and a length greater than or equal to 0.5 μm is detected shall be recorded on the count sheet. These will be designated asbestos structures and will be classified as fibers, bundles, clusters, or matrices. Record as individual fibers any contiguous grouping having 0, 1, or 2 definable intersections. Groupings having more than 2 intersections are to be described as cluster or matrix. An intersection is a nonparallel touching or crossing of fibers, with the projection having an aspect ratio of 5:1 or greater. See the following Figure 2:

FIGURE 2--COUNTING GUIDELINES USED IN DETERMINING ASBESTOS STRUCTURES

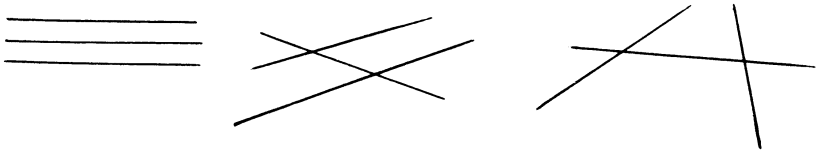
Count as 1 fiber; 1 Structure; no intersections.



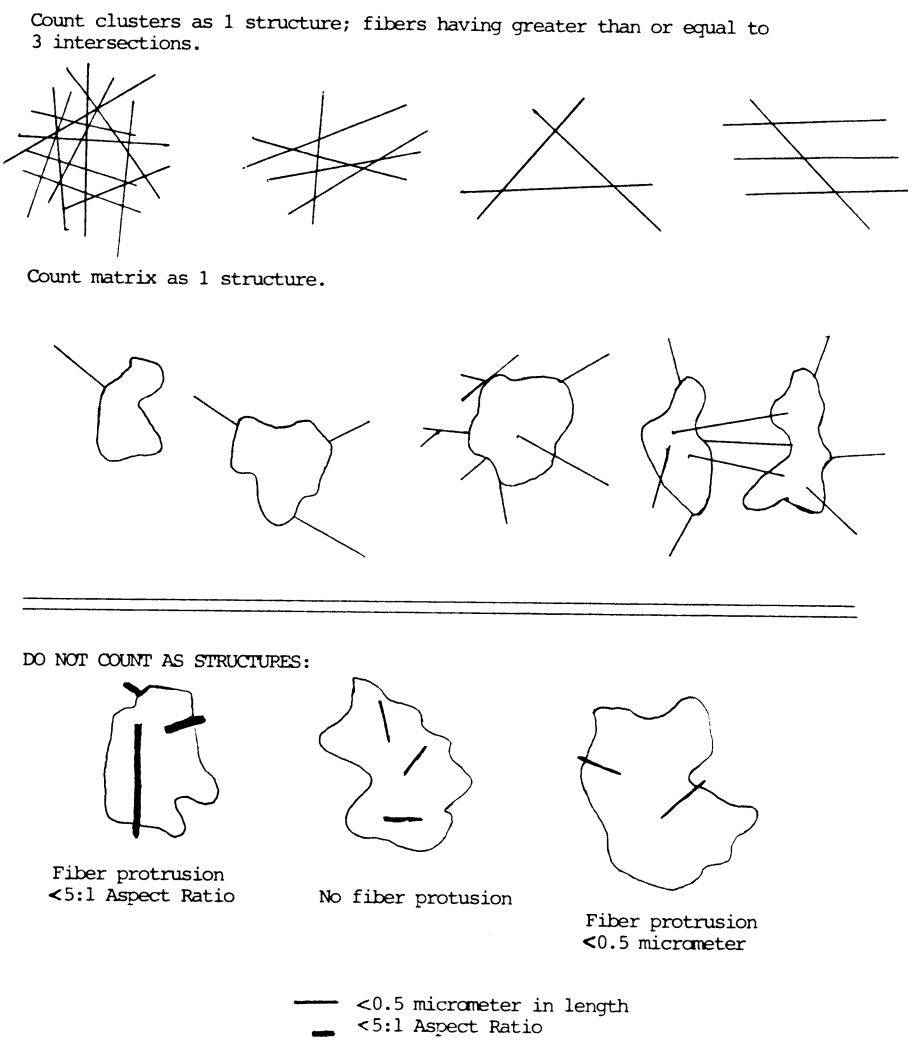
Count as 2 fibers if space between fibers is greater than width of 1 fiber diameter or number of intersections is equal to or less than 1.



Count as 3 structures if space between fibers is greater than width of 1 fiber diameter or if the number of intersections is equal to or less than 2.



Count bundles as 1 structure; 3 or more parallel fibrils less than 1 fiber diameter separation.



i. *Fiber.* A structure having a minimum length greater than or equal to 0.5 μm and an aspect ratio (length to width) of 5:1 or greater and substantially parallel sides. Note the appearance of the end of the fiber, i.e., whether it is flat, rounded or dovetailed.

ii. *Bundle.* A structure composed of three or more fibers in a parallel arrangement with each fiber closer than one fiber diameter.

iii. *Cluster.* A structure with fibers in a random arrangement such that all fibers are intermixed and no single fiber is isolated from the group. Groupings must have more than two intersections.

iv. *Matrix.* Fiber or fibers with one end free and the other end embedded in or hidden by a particulate. The exposed fiber must meet the fiber definition.

b. Separate categories will be maintained for fibers less than 5 μm and for fibers equal to or greater than 5 μm in length.

c. Record NSD when no structures are detected in the field.

d. Visual identification of electron diffraction (ED) patterns is required for each asbestos structure counted which would cause the

analysis to exceed the 70 s/mm^2 concentration. (Generally this means the first four fibers identified as asbestos must exhibit an identifiable diffraction pattern for chrysotile or amphibole.)

e. The micrograph number of the recorded diffraction patterns must be reported to the client and maintained in the laboratory's quality assurance records. In the event that examination of the pattern by a qualified individual indicates that the pattern has been misidentified visually, the client shall be contacted.

f. Energy Dispersive X-ray Analysis (EDXA) is required of all amphiboles which would cause the analysis results to exceed the 70 s/mm^2 concentration. (Generally speaking, the first 4 amphiboles would require EDXA.)

g. If the number of fibers in the non-asbestos class would cause the analysis to exceed the 70 s/mm^2 concentration, the fact that they are not asbestos must be confirmed by EDXA or measurement of a zone axis diffraction pattern.

h. Fibers classified as chrysotile must be identified by diffraction or X-ray analysis and recorded on a count sheet. X-ray analysis alone can be used only after 70 s/mm^2 have been exceeded for a particular sample.

i. Fibers classified as amphiboles must be identified by X-ray analysis and electron diffraction and recorded on the count sheet. (X-ray analysis alone can be used only after 70 s/mm^2 have been exceeded for a particular sample.)

j. If a diffraction pattern was recorded on film, record the micrograph number on the count sheet.

k. If an electron diffraction was attempted but no pattern was observed, record N on the count sheet.

l. If an EDXA spectrum was attempted but not observed, record N on the count sheet.

m. If an X-ray analysis spectrum is stored, record the file and disk number on the count sheet.

10. Classification Rules.

a. *Fiber*. A structure having a minimum length greater than or equal to 0.5 μm and an aspect ratio (length to width) of 5:1 or greater and substantially parallel sides. Note the appearance of the end of the fiber, i.e., whether it is flat, rounded or dovetailed.

b. *Bundle*. A structure composed of three or more fibers in a parallel arrangement with each fiber closer than one fiber diameter.

c. *Cluster*. A structure with fibers in a random arrangement such that all fibers are intermixed and no single fiber is isolated from the group. Groupings must have more than two intersections.

d. *Matrix*. Fiber or fibers with one end free and the other end embedded in or hidden by a particulate. The exposed fiber must meet the fiber definition.

11. After finishing with a grid, remove it from the microscope, and replace it in the appropriate grid holder. Sample grids must be stored for a minimum of 1 year from the date of the analysis; the sample cassette must be retained for a minimum of 30 days by the laboratory or returned at the client's request.

G. Sample Analytical Sequence

1. Under the present sampling requirements a minimum of 13 samples is to be collected for the clearance testing of an abatement site. These include five abatement area samples, five ambient samples, two field blanks, and one sealed blank.

2. Carry out visual inspection of work site prior to air monitoring.

3. Collect a minimum of 5 air samples inside the work site and 5 samples outside the work site. The indoor and outdoor samples shall be taken during the same time period.

4. Remaining steps in the analytical sequence are contained in Unit IV of this Appendix.

H. Reporting

1. The following information must be reported to the client for each sample analyzed:

a. Concentration in structures per square millimeter and structures per cubic centimeter.

b. Analytical sensitivity used for the analysis.

c. Number of asbestos structures.

d. Area analyzed.

e. Volume of air sampled (which must be initially supplied to lab by client).

f. Copy of the count sheet must be included with the report.

g. Signature of laboratory official to indicate that the laboratory met specifications of the method.

h. Report form must contain official laboratory identification (e.g., letterhead).

i. Type of asbestos.

I. Quality Control/Quality Assurance Procedures (Data Quality Indicators)

Monitoring the environment for airborne asbestos requires the use of sensitive sampling and analysis procedures. Because the test is sensitive, it may be influenced by a variety of factors. These include the supplies used in the sampling operation, the performance of the sampling, the preparation of the grid from the filter and the actual examination of this grid in the microscope. Each of these unit operations must produce a product of defined quality if the analytical result is to be a reliable and meaningful test result. Accordingly, a series of control checks and reference standards are to be performed along with the sample analysis as indicators that the materials used are adequate and the

operations are within acceptable limits. In this way, the quality of the data is defined and the results are of known value. These checks and tests also provide timely and specific warning of any problems which might develop within the sampling and analysis operations. A description of these quality control/quality assurance procedures is summarized in the following Table III:

TABLE III--SUMMARY OF LABORATORY DATA QUALITY OBJECTIVES

Unit Operation	QC Check	Frequency	Conformance Expectation
Sample receiving	Review of receiving report	Each sample	95% complete
Sample custody	Review of chain-of-custody record	Each sample	95% complete
Sample preparation	Supplies and reagents	On receipt	Meet specs. or reject
	Grid opening size	20 openings/20 grids/lot of 1000 or 1 opening/sample	100%
	Special clean area monitoring	After cleaning or service	Meet specs or reclean
	Laboratory blank	1 per prep series or 10%	Meet specs. or reanalyze series
	Plasma etch blank	1 per 20 samples	75%
	Multiple preps (3 per sample)	Each sample	One with cover of 15 complete grid sqs.
Sample analysis	System check	Each day	Each day
	Alignment check	Each day	Each day
	Magnification calibration with low and high standards	Each month or after service	95%
	ED calibration by gold standard	Weekly	95%
	EDS calibration by copper line	Daily	95%
Performance check	Laboratory blank (measure of cleanliness)	Prep 1 per series or 10% read 1 per 25 samples	Meet specs or reanalyze series
	Replicate counting (measure of precision)	1 per 100 samples	1.5 x Poisson Std. Dev.
	Duplicate analysis (measure of reproducibility)	1 per 100 samples	2 x Poisson Std. Dev.
	Known samples of typical materials (working standards)	Training and for comparison with unknowns	100%
	Analysis of NBS SRM 1876 and/or RM 8410 (measure of accuracy and comparability)	1 per analyst per year	1.5 x Poisson Std. Dev.
	Data entry review (data validation and measure of completeness)	Each sample	95%
	Record and verify ID electron diffraction pattern of structure	1 per 5 samples	80% accuracy
Calculations and data reduction	Hand calculation of automated data reduction procedure or independent recalculation of hand-calculated data	1 per 100 samples	85%

1. When the samples arrive at the laboratory, check the samples and documentation for completeness and requirements before initiating the analysis.

2. Check all laboratory reagents and supplies for acceptable asbestos background levels.

3. Conduct all sample preparation in a clean room environment monitored by laboratory blanks. Testing with blanks must also be done after cleaning or servicing the room.

4. Prepare multiple grids of each sample.

5. Provide laboratory blanks with each sample batch. Maintain a cumulative average of these results. If there are more than 53 fibers/mm^2 per 10 200-mesh grid openings, the system must be checked for possible sources of contamination.

6. Perform a system check on the transmission electron microscope daily.

7. Make periodic performance checks of magnification, electron diffraction and energy dispersive X-ray systems as set forth in Table III under Unit II.I.

8. Ensure qualified operator performance by evaluation of replicate analysis and standard sample comparisons as set forth in Table III under Unit II.I.

9. Validate all data entries.

10. Recalculate a percentage of all computations and automatic data reduction steps as specified in Table III under Unit II.I.

11. Record an electron diffraction pattern of one asbestos structure from every five samples that contain asbestos. Verify the identification of the pattern by measurement or comparison of the pattern with patterns collected from standards under the same conditions. The records must also demonstrate that the identification of the pattern has been verified by a qualified individual and that the operator who made the identification is maintaining at least an 80 percent correct visual identification based on his measured patterns.

12. Appropriate logs or records must be maintained by the analytical laboratory verifying that it is in compliance with the mandatory quality assurance procedures.

J. References

For additional background information on this method, the following references should be consulted.

1. ''Guidance for Controlling Asbestos-Containing Materials in Buildings,'' EPA 560/5–85–024, June 1985.

2. ''Measuring Airborne Asbestos Following an Abatement Action,'' USEPA, Office of Pollution Prevention and Toxics, EPA 600/4–85–049, 1985.

3. Small, John and E. Steel. Asbestos Standards: Materials and Analytical Methods. N.B.S. Special Publication 619, 1982.

4. Campbell, W.J., R.L. Blake, L.L. Brown, E.E. Cather, and J.J. Sjoberg. Selected Silicate Minerals and Their Asbestiform Varieties. Information Circular 8751, U.S. Bureau of Mines, 1977.

5. Quality Assurance Handbook for Air Pollution Measurement System. Ambient Air Methods, EPA 600/4–77–027a, USEPA, Office of Research and Development, 1977.

6. Method 2A: Direct Measurement of Gas Volume through Pipes and Small Ducts. 40 CFR Part 60 Appendix A.

7. Burdette, G.J., Health & Safety Exec. Research & Lab. Services Div., London, ''Proposed Analytical Method for Determination of Asbestos in Air.''

8. Chatfield, E.J., Chatfield Tech. Cons., Ltd., Clark, T., PEI Assoc., ''Standard Operating Procedure for Determination of Airborne Asbestos Fibers by Transmission Electron Microscopy Using Polycarbonate Membrane Filters,'' WERL SOP 87–1, March 5, 1987.

9. NIOSH Method 7402 for Asbestos Fibers, 12–11–86 Draft.

10. Yamate, G., Agarwall, S.C., Gibbons, R.D., IIT Research Institute, ''Methodology for the Measurement of Airborne Asbestos by Electron Microscopy,'' Draft report, USEPA Contract 68–02–3266, July 1984.

11. ''Guidance to the Preparation of Quality Assurance Project Plans,'' USEPA, Office of Pollution Prevention and Toxics, 1984.

III. Nonmandatory Transmission Electron Microscopy Method

A. Definitions of Terms

1. *Analytical sensitivity*—Airborne asbestos concentration represented by each fiber counted under the electron microscope. It is determined by the air volume collected and the proportion of the filter examined. This method requires that the analytical sensitivity be no greater than 0.005 s/cm^3.

2. *Asbestiform*—A specific type of mineral fibrosity in which the fibers and fibrils possess high tensile strength and flexibility.

3. *Aspect ratio*—A ratio of the length to the width of a particle. Minimum aspect ratio as defined by this method is equal to or greater than 5:1.

4. *Bundle*—A structure composed of three or more fibers in a parallel arrangement with each fiber closer than one fiber diameter.

5. *Clean area*—A controlled environment which is maintained and monitored to assure a low probability of asbestos contamination to materials in that space. Clean areas used in this method have HEPA filtered air under positive pressure and are capable of sustained operation with an open laboratory blank which on subsequent analysis has an average of less than 18 structures/mm^2 in an area of 0.057 mm^2 (nominally 10 200 mesh grid openings) and a maximum of 53 structures/mm^2 for no more than one single preparation for that same area.

6. *Cluster*—A structure with fibers in a random arrangement such that all fibers are intermixed and no single fiber is isolated from the group. Groupings must have more than two intersections.

7. *ED*—Electron diffraction.

8. *EDXA*—Energy dispersive X-ray analysis.

9. *Fiber*—A structure greater than or equal to 0.5 μm in length with an aspect ratio (length to width) of 5:1 or greater and having substantially parallel sides.

10. *Grid*—An open structure for mounting on the sample to aid in its examination in the TEM. The term is used here to denote a 200-mesh copper lattice approximately 3 mm in diameter.

11. *Intersection*—Nonparallel touching or crossing of fibers, with the projection having an aspect ratio of 5:1 or greater.

12. *Laboratory sample coordinator*—That person responsible for the conduct of sample handling and the certification of the testing procedures.

13. *Filter background level*—The concentration of structures per square millimeter of filter that is considered indistinguishable from the concentration measured on blanks (filters through which no air has been drawn). For this method the filter background level is defined as 70 structures/mm^2.

14. *Matrix*—Fiber or fibers with one end free and the other end embedded in or hidden by a particulate. The exposed fiber must meet the fiber definition.

15. *NSD*—No structure detected.

16. *Operator*—A person responsible for the TEM instrumental analysis of the sample.

17. *PCM*—Phase contrast microscopy.

18. *SAED*—Selected area electron diffraction.

19. *SEM*—Scanning electron microscope.

20. *STEM*—Scanning transmission electron microscope.

21. *Structure*—a microscopic bundle, cluster, fiber, or matrix which may contain asbestos.

22. *S/cm^3*—Structures per cubic centimeter.

23. *S/mm^2*—Structures per square millimeter.

24. *TEM*—Transmission electron microscope.

B. Sampling

1. Sampling operations must be performed by qualified individuals completely independent of the abatement contractor to avoid possible conflict of interest (See References 1, 2, and 5 of Unit III.L.) Special precautions should be taken to avoid contamination of the sample. For example, materials that have not been prescreened for their asbestos background content should not be used; also, sample handling procedures which do not take cross contamination possibilities into account should not be used.

2. Material and supply checks for asbestos contamination should be made on all critical supplies, reagents, and procedures before their use in a monitoring study.

3. Quality control and quality assurance steps are needed to identify problem areas and isolate the cause of the contamination (see Reference 5 of Unit III.L.). Control checks shall be permanently recorded to document the quality of the information produced. The sampling firm must have written quality control procedures and documents which verify compliance. Independent audits by a qualified consultant or firm should be performed once a year. All documentation of compliance should be retained indefinitely to provide a guarantee of quality. A summary of Sample Data Quality Objectives is shown in Table II of Unit II.B.

4. Sampling materials.

a. Sample for airborne asbestos following an abatement action using commercially available cassettes.

b. Use either a cowling or a filter-retaining middle piece. Conductive material may reduce the potential for particulates to adhere to the walls of the cowl.

c. Cassettes must be verified as ''clean'' prior to use in the field. If packaged filters are used for loading or preloaded cassettes are purchased from the manufacturer or a distributor, the manufacturer's name and lot number should be entered on all field data sheets provided to the laboratory, and are required to be listed on all reports from the laboratory.

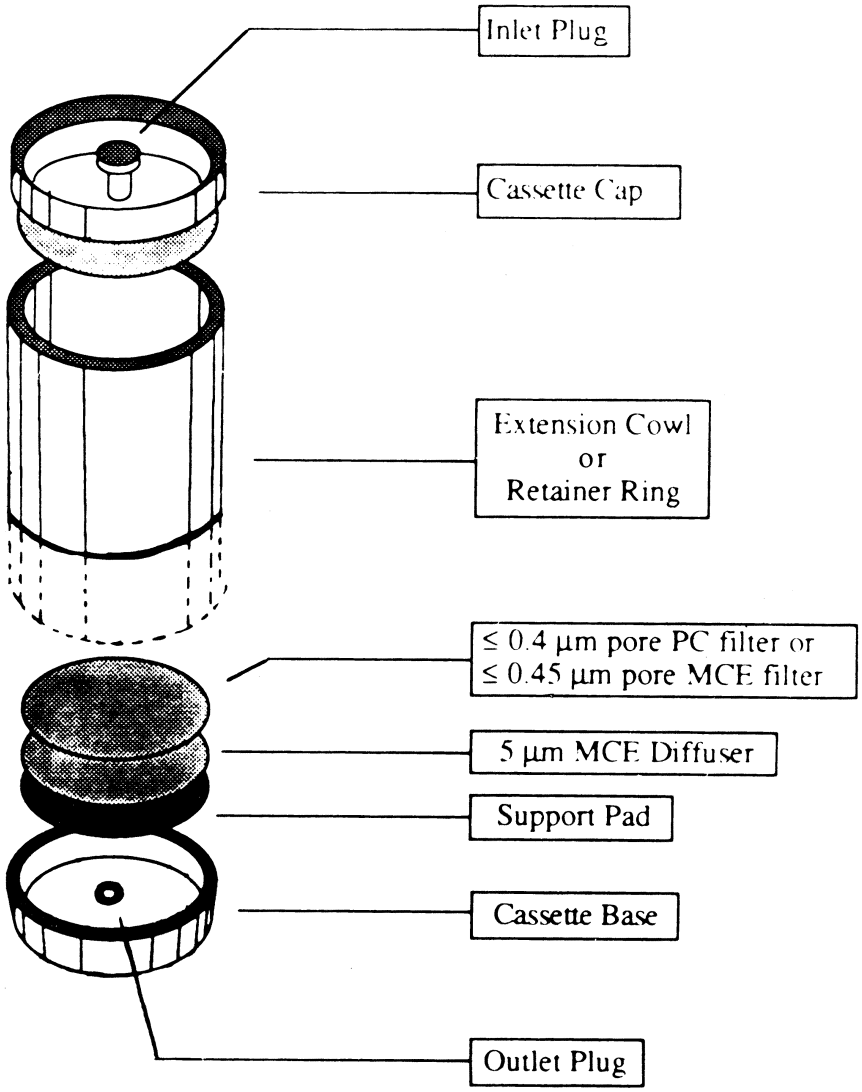
d. Assemble the cassettes in a clean facility (See definition of clean area under Unit III.A.).

e. Reloading of used cassettes is not permitted.

f. Use sample collection filters which are either polycarbonate having a pore size of less than or equal to 0.4 μm or mixed cellulose ester having a pore size of less than or equal to 0.45 μm.

g. Place these filters in series with a backup filter with a pore size of 5.0 μm (to serve as a diffuser) and a support pad. See the following Figure 1:

FIGURE I--SAMPLING CASSETTE CONFIGURATION



h. When polycarbonate filters are used, position the highly reflective face such that the incoming particulate is received on this surface.

i. Seal the cassettes to prevent leakage around the filter edges or between cassette part joints. A mechanical press may be useful to achieve a reproducible leak-free seal.

Shrink fit gel-bands may be used for this purpose and are available from filter manufacturers and their authorized distributors.

j. Use wrinkle-free loaded cassettes in the sampling operation.

5. Pump setup.

a. Calibrate the sampling pump over the range of flow rates and loads anticipated for the monitoring period with this flow measuring device in series. Perform this calibration using guidance from EPA Method 2A each time the unit is sent to the field (See Reference 6 of Unit III.L.).

b. Configure the sampling system to preclude pump vibrations from being transmitted to the cassette by using a sampling stand separate from the pump station and making connections with flexible tubing.

c. Maintain continuous smooth flow conditions by damping out any pump action fluctuations if necessary.

d. Check the sampling system for leaks with the end cap still in place and the pump operating before initiating sample collection. Trace and stop the source of any flow indicated by the flowmeter under these conditions.

e. Select an appropriate flow rate equal to or greater than 1 L/min or less than 10 L/min for 25 mm cassettes. Larger filters may be operated at proportionally higher flow rates.

f. Orient the cassette downward at approximately 45 degrees from the horizontal.

g. Maintain a log of all pertinent sampling information, such as pump identification number, calibration data, sample location, date, sample identification number, flow rates at the beginning, middle, and end, start and stop times, and other useful information or comments. Use of a sampling log form is recommended. See the following Figure 2:

FIGURE 2--SAMPLING LOG FORM

Sample Number	Location of Sample	Pump I.D.	Start Time	Middle Time	End Time	Flow Rate

Inspector: _____ Date: _____

h. Initiate a chain of custody procedure at the start of each sampling, if this is requested by the client.

i. Maintain a close check of all aspects of the sampling operation on a regular basis.

j. Continue sampling until at least the minimum volume is collected, as specified in the following Table I:

TABLE 1--NUMBER OF 200 MESH EM GRID OPENINGS ($0.0057\ MM^2$) THAT NEED TO BE ANALYZED TO MAINTAIN SENSITIVITY OF 0.005 STRUCTURES/CC BASED ON VOLUME AND EFFECTIVE FILTER AREA

	Effective Filter Area 385 sq mm		Effective Filter Area 855 sq mm	
	Volume (liters)	# of grid openings	Volume (liters)	# of grid openings
	560	*24*	*1,250*	*24*
	600	23	1,300	23
	700	19	1,400	21
	800	17	1,600	19
	900	15	1,800	17
	1,000	14	2,000	15
	1,100	12	2,200	14
Recommended Volume Range	**1,200**	**11**	2,400	13
	1,300	**10**	2,600	12
	1,400	**10**	**2,800**	**11**
	1,500	**9**	**3,000**	**10**
	1,600	**8**	**3,200**	**9**
	1,700	**8**	**3,400**	**9**
	1,800	**8**	**3,600**	**8**
	1,900	7	**3,800**	**8**
	2,000	7	**4,000**	**8**
	2,100	6	4,200	7
	2,200	6	4,400	7
	2,300	6	4,600	7
	2,400	6	4,800	6
	2,500	5	5,000	6
	2,600	5	5,200	6
	2,700	5	5,400	6
	2,800	5	5,600	5
	2,900	5	5,800	5
	3,000	5	6,000	5
	3,100	4	6,200	5
	3,200	4	6,400	5
	3,300	4	6,600	5
	3,400	4	6,800	4
	3,500	4	7,000	4
	3,600	4	7,200	4
	3,700	4	7,400	4
	3,800	4	7,600	4

Recommended Volume Range

Note minimum volumes required:
25 mm : 560 liters
37 mm : 1250 liters

Filter diameter of 25 mm = effective area of 385 sq mm
Filter diameter of 37 mm = effective area of 855 sq mm

k. At the conclusion of sampling, turn the cassette upward before stopping the flow to minimize possible particle loss. If the sampling is resumed, restart the flow before reorienting the cassette downward. Note the condition of the filter at the conclusion of sampling.

l. Double check to see that all information has been recorded on the data collection forms and that the cassette is securely closed and appropriately identified using a waterproof label. Protect cassettes in individual clean resealed polyethylene bags. Bags are to be used for storing cassette caps when they are removed for sampling purposes. Caps and plugs should only be removed or replaced using clean hands or clean disposable plastic gloves.

m. Do not change containers if portions of these filters are taken for other purposes.

6. Minimum sample number per site. A minimum of 13 samples are to be collected for each testing consisting of the following:

a. A minimum of five samples per abatement area.

b. A minimum of five samples per ambient area positioned at locations representative of the air entering the abatement site.

c. Two field blanks are to be taken by removing the cap for not more than 30 sec and replacing it at the time of sampling before sampling is initiated at the following places:

i. Near the entrance to each ambient area.

ii. At one of the ambient sites.

(NOTE: Do not leave the blank open during the sampling period.)

d. A sealed blank is to be carried with each sample set. This representative cassette is not to be opened in the field.

7. Abatement area sampling.

a. Conduct final clearance sampling only after the primary containment barriers have been removed; the abatement area has been thoroughly dried; and, it has passed visual inspection tests by qualified personnel. (See Reference 1 of Unit III.L.)

b. Containment barriers over windows, doors, and air passageways must remain in place until the TEM clearance sampling and analysis is completed and results meet clearance test criteria. The final plastic barrier remains in place for the sampling period.

c. Select sampling sites in the abatement area on a random basis to provide unbiased and representative samples.

d. After the area has passed a thorough visual inspection, use aggressive sampling conditions to dislodge any remaining dust.

i. Equipment used in aggressive sampling such as a leaf blower and/or fan should be properly cleaned and decontaminated before use.

ii. Air filtration units shall remain on during the air monitoring period.

iii. Prior to air monitoring, floors, ceiling and walls shall be swept with the exhaust of a minimum one (1) horsepower leaf blower.

iv. Stationary fans are placed in locations which will not interfere with air monitoring equipment. Fan air is directed toward the ceiling. One fan shall be used for each 10,000 ft^3 of worksite.

v. Monitoring of an abatement work area with high-volume pumps and the use of circulating fans will require electrical power. Electrical outlets in the abatement area may be used if available. If no such outlets are available, the equipment must be supplied with electricity by the use of extension cords and strip plug units. All electrical power supply equipment of this type must be approved Underwriter Laboratory equipment that has not been modified. All wiring must be grounded. Ground fault interrupters should be used. Extreme care must be taken to clean up any residual water and ensure that electrical equipment does not become wet while operational.

vi. Low volume pumps may be carefully wrapped in 6-mil polyethylene to insulate the pump from the air. High volume pumps cannot be sealed in this manner since the heat of the motor may melt the plastic. The pump exhausts should be kept free.

vii. If recleaning is necessary, removal of this equipment from the work area must be handled with care. It is not possible to completely decontaminate the pump motor and parts since these areas cannot be wetted. To minimize any problems in this area, all equipment such as fans and pumps should be carefully wet wiped prior to removal from the abatement area. Wrapping and sealing low volume pumps in 6-mil polyethylene will provide easier decontamination of this equipment. Use of clean water and disposable wipes should be available for this purpose.

e. Pump flow rate equal to or greater than 1 L/min or less than 10 L/min may be used for 25 mm cassettes. The larger cassette diameters may have comparably increased flow.

f. Sample a volume of air sufficient to ensure the minimum quantitation limits. (See Table I of Unit III.B.5.j.)

8. Ambient sampling.

a. Position ambient samplers at locations representative of the air entering the abatement site. If makeup air entering the abatement site is drawn from another area of the building which is outside of the abatement area, place the pumps in the building, pumps should be placed out of doors located near the building and away from any obstructions that may influence wind patterns. If construction is in progress immediately outside the enclosure, it may be necessary to select another ambient site. Samples should be representative of any air entering the work site.

b. Locate the ambient samplers at least 3 ft apart and protect them from adverse weather conditions.

c. Sample same volume of air as samples taken inside the abatement site.

C. Sample Shipment

1. Ship bulk samples in a separate container from air samples. Bulk samples and air samples delivered to the analytical laboratory in the same container shall be rejected.

2. Select a rigid shipping container and pack the cassettes upright in a noncontaminating nonfibrous medium such as a bubble pack. The use of resealable polyethylene bags may help to prevent jostling of individual cassettes.

3. Avoid using expanded polystyrene because of its static charge potential. Also avoid using particle-based packaging materials because of possible contamination.

4. Include a shipping bill and a detailed listing of samples shipped, their descriptions

and all identifying numbers or marks, sampling data, shipper's name, and contact information. For each sample set, designate which are the ambient samples, which are the abatement area samples, which are the field blanks, and which is the sealed blank if sequential analysis is to be performed.

5. Hand-carry samples to the laboratory in an upright position if possible; otherwise choose that mode of transportation least likely to jar the samples in transit.

6. Address the package to the laboratory sample coordinator by name when known and alert him or her of the package description, shipment mode, and anticipated arrival as part of the chain of custody and sample tracking procedures. This will also help the laboratory schedule timely analysis for the samples when they are received.

D. Quality Control/Quality Assurance Procedures (Data Quality Indicators)

Monitoring the environment for airborne asbestos requires the use of sensitive sampling and analysis procedures. Because the test is sensitive, it may be influenced by a variety of factors. These include the supplies used in the sampling operation, the performance of the sampling, the preparation of the grid from the filter and the actual examination of this grid in the microscope. Each of these unit operations must produce a product of defined quality if the analytical result is to be a reliable and meaningful test result. Accordingly, a series of control checks and reference standards is performed along with the sample analysis as indicators that the materials used are adequate and the operations are within acceptable limits. In this way, the quality of the data is defined, and the results are of known value. These checks and tests also provide timely and specific warning of any problems which might develop within the sampling and analysis operations. A description of these quality control/quality assurance procedures is summarized in the text below.

1. Prescreen the loaded cassette collection filters to assure that they do not contain concentrations of asbestos which may interfere with the analysis of the sample. A filter blank average of less than 18 s/mm^2 in an area of 0.057 mm^2 (nominally 10 200-mesh grid openings) and a maximum of 53 s/mm^2 for that same area for any single preparation is acceptable for this method.

2. Calibrate sampling pumps and their flow indicators over the range of their intended use with a recognized standard. Assemble the sampling system with a representative filter—not the filter which will be used in sampling—before and after the sampling operation.

3. Record all calibration information with the data to be used on a standard sampling form.

4. Ensure that the samples are stored in a secure and representative location.

5. Ensure that mechanical calibrations from the pump will be minimized to prevent transferral of vibration to the cassette.

6. Ensure that a continuous smooth flow of negative pressure is delivered by the pump by installing a damping chamber if necessary.

7. Open a loaded cassette momentarily at one of the indoor sampling sites when sampling is initiated. This sample will serve as an indoor field blank.

8. Open a loaded cassette momentarily at one of the outdoor sampling sites when sampling is initiated. This sample will serve as an outdoor field blank.

9. Carry a sealed blank into the field with each sample series. Do not open this cassette in the field.

10. Perform a leak check of the sampling system at each indoor and outdoor sampling site by activating the pump with the closed sampling cassette in line. Any flow indicates a leak which must be eliminated before initiating the sampling operation.

11. Ensure that the sampler is turned upright before interrupting the pump flow.

12. Check that all samples are clearly labeled and that all pertinent information has been enclosed before transfer of the samples to the laboratory.

E. Sample Receiving

1. Designate one individual as sample coordinator at the laboratory. While that individual will normally be available to receive samples, the coordinator may train and supervise others in receiving procedures for those times when he/she is not available.

2. Adhere to the following procedures to ensure both the continued chain-of-custody and the accountability of all samples passing through the laboratory:

a. Note the condition of the shipping package and data written on it upon receipt.

b. Retain all bills of lading or shipping slips to document the shipper and delivery time.

c. Examine the chain-of-custody seal, if any, and the package for its integrity.

d. If there has been a break in the seal or substantive damage to the package, the sample coordinator shall immediately notify the shipper and a responsible laboratory manager before any action is taken to unpack the shipment.

e. Packages with significant damage shall be accepted only by the responsible laboratory manager after discussions with the client.

3. Unwrap the shipment in a clean, uncluttered facility. The sample coordinator or his or her designee will record the contents, including a description of each item and all identifying numbers or marks. A

Sample Receiving Form to document this information is attached for use when necessary. (See the following Figure 3.)

FIGURE 3--SAMPLE RECEIVING FORM

Date of package delivery _____ Package shipped from _____

Carrier _____ Shipping bill retained _____

*Condition of package on receipt_____

*Condition of custody seal _____

Number of samples received _____ Shipping manifest attached _____

Purchase Order No. _____ Project I.D. _____

Comments _____

No.	Description	Sampling Medium PC	Sampling Medium MCE	Sampled Volume Liters	Receiving ID #	Assigned #
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						

(Use as many additional sheets as needed.)

Comments _____

Date of acceptance into sample bank _____

Signature of chain-of-custody recipient _____

Disposition of samples_____

*Note: If the package has sustained substantial damage or the custody seal is broken, stop and contact the project manager and the shipper.

NOTE: The person breaking the chain-of-custody seal and itemizing the contents assumes responsibility for the shipment and signs documents accordingly.

4. Assign a laboratory number and schedule an analysis sequence.

5. Manage all chain-of-custody samples within the laboratory such that their integrity can be ensured and documented.

F. Sample Preparation

1. Personnel not affiliated with the Abatement Contractor shall be used to prepare samples and conduct TEM analysis. Wetwipe the exterior of the cassettes to minimize contamination possibilities before taking them to the clean sample preparation facility.

2. Perform sample preparation in a well-equipped clean facility.

NOTE: The clean area is required to have the following minimum characteristics. The area or hood must be capable of maintaining a positive pressure with make-up air being HEPA filtered. The cumulative analytical blank concentration must average less than 18 s/mm^2 in an area of 0.057 s/mm^2 (nominally 10 200-mesh grid openings) with no more than one single preparation to exceed 53 s/mm^2 for that same area.

3. Preparation areas for air samples must be separated from preparation areas for bulk samples. Personnel must not prepare air samples if they have previously been preparing bulk samples without performing appropriate personal hygiene procedures, i.e., clothing change, showering, etc.

4. *Preparation.* Direct preparation techniques are required. The objective is to produce an intact carbon film containing the particulates from the filter surface which is sufficiently clear for TEM analysis. Currently recommended direct preparation procedures for polycarbonate (PC) and mixed cellulose ester (MCE) filters are described in Unit III.F.7. and 8. Sample preparation is a subject requiring additional research. Variation on those steps which do not substantively change the procedure, which improve filter clearing or which reduce contamination problems in a laboratory are permitted.

a. Use only TEM grids that have had grid opening areas measured according to directions in Unit III.J.

b. Remove the inlet and outlet plugs prior to opening the cassette to minimize any pressure differential that may be present.

c. Examples of techniques used to prepare polycarbonate filters are described in Unit III.F.7.

d. Examples of techniques used to prepare mixed cellulose ester filters are described in Unit III.F.8.

e. Prepare multiple grids for each sample.

f. Store the three grids to be measured in appropriately labeled grid holders or polyethylene capsules.

5. Equipment.

a. Clean area.

b. Tweezers. Fine-point tweezers for handling of filters and TEM grids.

c. Scalpel Holder and Curved No. 10 Surgical Blades.

d. Microscope slides.

e. Double-coated adhesive tape.

f. Gummed page reinforcements.

g. Micro-pipet with disposal tips 10 to 100 µL variable volume.

h. Vacuum coating unit with facilities for evaporation of carbon. Use of a liquid nitrogen cold trap above the diffusion pump will minimize the possibility of contamination of the filter surface by oil from the pumping system. The vacuum-coating unit can also be used for deposition of a thin film of gold.

i. *Carbon rod electrodes.* Spectrochemically pure carbon rods are required for use in the vacuum evaporator for carbon coating of filters.

j. *Carbon rod sharpener.* This is used to sharpen carbon rods to a neck. The use of necked carbon rods (or equivalent) allows the carbon to be applied to the filters with a minimum of heating.

k. *Low-temperature plasma asher.* This is used to etch the surface of collapsed mixed cellulose ester (MCE) filters. The asher should be supplied with oxygen, and should be modified as necessary to provide a throttle or bleed valve to control the speed of the vacuum to minimize disturbance of the filter. Some early models of ashers admit air too rapidly, which may disturb particulates on the surface of the filter during the etching step.

l. *Glass petri dishes, 10 cm in diameter, 1 cm high.* For prevention of excessive evaporation of solvent when these are in use, a good seal must be provided between the base and the lid. The seal can be improved by grinding the base and lid together with an abrasive grinding material.

m. Stainless steel mesh.

n. Lens tissue.

o. Copper 200-mesh TEM grids, 3 mm in diameter, or equivalent.

p. Gold 200-mesh TEM grids, 3 mm in diameter, or equivalent.

q. Condensation washer.

r. Carbon-coated, 200-mesh TEM grids, or equivalent.

s. Analytical balance, 0.1 mg sensitivity.

t. Filter paper, 9 cm in diameter.

u. Oven or slide warmer. Must be capable of maintaining a temperature of 65–70 °C.

v. Polyurethane foam, 6 mm thickness.

w. Gold wire for evaporation.

6. Reagents.

a. *General.* A supply of ultra-clean, fiber-free water must be available for washing of all components used in the analysis. Water

that has been distilled in glass or filtered or deionized water is satisfactory for this purpose. Reagents must be fiber-free.

b. Polycarbonate preparation method—chloroform.

c. Mixed Cellulose Ester (MCE) preparation method—acetone or the Burdette procedure (Ref. 7 of Unit III.L.).

7. TEM specimen preparation from polycarbonate filters.

a. *Specimen preparation laboratory*. It is most important to ensure that contamination of TEM specimens by extraneous asbestos fibers is minimized during preparation.

b. Cleaning of sample cassettes. Upon receipt at the analytical laboratory and before they are taken into the clean facility or laminar flow hood, the sample cassettes must be cleaned of any contamination adhering to the outside surfaces.

c. Preparation of the carbon evaporator. If the polycarbonate filter has already been carbon-coated prior to receipt, the carbon coating step will be omitted, unless the analyst believes the carbon film is too thin. If there is a need to apply more carbon, the filter will be treated in the same way as an uncoated filter. Carbon coating must be performed with a high-vacuum coating unit. Units that are based on evaporation of carbon filaments in a vacuum generated only by an oil rotary pump have not been evaluated for this application, and must not be used. The carbon rods should be sharpened by a carbon rod sharpener to necks of about 4 mm long and 1 mm in diameter. The rods are installed in the evaporator in such a manner that the points are approximately 10 to 12 cm from the surface of a microscope slide held in the rotating and tilting device.

d. Selection of filter area for carbon coating. Before preparation of the filters, a 75 mm × 50 mm microscope slide is washed and dried. This slide is used to support strips of filter during the carbon evaporation. Two parallel strips of double-sided adhesive tape are applied along the length of the slide. Polycarbonate filters are easily stretched during handling, and cutting of areas for further preparation must be performed with great care. The filter and the MCE backing filter are removed together from the cassette and placed on a cleaned glass microscope slide. The filter can be cut with a curved scalpel blade by rocking the blade from the point placed in contact with the filter. The process can be repeated to cut a strip approximately 3 mm wide across the diameter of the filter. The strip of polycarbonate filter is separated from the corresponding strip of backing filter and carefully placed so that it bridges the gap between the adhesive tape strips on the microscope slide. The filter strip can be held with fine-point tweezers and supported underneath by the scalpel blade during placement on the microscope slide. The analyst can place several such strips on the same microscope slide, taking care to rinse and wet-wipe the scalpel blade and tweezers before handling a new sample. The filter strips should be identified by etching the glass slide or marking the slide using a marker insoluble in water and solvents. After the filter strip has been cut from each filter, the residual parts of the filter must be returned to the cassette and held in position by reassembly of the cassette. The cassette will then be archived for a period of 30 days or returned to the client upon request.

e. Carbon coating of filter strips. The glass slide holding the filter strips is placed on the rotation-tilting device, and the evaporator chamber is evacuated. The evaporation must be performed in very short bursts, separated by some seconds to allow the electrodes to cool. If evaporation is too rapid, the strips of polycarbonate filter will begin to curl, which will lead to cross-linking of the surface material and make it relatively insoluble in chloroform. An experienced analyst can judge the thickness of carbon film to be applied, and some test should be made first on unused filters. If the film is too thin, large particles will be lost from the TEM specimen, and there will be few complete and undamaged grid openings on the specimen. If the coating is too thick, the filter will tend to curl when exposed to chloroform vapor and the carbon film may not adhere to the support mesh. Too thick a carbon film will also lead to a TEM image that is lacking in contrast, and the ability to obtain ED patterns will be compromised. The carbon film should be as thin as possible and remain intact on most of the grid openings of the TEM specimen intact.

f. Preparation of the Jaffe washer. The precise design of the Jaffe washer is not considered important, so any one of the published designs may be used. A washer consisting of a simple stainless steel bridge is recommended. Several pieces of lens tissue approximately 1.0 cm × 0.5 cm are placed on the stainless steel bridge, and the washer is filled with chloroform to a level where the meniscus contacts the underside of the mesh, which results in saturation of the lens tissue. See References 8 and 10 of Unit III.L.

g. Placing of specimens into the Jaffe washer. The TEM grids are first placed on a piece of lens tissue so that individual grids can be picked up with tweezers. Using a curved scalpel blade, the analyst excises three 3 mm square pieces of the carbon-coated polycarbonate filter from the filter strip. The three squares are selected from the center of the strip and from two points between the outer periphery of the active surface and the center. The piece of filter is placed on a TEM specimen grid with the shiny side of the TEM grid facing upwards, and the whole assembly is placed boldly onto the saturated lens tissue in the Jaffe washer. If carbon-coated grids are used, the filter should be

placed carbon-coated side down. The three excised squares of filters are placed on the same piece of lens tissue. Any number of separate pieces of lens tissue may be placed in the same Jaffe washer. The lid is then placed on the Jaffe washer, and the system is allowed to stand for several hours, preferably overnight.

h. *Condensation washing.* It has been found that many polycarbonate filters will not dissolve completely in the Jaffe washer, even after being exposed to chloroform for as long as 3 days. This problem becomes more serious if the surface of the filter was overheated during the carbon evaporation. The presence of undissolved filter medium on the TEM preparation leads to partial or complete obscuration of areas of the sample, and fibers that may be present in these areas of the specimen will be overlooked; this will lead to a low result. Undissolved filter medium also compromises the ability to obtain ED patterns. Before they are counted, TEM grids must be examined critically to determine whether they are adequately cleared of residual filter medium. It has been found that condensation washing of the grids after the initial Jaffe washer treatment, with chloroform as the solvent, clears all residual filter medium in a period of approximately 1 hour. In practice, the piece of lens tissue supporting the specimen grids is transferred to the cold finger of the condensation washer, and the washer is operated for about 1 hour. If the specimens are cleared satisfactorily by the Jaffe washer alone, the condensation washer step may be unnecessary.

8. TEM specimen preparation from MCE filters.

a. This method of preparing TEM specimens from MCE filters is similar to that specified in NIOSH Method 7402. See References 7, 8, and 9 of Unit III.L.

b. Upon receipt at the analytical laboratory, the sample cassettes must be cleaned of any contamination adhering to the outside surfaces before entering the clean sample preparation area.

c. Remove a section from any quadrant of the sample and blank filters.

d. Place the section on a clean microscope slide. Affix the filter section to the slide with a gummed paged reinforcement or other suitable means. Label the slide with a water and solvent-proof marking pen.

e. Place the slide in a petri dish which contains several paper filters soaked with 2 to 3 mL acetone. Cover the dish. Wait 2 to 4 minutes for the sample filter to fuse and clear.

f. Plasma etching of the collapsed filter is required.

i. The microscope slide to which the collapsed filter pieces are attached is placed in a plasma asher. Because plasma ashers vary greatly in their performance, both from unit to unit and between different positions in the asher chamber, it is difficult to specify the conditions that should be used. This is one area of the method that requires further evaluation. Insufficient etching will result in a failure to expose embedded filters, and too much etching may result in loss of particulate from the surface. As an interim measure, it is recommended that the time for ashing of a known weight of a collapsed filter be established and that the etching rate be calculated in terms of micrometers per second. The actual etching time used for a particular asher and operating conditions will then be set such that a 1–2 μm (10 percent) layer of collapsed surface will be removed.

ii. Place the slide containing the collapsed filters into a low-temperature plasma asher, and etch the filter.

g. Transfer the slide to a rotating stage inside the bell jar of a vacuum evaporator. Evaporate a 1 mm × 5 mm section of graphite rod onto the cleared filter. Remove the slide to a clean, dry, covered petri dish.

h. Prepare a second petri dish as a Jaffe washer with the wicking substrate prepared from filter or lens paper placed on top of a 6 mm thick disk of clean spongy polyurethane foam. Cut a V-notch on the edge of the foam and filter paper. Use the V-notch as a reservoir for adding solvent. The wicking substrate should be thin enough to fit into the petri dish without touching the lid.

i. Place carbon-coated TEM grids face up on the filter or lens paper. Label the grids by marking with a pencil on the filter paper or by putting registration marks on the petri dish lid and marking with a waterproof marker on the dish lid. In a fume hood, fill the dish with acetone until the wicking substrate is saturated. The level of acetone should be just high enough to saturate the filter paper without creating puddles.

j. Remove about a quarter section of the carbon-coated filter samples from the glass slides using a surgical knife and tweezers. Carefully place the section of the filter, carbon side down, on the appropriately labeled grid in the acetone-saturated petri dish. When all filter sections have been transferred, slowly add more solvent to the wedge-shaped trough to bring the acetone level up to the highest possible level without disturbing the sample preparations. Cover the petri dish. Elevate one side of the petri dish by placing a slide under it. This allows drops of condensed solvent vapors to form near the edge rather than in the center where they would drip onto the grid preparation.

G. TEM Method

1. *Instrumentation.*

a. Use an 80–120 kV TEM capable of performing electron diffraction with a fluorescent screen inscribed with calibrated gradations. If the TEM is equipped with EDXA it must either have a STEM attachment or be capable of producing a spot less than 250 nm

in diameter at crossover. The microscope shall be calibrated routinely (see Unit III.J.) for magnification and camera constant.

b. While not required on every microscope in the laboratory, the laboratory must have either one microscope equipped with energy dispersive X-ray analysis or access to an equivalent system on a TEM in another laboratory. This must be an Energy Dispersive X-ray Detector mounted on TEM column and associated hardware/software to collect, save, and read out spectral information. Calibration of Multi-Channel Analyzer shall be checked regularly for A1 at 1.48 KeV and Cu at 8.04 KeV, as well as the manufacturer's procedures.

i. Standard replica grating may be used to determine magnification (e.g., 2160 lines/mm).

ii. Gold standard may be used to determine camera constant.

c. Use a specimen holder with single tilt and/or double tilt capabilities.

2. Procedure.

a. Start a new Count Sheet for each sample to be analyzed. Record on count sheet: analyst's initials and date; lab sample number; client sample number microscope identification; magnification for analysis; number of predetermined grid openings to be analyzed; and grid identification. See the following Figure 4:

FIGURE 4--COUNT SHEET

Lab Sample No. _____ Filter Type _____ Operator _____
Client Sample No. _____ Filter Area _____ Date _____
Instrument I.D. _____ Grid I.D. _____ Comments _____
Magnification _____ Grid Opening (GO) Area _____ _____
Acc. Voltage _____ No. GO to be Analyzed _____ _____

GO	Structure No.	Structure Type*	Length		ED Observation				EDAX
			< 5μm	≥ 5 μm	Chrys.	Amph.	Nonasb.	Neg. ID	

GO	Structure No.	Structure Type*	Length		ED Observation				EDAX
			< 5μm	≥ 5 μm	Chrys.	Amph.	Nonasb.	Neg. ID	

*B = Bundle
C = Cluster
F = Fiber
M = Matrix

NFD = No fibers detected
N = No diffraction obtained

b. Check that the microscope is properly aligned and calibrated according to the manufacturer's specifications and instructions.

c. Microscope settings: 80–120 kV, grid assessment 250–1000X, then 15,000–20,000X screen magnification for analysis.

d. Approximately one-half (0.5) of the predetermined sample area to be analyzed shall be performed on one sample grid preparation and the remaining half on a second sample grid preparation.

e. Determine the suitability of the grid.

i. Individual grid openings with greater than 5 percent openings (holes) or covered with greater than 25 percent particulate matter or obviously having nonuniform loading shall not be analyzed.

ii. Examine the grid at low magnification (<1000X) to determine its suitability for detailed study at higher magnifications.

iii. Reject the grid if:

(1) Less than 50 percent of the grid openings covered by the replica are intact.

(2) It is doubled or folded.

(3) It is too dark because of incomplete dissolution of the filter.

iv. If the grid is rejected, load the next sample grid.

v. If the grid is acceptable, continue on to Step 6 if mapping is to be used; otherwise proceed to Step 7.

f. Grid Map (Optional).

i. Set the TEM to the low magnification mode.

ii. Use flat edge or finder grids for mapping.

iii. Index the grid openings (fields) to be counted by marking the acceptable fields for one-half (0.5) of the area needed for analysis on each of the two grids to be analyzed. These may be marked just before examining each grid opening (field), if desired.

iv. Draw in any details which will allow the grid to be properly oriented if it is reloaded into the microscope and a particular field is to be reliably identified.

g. Scan the grid.

i. Select a field to start the examination.

ii. Choose the appropriate magnification (15,000 to 20,000X screen magnification).

iii. Scan the grid as follows.

(1) At the selected magnification, make a series of parallel traverses across the field. On reaching the end of one traverse, move the image one window and reverse the traverse.

NOTE: A slight overlap should be used so as not to miss any part of the grid opening (field).

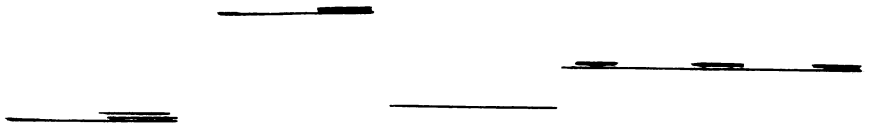
(2) Make parallel traverses until the entire grid opening (field) has been scanned.

h. Identify each structure for appearance and size.

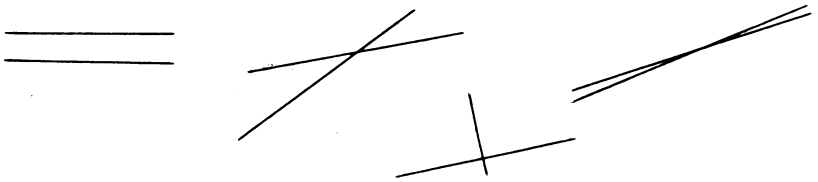
i. Appearance and size: Any continuous grouping of particles in which an asbestos fiber within aspect ratio greater than or equal to 5:1 and a length greater than or equal to 0.5 μm is detected shall be recorded on the count sheet. These will be designated asbestos structures and will be classified as fibers, bundles, clusters, or matrices. Record as individual fibers any contiguous grouping having 0, 1, or 2 definable intersections. Groupings having more than 2 intersections are to be described as cluster or matrix. See the following Figure 5:

FIGURE 5--COUNTING GUIDELINES USED IN DETERMINING ASBESTOS STRUCTURES

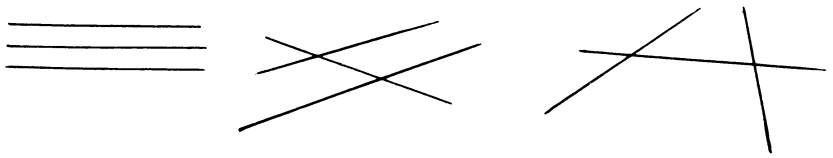
Count as 1 fiber; 1 Structure; no intersections.



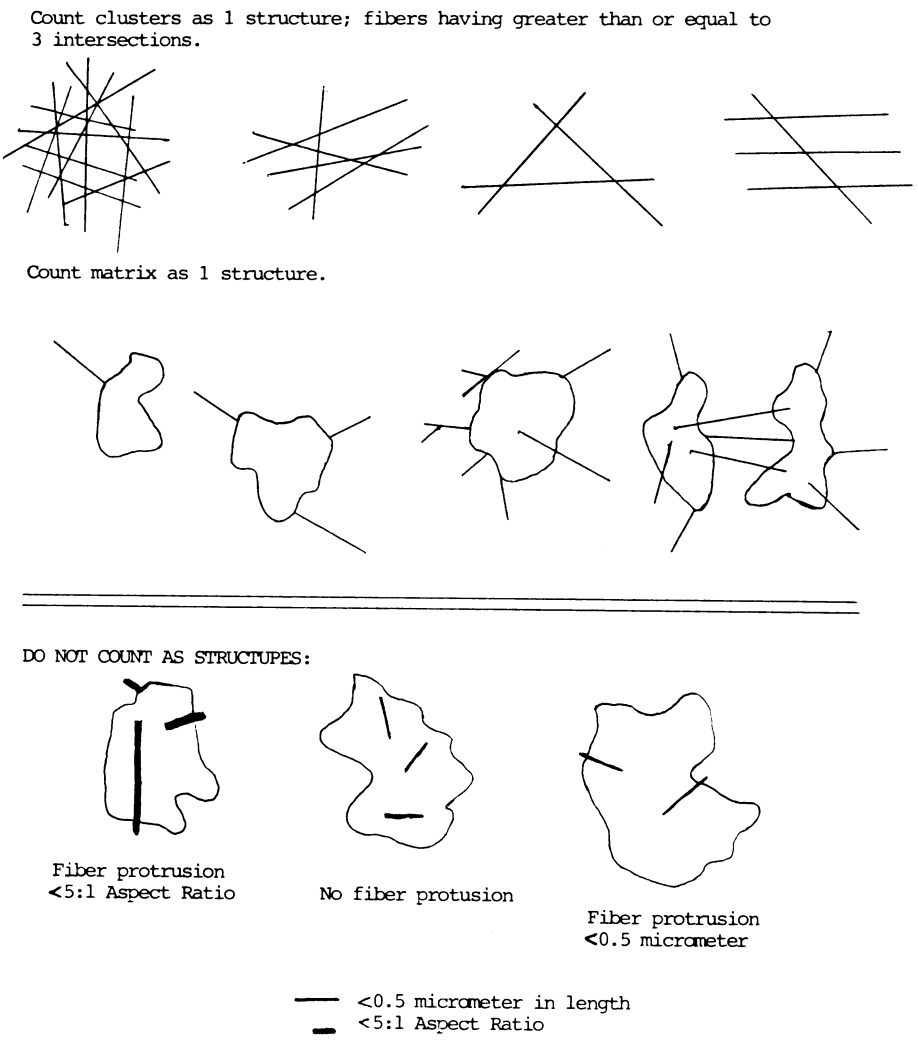
Count as 2 fibers if space between fibers is greater than width of 1 fiber diameter or number of intersections is equal to or less than 1.



Count as 3 structures if space between fibers is greater than width of 1 fiber diameter or if the number of intersections is equal to or less than 2.



Count bundles as 1 structure; 3 or more parallel fibrils less than 1 fiber diameter separation.



An intersection is a non-parallel touching or crossing of fibers, with the projection having an aspect ratio of 5:1 or greater. Combinations such as a matrix and cluster, matrix and bundle, or bundle and cluster are categorized by the dominant fiber quality—cluster, bundle, and matrix, respectively. Separate categories will be maintained for fibers less than 5 μm and for fibers greater than or equal to 5 μm in length. Not required, but useful, may be to record the fiber length in 1 μm intervals. (Identify each structure morphologically and analyze it as it enters the ''window''.)

(1) *Fiber.* A structure having a minimum length greater than 0.5 μm and an aspect ratio (length to width) of 5:1 or greater and substantially parallel sides. Note the appearance of the end of the fiber, i.e., whether it is flat, rounded or dovetailed, no intersections.

(2) *Bundle.* A structure composed of 3 or more fibers in a parallel arrangement with each fiber closer than one fiber diameter.

(3) *Cluster.* A structure with fibers in a random arrangement such that all fibers are intermixed and no single fiber is isolated from the group; groupings must have more than 2 intersections.

(4) *Matrix*. Fiber or fibers with one end free and the other end embedded in or hidden by a particulate. The exposed fiber must meet the fiber definition.

(5) *NSD*. Record NSD when no structures are detected in the field.

(6) *Intersection*. Non-parallel touching or crossing of fibers, with the projection having an aspect ratio 5:1 or greater.

ii. Structure Measurement.

(1) Recognize the structure that is to be sized.

(2) Memorize its location in the ''window'' relative to the sides, inscribed square and to other particulates in the field so this exact location can be found again when scanning is resumed.

(3) Measure the structure using the scale on the screen.

(4) Record the length category and structure type classification on the count sheet after the field number and fiber number.

(5) Return the fiber to its original location in the window and scan the rest of the field for other fibers; if the direction of travel is not remembered, return to the right side of the field and begin the traverse again.

i. Visual identification of Electron Diffraction (ED) patterns is required for each asbestos structure counted which would cause the analysis to exceed the 70 s/mm^2 concentration. (Generally this means the first four fibers identified as asbestos must exhibit an identifiable diffraction pattern for chrysotile or amphibole.)

i. Center the structure, focus, and obtain an ED pattern. (See Microscope Instruction Manual for more detailed instructions.)

ii. From a visual examination of the ED pattern, obtained with a short camera length, classify the observed structure as belonging to one of the following classifications: chrysotile, amphibole, or nonasbestos.

(1) Chrysotile: The chrysotile asbestos pattern has characteristic streaks on the layer lines other than the central line and some streaking also on the central line. There will be spots of normal sharpness on the central layer line and on alternate lines (2nd, 4th, etc.). The repeat distance between layer lines is 0.53 nm and the center doublet is at 0.73 nm. The pattern should display (002), (110), (130) diffraction maxima; distances and geometry should match a chrysotile pattern and be measured semiquantitatively.

(2) Amphibole Group [includes grunerite (amosite), crocidolite, anthophyllite, tremolite, and actinolite]: Amphibole asbestos fiber patterns show layer lines formed by very closely spaced dots, and the repeat distance between layer lines is also about 0.53 nm. Streaking in layer lines is occasionally present due to crystal structure defects.

(3) Nonasbestos: Incomplete or unobtainable ED patterns, a nonasbestos EDXA, or a nonasbestos morphology.

iii. The micrograph number of the recorded diffraction patterns must be reported to the client and maintained in the laboratory's quality assurance records. The records must also demonstrate that the identification of the pattern has been verified by a qualified individual and that the operator who made the identification is maintaining at least an 80 percent correct visual identification based on his measured patterns. In the event that examination of the pattern by the qualified individual indicates that the pattern had been misidentified visually, the client shall be contacted. If the pattern is a suspected chrysotile, take a photograph of the diffraction pattern at 0 degrees tilt. If the structure is suspected to be amphibole, the sample may have to be tilted to obtain a simple geometric array of spots.

j. Energy Dispersive X-Ray Analysis (EDXA).

i. Required of all amphiboles which would cause the analysis results to exceed the 70 s/mm^2 concentration. (Generally speaking, the first 4 amphiboles would require EDXA.)

ii. Can be used alone to confirm chrysotile after the 70 s/mm^2 concentration has been exceeded.

iii. Can be used alone to confirm all nonasbestos.

iv. Compare spectrum profiles with profiles obtained from asbestos standards. The closest match identifies and categorizes the structure.

v. If the EDXA is used for confirmation, record the properly labeled spectrum on a computer disk, or if a hard copy, file with analysis data.

vi. If the number of fibers in the nonasbestos class would cause the analysis to exceed the 70 s/mm^2 concentration, their identities must be confirmed by EDXA or measurement of a zone axis diffraction pattern to establish that the particles are nonasbestos.

k. Stopping Rules.

i. If more than 50 asbestiform structures are counted in a particular grid opening, the analysis may be terminated.

ii. After having counted 50 asbestiform structures in a minimum of 4 grid openings, the analysis may be terminated. The grid opening in which the 50th fiber was counted must be completed.

iii. For blank samples, the analysis is always continued until 10 grid openings have been analyzed.

iv. In all other samples the analysis shall be continued until an analytical sensitivity of 0.005 s/cm^3 is reached.

l. Recording Rules. The count sheet should contain the following information:

i. Field (grid opening): List field number.

ii. Record ''NSD'' if no structures are detected.

iii. Structure information.

(1) If fibers, bundles, clusters, and/or matrices are found, list them in consecutive numerical order, starting over with each field.

(2) Length. Record length category of asbestos fibers examined. Indicate if less than 5 μm or greater than or equal to 5 μm.

(3) Structure Type. Positive identification of asbestos fibers is required by the method. At least one diffraction pattern of each fiber type from every five samples must be recorded and compared with a standard diffraction pattern. For each asbestos fiber reported, both a morphological descriptor and an identification descriptor shall be specified on the count sheet.

(4) Fibers classified as chrysotile must be identified by diffraction and/or X-ray analysis and recorded on the count sheet. X-ray analysis alone can be used as sole identification only after 70s/mm^2 have been exceeded for a particular sample.

(5) Fibers classified as amphiboles must be identified by X-ray analysis and electron diffraction and recorded on the count sheet. (X-ray analysis alone can be used as sole identification only after 70s/mm^2 have been exceeded for a particular sample.)

(6) If a diffraction pattern was recorded on film, the micrograph number must be indicated on the count sheet.

(7) If an electron diffraction was attempted and an appropriate spectra is not observed, N should be recorded on the count sheet.

(8) If an X-ray analysis is attempted but not observed, N should be recorded on the count sheet.

(9) If an X-ray analysis spectrum is stored, the file and disk number must be recorded on the count sheet.

m. Classification Rules.

i. *Fiber.* A structure having a minimum length greater than or equal to 0.5 μm and an aspect ratio (length to width) of 5:1 or greater and substantially parallel sides. Note the appearance of the end of the fiber, i.e., whether it is flat, rounded or dovetailed.

ii. *Bundle.* A structure composed of three or more fibers in a parallel arrangement with each fiber closer than one fiber diameter.

iii. *Cluster.* A structure with fibers in a random arrangement such that all fibers are intermixed and no single fiber is isolated from the group. Groupings must have more than two intersections.

iv. *Matrix.* Fiber or fibers with one end free and the other end embedded in or hidden by a particulate. The exposed fiber must meet the fiber definition.

v. *NSD.* Record NSD when no structures are detected in the field.

n. After all necessary analyses of a particle structure have been completed, return the goniometer stage to 0 degrees, and return the structure to its original location by recall of the original location.

o. Continue scanning until all the structures are identified, classified and sized in the field.

p. Select additional fields (grid openings) at low magnification; scan at a chosen magnification (15,000 to 20,000X screen magnification); and analyze until the stopping rule becomes applicable.

q. Carefully record all data as they are being collected, and check for accuracy.

r. After finishing with a grid, remove it from the microscope, and replace it in the appropriate grid hold. Sample grids must be stored for a minimum of 1 year from the date of the analysis; the sample cassette must be retained for a minimum of 30 days by the laboratory or returned at the client's request.

H. Sample Analytical Sequence

1. Carry out visual inspection of work site prior to air monitoring.

2. Collect a minimum of five air samples inside the work site and five samples outside the work site. The indoor and outdoor samples shall be taken during the same time period.

3. Analyze the abatement area samples according to this protocol. The analysis must meet the 0.005 s/cm^3 analytical sensitivity.

4. Remaining steps in the analytical sequence are contained in Unit IV. of this Appendix.

I. Reporting

The following information must be reported to the client. See the following Table II:

TABLE II--EXAMPLE LABORATORY LETTERHEAD

Laboratory I.D.	Client I.D.	FILTER MEDIA DATA				Analyzed Area, mm^2	Sample Volume, cc
		Type	Diameter, mm	Effective Area, mm^2	Pore Size, µm		

INDIVIDUAL ANALYTICAL RESULTS

Laboratory I.D.	Client I.D.	# Asbestos Structures	Analytical Sensitivity, s/cc	CONCENTRATION	
				Structures/mm^2	Structures/cc

The analysis was carried out to the approved TEM method. This laboratory is in compliance with the quality specified by the method.

Authorized Signature

1. Concentration in structures per square millimeter and structures per cubic centimeter.
2. Analytical sensitivity used for the analysis.
3. Number of asbestos structures.
4. Area analyzed.
5. Volume of air samples (which was initially provided by client).
6. Average grid size opening.
7. Number of grids analyzed.
8. Copy of the count sheet must be included with the report.

9. Signature of laboratory official to indicate that the laboratory met specifications of the AHERA method.

10. Report form must contain official laboratory identification (e.g., letterhead).

11. Type of asbestos.

J. Calibration Methodology

NOTE: Appropriate implementation of the method requires a person knowledgeable in electron diffraction and mineral identification by ED and EDXA. Those inexperienced laboratories wishing to develop capabilities may acquire necessary knowledge through analysis of appropriate standards and by following detailed methods as described in References 8 and 10 of Unit III.L.

1. *Equipment Calibration.* In this method, calibration is required for the air-sampling equipment and the transmission electron microscope (TEM).

a. *TEM Magnification.* The magnification at the fluorescent screen of the TEM must be calibrated at the grid opening magnification (if used) and also at the magnification used for fiber counting. This is performed with a cross grating replica. A logbook must be maintained, and the dates of calibration depend on the past history of the particular microscope; no frequency is specified. After any maintenance of the microscope that involved adjustment of the power supplied to the lenses or the high-voltage system or the mechanical disassembly of the electron optical column apart from filament exchange, the magnification must be recalibrated. Before the TEM calibration is performed, the analyst must ensure that the cross grating replica is placed at the same distance from the objective lens as the specimens are. For instruments that incorporate an eucentric tilting specimen stage, all speciments and the cross grating replica must be placed at the eucentric position.

b. Determination of the TEM magnification on the fluorescent screen.

i. Define a field of view on the fluorescent screen either by markings or physical boundaries. The field of view must be measurable or previously inscribed with a scale or concentric circles (all scales should be metric).

ii. Insert a diffraction grating replica (for example a grating containing 2,160 lines/mm) into the specimen holder and place into the microscope. Orient the replica so that the grating lines fall perpendicular to the scale on the TEM fluorescent screen. Ensure that the goniometer stage tilt is 0 degrees.

iii. Adjust microscope magnification to 10,000X or 20,000X. Measure the distance (mm) between two widely separated lines on the grating replica. Note the number of spaces between the lines. Take care to measure between the same relative positions on the lines (e.g., between left edges of lines).

NOTE: The more spaces included in the measurement, the more accurate the final calculation. On most microscopes, however, the magnification is substantially constant only within the central 8–10 cm diameter region of the fluorescent screen.

iv. Calculate the true magnification (M) on the fluorescent screen:

$M = XG/Y$

where:

X = total distance (mm) between the designated grating lines;
G = calibration constant of the grating replica (lines/mm):
Y = number of grating replica spaces counted along X.

c. Calibration of the EDXA System. Initially, the EDXA system must be calibrated by using two reference elements to calibrate the energy scale of the instrument. When this has been completed in accordance with the manufacturer's instructions, calibration in terms of the different types of asbestos can proceed. The EDXA detectors vary in both solid angle of detection and in window thickness. Therefore, at a particular accelerating voltage in use on the TEM, the count rate obtained from specific dimensions of fiber will vary both in absolute X-ray count rate and in the relative X-ray peak heights for different elements. Only a few minerals are relevant for asbestos abatement work, and in this procedure the calibration is specified in terms of a ''fingerprint'' technique. The EDXA spectra must be recorded from individual fibers of the relevant minerals, and identifications are made on the basis of semiquantitative comparisons with these reference spectra.

d. Calibration of Grid Openings.

i. Measure 20 grid openings on each of 20 random 200-mesh copper grids by placing a grid on a glass slide and examining it under the PCM. Use a calibrated graticule to measure the average field diameter and use this number to calculate the field area for an average grid opening. Grids are to be randomly selected from batches up to 1,000.

NOTE: A grid opening is considered as one field.

ii. The mean grid opening area must be measured for the type of specimen grids in use. This can be accomplished on the TEM at a properly calibrated low magnification or on an optical microscope at a magnification of approximately 400X by using an eyepiece fitted with a scale that has been calibrated against a stage micrometer. Optical microscopy utilizing manual or automated procedures may be used providing instrument calibration can be verified.

e. Determination of Camera Constant and ED Pattern Analysis.

i. The camera length of the TEM in ED operating mode must be calibrated before ED patterns on unknown samples are observed. This can be achieved by using a carbon-coated grid on which a thin film of gold has been

sputtered or evaporated. A thin film of gold is evaporated on the specimen TEM grid to obtain zone-axis ED patterns superimposed with a ring pattern from the polycrystalline gold film.

ii. In practice, it is desirable to optimize the thickness of the gold film so that only one or two sharp rings are obtained on the superimposed ED pattern. Thicker gold film would normally give multiple gold rings, but it will tend to mask weaker diffraction spots from the unknown fibrous particulates. Since the unknown d-spacings of most interest in asbestos analysis are those which lie closest to the transmitted beam, multiple gold rings are unnecessary on zone-axis ED patterns. An average camera constant using multiple gold rings can be determined. The camera constant is one-half the diameter, D, of the rings times the interplanar spacing, d, of the ring being measured.

K. Quality Control/Quality Assurance Procedures (Data Quality Indicators)

Monitoring the environment for airborne asbestos requires the use of sensitive sampling and analysis procedures. Because the test is sensitive, it may be influenced by a variety of factors. These include the supplies used in the sampling operation, the performance of the sampling, the preparation of the grid from the filter and the actual examination of this grid in the microscope. Each of these unit operations must produce a product of defined quality if the analytical result is to be a reliable and meaningful test result. Accordingly, a series of control checks and reference standards is performed along with the sample analysis as indicators that the materials used are adequate and the operations are within acceptable limits. In this way, the quality of the data is defined and the results are of known value. These checks and tests also provide timely and specific warning of any problems which might develop within the sampling and analysis operations. A description of these quality control/quality assurance procedures is summarized in the following Table III:

TABLE III--SUMMARY OF LABORATORY DATA QUALITY OBJECTIVES

Unit Operation	QC Check	Frequency	Conformance Expectation
Sample receiving	Review of receiving report	Each sample	95% complete
Sample custody	Review of chain-of-custody record	Each sample	95% complete
Sample preparation	Supplies and reagents	On receipt	Meet specs. or reject
	Grid opening size	20 openings/20 grids/lot of 1000 or 1 opening/sample	100%
	Special clean area monitoring	After cleaning or service	Meet specs or reclean
	Laboratory blank	1 per prep series or 10%	Meet specs. or reanalyze series
	Plasma etch blank	1 per 20 samples	75%
	Multiple preps (3 per sample)	Each sample	One with cover of 15 complete grid sqs.
Sample analysis	System check	Each day	Each day
	Alignment check	Each day	Each day
	Magnification calibration with low and high standards	Each month or after service	95%
	ED calibration by gold standard	Weekly	95%
	EDS calibration by copper line	Daily	95%
Performance check	Laboratory blank (measure of cleanliness)	Prep 1 per series or 10% read 1 per 25 samples	Meet specs or reanalyze series
	Replicate counting (measure of precision)	1 per 100 samples	1.5 x Poisson Std. Dev.
	Duplicate analysis (measure of reproducibility)	1 per 100 samples	2 x Poisson Std. Dev.
	Known samples of typical materials (working standards)	Training and for comparison with unknowns	100%
	Analysis of NBS SRM 1876 and/or RM 8410 (measure of accuracy and comparability)	1 per analyst per year	1.5 x Poisson Std. Dev.
	Data entry review (data validation and measure of completeness)	Each sample	95%
	Record and verify ID electron diffraction pattern of structure	1 per 5 samples	80% accuracy
Calculations and data reduction	Hand calculation of automated data reduction procedure or independent recalculation of hand-calculated data	1 per 100 samples	85%

1. When the samples arrive at the laboratory, check the samples and documentation for completeness and requirements before initiating the analysis.

2. Check all laboratory reagents and supplies for acceptable asbestos background levels.

3. Conduct all sample preparation in a clean room environment monitored by laboratory blanks and special testing after cleaning or servicing the room.

4. Prepare multiple grids of each sample.

5. Provide laboratory blanks with each sample batch. Maintain a cumulative average of these results. If this average is greater than 53 f/mm^2 per 10 200-mesh grid openings, check the system for possible sources of contamination.

6. Check for recovery of asbestos from cellulose ester filters submitted to plasma asher.

7. Check for asbestos carryover in the plasma asher by including a blank alongside the positive control sample.

8. Perform a systems check on the transmission electron microscope daily.

9. Make periodic performance checks of magnification, electron diffraction and energy dispersive X-ray systems as set forth in Table III of Unit III.K.

10. Ensure qualified operator performance by evaluation of replicate counting, duplicate analysis, and standard sample comparisons as set forth in Table III of Unit III.K.

11. Validate all data entries.

12. Recalculate a percentage of all computations and automatic data reduction steps as specified in Table III.

13. Record an electron diffraction pattern of one asbestos structure from every five samples that contain asbestos. Verify the identification of the pattern by measurement or comparison of the pattern with patterns collected from standards under the same conditions.

The outline of quality control procedures presented above is viewed as the minimum required to assure that quality data is produced for clearance testing of an asbestos abated area. Additional information may be gained by other control tests. Specifics on those control procedures and options available for environmental testing can be obtained by consulting References 6, 7, and 11 of Unit III.L.

L. References

For additional background information on this method the following references should be consulted.

1. ''Guidelines for Controlling Asbestos-Containing Materials in Buildings,'' EPA 560/5–85–024, June 1985.

2. ''Measuring Airborne Asbestos Following an Abatement Action,'' USEP/Office of Pollution Prevention and Toxics, EPA 600/4–85–049, 1985.

3. Small, John and E. Steel. Asbestos Standards: Materials and Analytical Methods. N.B.S. Special Publication 619, 1982.

4. Campbell, W.J., R.L. Blake, L.L. Brown, E.E. Cather, and J.J. Sjoberg. Selected Silicate Minerals and Their Asbestiform Varieties. Information Circular 8751, U.S. Bureau of Mines, 1977.

5. Quality Assurance Handbook for Air Pollution Measurement System. Ambient Air Methods, EPA 600/4–77–027a, USEPA, Office of Research and Development, 1977.

6. Method 2A: Direct Measurement of Gas Volume Through Pipes and Small Ducts. 40 CFR Part 60 Appendix A.

7. Burdette, G.J. Health & Safety Exec., Research & Lab. Services Div., London, ''Proposed Analytical Method for Determination of Asbestos in Air.''

8. Chatfield, E.J., Chatfield Tech. Cons., Ltd., Clark, T., PEI Assoc. ''Standard Operating Procedure for Determination of Airborne Asbestos Fibers by Transmission Electron Microscopy Using Polycarbonate Membrane Filters.'' WERL SOP 87–1, March 5, 1987.

9. NIOSH. Method 7402 for Asbestos Fibers, December 11, 1986 Draft.

10. Yamate, G., S.C. Agarwall, R.D. Gibbons, IIT Research Institute, ''Methodology for the Measurement of Airborne Asbestos by Electron Microscopy.'' Draft report, USEPA Contract 68–02–3266, July 1984.

11. Guidance to the Preparation of Quality Assurance Project Plans. USEPA, Office of Pollution Prevention and Toxics, 1984.

IV. Mandatory Interpretation of Transmission Electron Microscopy Results To Determine Completion of Response Actions

A. Introduction

A response action is determined to be completed by TEM when the abatement area has been cleaned and the airborne asbestos concentration inside the abatement area is no higher than concentrations at locations outside the abatement area. ''Outside'' means outside the abatement area, but not necessarily outside the building. EPA reasons that an asbestos removal contractor cannot be expected to clean an abatement area to an airborne asbestos concentration that is lower than the concentration of air entering the abatement area from outdoors or from other parts of the building. After the abatement area has passed a thorough visual inspection, and before the outer containment barrier is removed, a minimum of five air samples inside the abatement area and a minimum of five air samples outside the abatement area must be collected. Hence, the response action is determined to be completed when the average airborne asbestos concentration measured inside the abatement area is not statistically different from the average airborne asbestos concentration measured outside the abatement area.

The inside and outside concentrations are compared by the Z-test, a statistical test that takes into account the variability in the measurement process. A minimum of five samples inside the abatement area and five samples outside the abatement area are required to control the false negative error rate, i.e., the probability of declaring the removal complete when, in fact, the air concentration inside the abatement area is significantly higher than outside the abatement area. Additional quality control is provided by requiring three blanks (filters through which no air has been drawn) to be analyzed to check for unusually high filter contamination that would distort the test results.

When volumes greater than or equal to 1,199 L for a 25 mm filter and 2,799 L for a 37 mm filter have been collected and the average number of asbestos structures on samples inside the abatement area is no greater than 70 s/mm^2 of filter, the response action

may be considered complete without comparing the inside samples to the outside samples. EPA is permitting this initial screening test to save analysis costs in situations where the airborne asbestos concentration is sufficiently low so that it cannot be distinguished from the filter contamination/background level (fibers deposited on the filter that are unrelated to the air being sampled). The screening test cannot be used when volumes of less than 1,199 L for 25 mm filter or 2,799 L for a 37 mm filter are collected because the ability to distinguish levels significantly different from filter background is reduced at low volumes.

The initial screening test is expressed in structures per square millimeter of filter because filter background levels come from sources other than the air being sampled and cannot be meaningfully expressed as a concentration per cubic centimeter of air. The value of 70 s/mm^2 is based on the experience of the panel of microscopists who consider one structure in 10 grid openings (each grid opening with an area of 0.0057 mm^2) to be comparable with contamination/background levels of blank filters. The decision is based, in part, on Poisson statistics which indicate that four structures must be counted on a filter before the fiber count is statistically distinguishable from the count for one structure. As more information on the performance of the method is collected, this criterion may be modified. Since different combinations of the number and size of grid openings are permitted under the TEM protocol, the criterion is expressed in structures per square millimeter of filter to be consistent across all combinations. Four structures per 10 grid openings corresponds to approximately 70 s/mm^2.

B. Sample Collection and Analysis

1. A minimum of 13 samples is required: five samples collected inside the abatement area, five samples collected outside the abatement area, two field blanks, and one sealed blank.

2. Sampling and TEM analysis must be done according to either the mandatory or nonmandatory protocols in Appendix A. At least 0.057 mm^2 of filter must be examined on blank filters.

C. Interpretation of Results

1. The response action shall be considered complete if either:

a. Each sample collected inside the abatement area consists of at least 1,199 L of air for a 25 mm filter, or 2,799 L of air for a 37 mm filter, and the arithmetic mean of their asbestos structure concentrations per square millimeter of filter is less than or equal to 70 s/mm^2; or

b. The three blank samples have an arithmetic mean of the asbestos structure concentration on the blank filters that is less than or equal to 70 s/mm^2 and the average airborne asbestos concentration measured inside the abatement area is not statistically higher than the average airborne asbestos concentration measured outside the abatement area as determined by the Z-test. The Z-test is carried out by calculating

$$Z = \frac{\bar{Y}_I - \bar{Y}_O}{0.8\left(1/n_I + 1/n_O\right)^{1/2}}$$

where Y_I is the average of the natural logarithms of the inside samples and Y_O is the average of the natural logarithms of the outside samples, n_I is the number of inside samples and n_O is the number of outside samples. The response action is considered complete if Z is less than or equal to 1.65.

NOTE: When no fibers are counted, the calculated detection limit for that analysis is inserted for the concentration.

2. If the abatement site does not satisfy either (1) or (2) of this Section C, the site must be recleaned and a new set of samples collected.

D. Sequence for Analyzing Samples

It is possible to determine completion of the response action without analyzing all samples. Also, at any point in the process, a decision may be made to terminate the analysis of existing samples, reclean the abatement site, and collect a new set of samples. The following sequence is outlined to minimize the number of analyses needed to reach a decision.

1. Analyze the inside samples.

2. If at least 1,199 L of air for a 25 mm filter or 2,799 L of air for a 37 mm filter is collected for each inside sample and the arithmetic mean concentration of structures per square millimeter of filter is less than or equal to 70 s/mm^2, the response action is complete and no further analysis is needed.

3. If less than 1,199 L of air for a 25 mm filter or 2,799 L of air for a 37 mm filter is collected for any of the inside samples, or the arithmetic mean concentration of structures per square millimeter of filter is greater than 70 s/mm^2, analyze the three blanks.

4. If the arithmetic mean concentration of structures per square millimeter on the blank filters is greater than 70 s/mm^2, terminate the analysis, identify and correct the source of blank contamination, and collect a new set of samples.

5. If the arithmetic mean concentration of structures per square millimeter on the blank filters is less than or equal to 70 s/mm^2, analyze the outside samples and perform the Z-test.

6. If the Z-statistic is less than or equal to 1.65, the response action is complete. If the Z-statistic is greater than 1.65, reclean the abatement site and collect a new set of samples.

[52 FR 41857, Oct. 30, 1987]

APPENDIX B TO SUBPART E OF PART 763 [RESERVED]

APPENDIX C TO SUBPART E OF PART 763—ASBESTOS MODEL ACCREDITATION PLAN

I. Asbestos Model Accreditation Plan for States

The Asbestos Model Accreditation Plan (MAP) for States has eight components:

(A) Definitions
(B) Initial Training
(C) Examinations
(D) Continuing Education
(E) Qualifications
(F) Recordkeeping Requirements for Training Providers
(G) Deaccreditation
(H) Reciprocity
(I) Electronic reporting

A. Definitions

For purposes of Appendix C:

1. ''Friable asbestos-containing material (ACM)'' means any material containing more than one percent asbestos which has been applied on ceilings, walls, structural members, piping, duct work, or any other part of a building, which when dry, may be crumbled, pulverized, or reduced to powder by hand pressure. The term includes non-friable asbestos-containing material after such previously non-friable material becomes damaged to the extent that when dry it may be crumbled, pulverized, or reduced to powder by hand pressure.

2. ''Friable asbestos-containing building material (ACBM)'' means any friable ACM that is in or on interior structural members or other parts of a school or public and commercial building.

3. ''Inspection'' means an activity undertaken in a school building, or a public and commercial building, to determine the presence or location, or to assess the condition of, friable or non-friable asbestos-containing building material (ACBM) or suspected ACBM, whether by visual or physical examination, or by collecting samples of such material. This term includes reinspections of friable and non-friable known or assumed ACBM which has been previously identified. The term does not include the following:

a. Periodic surveillance of the type described in 40 CFR 763.92(b) solely for the purpose of recording or reporting a change in the condition of known or assumed ACBM;

b. Inspections performed by employees or agents of Federal, State, or local government solely for the purpose of determining compliance with applicable statutes or regulations; or

c. visual inspections of the type described in 40 CFR 763.90(i) solely for the purpose of determining completion of response actions.

4. ''Major fiber release episode'' means any uncontrolled or unintentional disturbance of ACBM, resulting in a visible emission, which involves the falling or dislodging of more than 3 square or linear feet of friable ACBM.

5. ''Minor fiber release episode'' means any uncontrolled or unintentional disturbance of ACBM, resulting in a visible emission, which involves the falling or dislodging of 3 square or linear feet or less of friable ACBM.

6. ''Public and commercial building'' means the interior space of any building which is not a school building, except that the term does not include any residential apartment building of fewer than 10 units or detached single-family homes. The term includes, but is not limited to: industrial and office buildings, residential apartment buildings and condominiums of 10 or more dwelling units, government-owned buildings, colleges, museums, airports, hospitals, churches, preschools, stores, warehouses and factories. Interior space includes exterior hallways connecting buildings, porticos, and mechanical systems used to condition interior space.

7. ''Response action'' means a method, including removal, encapsulation, enclosure, repair, and operation and maintenance, that protects human health and the environment from friable ACBM.

8. ''Small-scale, short-duration activities (SSSD)'' are tasks such as, but not limited to:

a. Removal of asbestos-containing insulation on pipes.

b. Removal of small quantities of asbestos-containing insulation on beams or above ceilings.

c. Replacement of an asbestos-containing gasket on a valve.

d. Installation or removal of a small section of drywall.

e. Installation of electrical conduits through or proximate to asbestos-containing materials.

SSSD can be further defined by the following considerations:

f. Removal of small quantities of ACM only if required in the performance of another maintenance activity not intended as asbestos abatement.

g. Removal of asbestos-containing thermal system insulation not to exceed amounts greater than those which can be contained in a single glove bag.

h. Minor repairs to damaged thermal system insulation which do not require removal.

i. Repairs to a piece of asbestos-containing wallboard.

j. Repairs, involving encapsulation, enclosure, or removal, to small amounts of friable ACM only if required in the performance of emergency or routine maintenance activity and not intended solely as asbestos abatement. Such work may not exceed amounts greater than those which can be contained in a single prefabricated mini-enclosure. Such an enclosure shall conform spatially and geometrically to the localized work area, in order to perform its intended containment function.

B. Initial Training

Training requirements for purposes of accreditation are specified both in terms of required subjects of instruction and in terms of length of training. Each initial training course has a prescribed curriculum and number of days of training. One day of training equals 8 hours, including breaks and lunch. Course instruction must be provided by EPA or State-approved instructors. EPA or State instructor approval shall be based upon a review of the instructor's academic credentials and/or field experience in asbestos abatement.

Beyond the initial training requirements, individual States may wish to consider requiring additional days of training for purposes of supplementing hands-on activities or for reviewing relevant state regulations. States also may wish to consider the relative merits of a worker apprenticeship program. Further, they might consider more stringent minimum qualification standards for the approval of training instructors. EPA recommends that the enrollment in any given course be limited to 25 students so that adequate opportunities exist for individual hands-on experience.

States have the option to provide initial training directly or approve other entities to offer training. The following requirements are for the initial training of persons required to have accreditation under TSCA Title II.

Training requirements for each of the five accredited disciplines are outlined below. Persons in each discipline perform a different job function and distinct role. Inspectors identify and assess the condition of ACBM, or suspect ACBM. Management planners use data gathered by inspectors to assess the degree of hazard posed by ACBM in schools to determine the scope and timing of appropriate response actions needed for schools. Project designers determine how asbestos abatement work should be conducted. Lastly, workers and contractor/supervisors carry out and oversee abatement work. In addition, a recommended training curriculum is also presented for a sixth discipline, which is not federally-accredited, that of ''Project Monitor.'' Each accredited discipline and training curriculum is separate and distinct from the others. A person seeking accreditation in any of the five accredited MAP disciplines cannot attend two or more courses concurrently, but may attend such courses sequentially.

In several instances, initial training courses for a specific discipline (e.g., workers, inspectors) require hands-on training. For asbestos abatement contractor/supervisors and workers, hands-on training should include working with asbestos-substitute materials, fitting and using respirators, use of glovebags, donning protective clothing, and constructing a decontamination unit as well as other abatement work activities.

1. WORKERS

A person must be accredited as a worker to carry out any of the following activities with respect to friable ACBM in a school or public and commercial building: (1) A response action other than a SSSD activity, (2) a maintenance activity that disturbs friable ACBM other than a SSSD activity, or (3) a response action for a major fiber release episode. All persons seeking accreditation as asbestos abatement workers shall complete at least a 4–day training course as outlined below. The 4–day worker training course shall include lectures, demonstrations, at least 14 hours of hands-on training, individual respirator fit testing, course review, and an examination. Hands-on training must permit workers to have actual experience performing tasks associated with asbestos abatement. A person who is otherwise accredited as a contractor/supervisor may perform in the role of a worker without possessing separate accreditation as a worker.

Because of cultural diversity associated with the asbestos workforce, EPA recommends that States adopt specific standards for the approval of foreign language courses for abatement workers. EPA further recommends the use of audio-visual materials to complement lectures, where appropriate.

The training course shall adequately address the following topics:

(a) *Physical characteristics of asbestos.* Identification of asbestos, aerodynamic characteristics, typical uses, and physical appearance, and a summary of abatement control options.

(b) *Potential health effects related to asbestos exposure.* The nature of asbestos-related diseases; routes of exposure; dose-response relationships and the lack of a safe exposure level; the synergistic effect between cigarette smoking and asbestos exposure; the latency periods for asbestos-related diseases; a discussion of the relationship of asbestos exposure to asbestosis, lung cancer, mesothelioma, and cancers of other organs.

(c) *Employee personal protective equipment.* Classes and characteristics of respirator

types; limitations of respirators; proper selection, inspection; donning, use, maintenance, and storage procedures for respirators; methods for field testing of the facepiece-to-face seal (positive and negative-pressure fit checks); qualitative and quantitative fit testing procedures; variability between field and laboratory protection factors that alter respiratory fit (e.g., facial hair); the components of a proper respiratory protection program; selection and use of personal protective clothing; use, storage, and handling of non-disposable clothing; and regulations covering personal protective equipment.

(d) *State-of-the-art work practices.* Proper work practices for asbestos abatement activities, including descriptions of proper construction; maintenance of barriers and decontamination enclosure systems; positioning of warning signs; lock-out of electrical and ventilation systems; proper working techniques for minimizing fiber release; use of wet methods; use of negative pressure exhaust ventilation equipment; use of high-efficiency particulate air (HEPA) vacuums; proper clean-up and disposal procedures; work practices for removal, encapsulation, enclosure, and repair of ACM; emergency procedures for sudden releases; potential exposure situations; transport and disposal procedures; and recommended and prohibited work practices.

(e) *Personal hygiene.* Entry and exit procedures for the work area; use of showers; avoidance of eating, drinking, smoking, and chewing (gum or tobacco) in the work area; and potential exposures, such as family exposure.

(f) *Additional safety hazards.* Hazards encountered during abatement activities and how to deal with them, including electrical hazards, heat stress, air contaminants other than asbestos, fire and explosion hazards, scaffold and ladder hazards, slips, trips, and falls, and confined spaces.

(g) *Medical monitoring.* OSHA and EPA Worker Protection Rule requirements for physical examinations, including a pulmonary function test, chest X-rays, and a medical history for each employee.

(h) *Air monitoring.* Procedures to determine airborne concentrations of asbestos fibers, focusing on how personal air sampling is performed and the reasons for it.

(i) *Relevant Federal, State, and local regulatory requirements, procedures, and standards.* With particular attention directed at relevant EPA, OSHA, and State regulations concerning asbestos abatement workers.

(j) *Establishment of respiratory protection programs.*

(k) *Course review.* A review of key aspects of the training course.

2. CONTRACTOR/SUPERVISORS

A person must be accredited as a contractor/supervisor to supervise any of the following activities with respect to friable ACBM in a school or public and commercial building: (1) A response action other than a SSSD activity, (2) a maintenance activity that disturbs friable ACBM other than a SSSD activity, or (3) a response action for a major fiber release episode. All persons seeking accreditation as asbestos abatement contractor/supervisors shall complete at least a 5–day training course as outlined below. The training course must include lectures, demonstrations, at least 14 hours of hands-on training, individual respirator fit testing, course review, and a written examination. Hands-on training must permit supervisors to have actual experience performing tasks associated with asbestos abatement.

EPA recommends the use of audiovisual materials to complement lectures, where appropriate.

Asbestos abatement supervisors include those persons who provide supervision and direction to workers performing response actions. Supervisors may include those individuals with the position title of foreman, working foreman, or leadman pursuant to collective bargaining agreements. At least one supervisor is required to be at the worksite at all times while response actions are being conducted. Asbestos workers must have access to accredited supervisors throughout the duration of the project.

The contractor/supervisor training course shall adequately address the following topics:

(a) *The physical characteristics of asbestos and asbestos-containing materials.* Identification of asbestos, aerodynamic characteristics, typical uses, physical appearance, a review of hazard assessment considerations, and a summary of abatement control options.

(b) *Potential health effects related to asbestos exposure.* The nature of asbestos-related diseases; routes of exposure; dose-response relationships and the lack of a safe exposure level; synergism between cigarette smoking and asbestos exposure; and latency period for diseases.

(c) *Employee personal protective equipment.* Classes and characteristics of respirator types; limitations of respirators; proper selection, inspection, donning, use, maintenance, and storage procedures for respirators; methods for field testing of the facepiece-to-face seal (positive and negative-pressure fit checks); qualitative and quantitative fit testing procedures; variability between field and laboratory protection factors that alter respiratory fit (e.g., facial hair); the components of a proper respiratory protection program; selection and use of personal protective clothing; and use, storage,

and handling of non-disposable clothing; and regulations covering personal protective equipment.

(d) *State-of-the-art work practices.* Proper work practices for asbestos abatement activities, including descriptions of proper construction and maintenance of barriers and decontamination enclosure systems; positioning of warning signs; lock-out of electrical and ventilation systems; proper working techniques for minimizing fiber release; use of wet methods; use of negative pressure exhaust ventilation equipment; use of HEPA vacuums; and proper clean-up and disposal procedures. Work practices for removal, encapsulation, enclosure, and repair of ACM; emergency procedures for unplanned releases; potential exposure situations; transport and disposal procedures; and recommended and prohibited work practices. New abatement-related techniques and methodologies may be discussed.

(e) *Personal hygiene.* Entry and exit procedures for the work area; use of showers; and avoidance of eating, drinking, smoking, and chewing (gum or tobacco) in the work area. Potential exposures, such as family exposure, shall also be included.

(f) *Additional safety hazards.* Hazards encountered during abatement activities and how to deal with them, including electrical hazards, heat stress, air contaminants other than asbestos, fire and explosion hazards, scaffold and ladder hazards, slips, trips, and falls, and confined spaces.

(g) *Medical monitoring.* OSHA and EPA Worker Protection Rule requirements for physical examinations, including a pulmonary function test, chest X-rays and a medical history for each employee.

(h) *Air monitoring.* Procedures to determine airborne concentrations of asbestos fibers, including descriptions of aggressive air sampling, sampling equipment and methods, reasons for air monitoring, types of samples and interpretation of results.

EPA recommends that transmission electron microscopy (TEM) be used for analysis of final air clearance samples, and that sample analyses be performed by laboratories accredited by the National Institute of Standards and Technology's (NIST) National Voluntary Laboratory Accreditation Program (NVLAP).

(i) *Relevant Federal, State, and local regulatory requirements, procedures, and standards, including:*

(i) Requirements of TSCA Title II.

(ii) National Emission Standards for Hazardous Air Pollutants (40 CFR part 61), Subparts A (General Provisions) and M (National Emission Standard for Asbestos).

(iii) OSHA standards for permissible exposure to airborne concentrations of asbestos fibers and respiratory protection (29 CFR 1910.134).

(iv) OSHA Asbestos Construction Standard (29 CFR 1926.58). (v)EPA Worker Protection Rule, (40 CFR part 763, subpart G).

(j) *Respiratory Protection Programs and Medical Monitoring Programs.*

(k) *Insurance and liability issues.* Contractor issues; worker's compensation coverage and exclusions; third-party liabilities and defenses; insurance coverage and exclusions.

(l) *Recordkeeping for asbestos abatement projects.* Records required by Federal, State, and local regulations; records recommended for legal and insurance purposes.

(m) *Supervisory techniques for asbestos abatement activities.* Supervisory practices to enforce and reinforce the required work practices and discourage unsafe work practices.

(n) *Contract specifications.* Discussions of key elements that are included in contract specifications.

(o) *Course review.* A review of key aspects of the training course.

3. INSPECTOR

All persons who inspect for ACBM in schools or public and commercial buildings must be accredited. All persons seeking accreditation as an inspector shall complete at least a 3–day training course as outlined below. The course shall include lectures, demonstrations, 4 hours of hands-on training, individual respirator fit-testing, course review, and a written examination.

EPA recommends the use of audiovisual materials to complement lectures, where appropriate. Hands-on training should include conducting a simulated building walk-through inspection and respirator fit testing. The inspector training course shall adequately address the following topics:

(a) *Background information on asbestos.* Identification of asbestos, and examples and discussion of the uses and locations of asbestos in buildings; physical appearance of asbestos.

(b) *Potential health effects related to asbestos exposure.* The nature of asbestos-related diseases; routes of exposure; dose-response relationships and the lack of a safe exposure level; the synergistic effect between cigarette smoking and asbestos exposure; the latency periods for asbestos-related diseases; a discussion of the relationship of asbestos exposure to asbestosis, lung cancer, mesothelioma, and cancers of other organs.

(c) *Functions/qualifications and role of inspectors.* Discussions of prior experience and qualifications for inspectors and management planners; discussions of the functions of an accredited inspector as compared to those of an accredited management planner; discussion of inspection process including inventory of ACM and physical assessment.

(d) *Legal liabilities and defenses.* Responsibilities of the inspector and management

planner; a discussion of comprehensive general liability policies, claims-made, and occurrence policies, environmental and pollution liability policy clauses; state liability insurance requirements; bonding and the relationship of insurance availability to bond availability.

(e) *Understanding building systems.* The interrelationship between building systems, including: an overview of common building physical plan layout; heat, ventilation, and air conditioning (HVAC) system types, physical organization, and where asbestos is found on HVAC components; building mechanical systems, their types and organization, and where to look for asbestos on such systems; inspecting electrical systems, including appropriate safety precautions; reading blueprints and as-built drawings.

(f) *Public/employee/building occupant relations.* Notifying employee organizations about the inspection; signs to warn building occupants; tact in dealing with occupants and the press; scheduling of inspections to minimize disruptions; and education of building occupants about actions being taken.

(g) *Pre-inspection planning and review of previous inspection records.* Scheduling the inspection and obtaining access; building record review; identification of probable homogeneous areas from blueprints or as-built drawings; consultation with maintenance or building personnel; review of previous inspection, sampling, and abatement records of a building; the role of the inspector in exclusions for previously performed inspections.

(h) *Inspecting for friable and non-friable ACM and assessing the condition of friable ACM.* Procedures to follow in conducting visual inspections for friable and non-friable ACM; types of building materials that may contain asbestos; touching materials to determine friability; open return air plenums and their importance in HVAC systems; assessing damage, significant damage, potential damage, and potential significant damage; amount of suspected ACM, both in total quantity and as a percentage of the total area; type of damage; accessibility; material's potential for disturbance; known or suspected causes of damage or significant damage; and deterioration as assessment factors.

(i) *Bulk sampling/documentation of asbestos.* Detailed discussion of the ''Simplified Sampling Scheme for Friable Surfacing Materials (EPA 560/5-85-030a October 1985)''; techniques to ensure sampling in a randomly distributed manner for other than friable surfacing materials; sampling of non-friable materials; techniques for bulk sampling; inspector's sampling and repair equipment; patching or repair of damage from sampling; discussion of polarized light microscopy; choosing an accredited laboratory to analyze bulk samples; quality control and quality assurance procedures. EPA's recommendation that all bulk samples collected from school or public and commercial buildings be analyzed by a laboratory accredited under the NVLAP administered by NIST.

(j) *Inspector respiratory protection and personal protective equipment.* Classes and characteristics of respirator types; limitations of respirators; proper selection, inspection; donning, use, maintenance, and storage procedures for respirators; methods for field testing of the facepiece-to-face seal (positive and negative-pressure fit checks); qualitative and quantitative fit testing procedures; variability between field and laboratory protection factors that alter respiratory fit (e.g., facial hair); the components of a proper respiratory protection program; selection and use of personal protective clothing; use, storage, and handling of non-disposable clothing.

(k) *Recordkeeping and writing the inspection report.* Labeling of samples and keying sample identification to sampling location; recommendations on sample labeling; detailing of ACM inventory; photographs of selected sampling areas and examples of ACM condition; information required for inclusion in the management plan required for school buildings under TSCA Title II, section 203 (i)(1). EPA recommends that States develop and require the use of standardized forms for recording the results of inspections in schools or public or commercial buildings, and that the use of these forms be incorporated into the curriculum of training conducted for accreditation.

(l) *Regulatory review.* The following topics should be covered: National Emission Standards for Hazardous Air Pollutants (NESHAP; 40 CFR part 61, subparts A and M); EPA Worker Protection Rule (40 CFR part 763, subpart G); OSHA Asbestos Construction Standard (29 CFR 1926.58); OSHA respirator requirements (29 CFR 1910.134); the Asbestos-Containing Materials in School Rule (40 CFR part 763, subpart E; applicable State and local regulations, and differences between Federal and State requirements where they apply, and the effects, if any, on public and nonpublic schools or commercial or public buildings.

(m) *Field trip.* This includes a field exercise, including a walk-through inspection; on-site discussion about information gathering and the determination of sampling locations; on-site practice in physical assessment; classroom discussion of field exercise.

(n) *Course review.* A review of key aspects of the training course.

4. MANAGEMENT PLANNER

All persons who prepare management plans for schools must be accredited. All persons seeking accreditation as management planners shall complete a 3–day inspector training course as outlined above and a 2–day

management planner training course. Possession of current and valid inspector accreditation shall be a prerequisite for admission to the management planner training course. The management planner course shall include lectures, demonstrations, course review, and a written examination.

EPA recommends the use of audiovisual materials to complement lectures, where appropriate.

TSCA Title II does not require accreditation for persons performing the management planner role in public and commercial buildings. Nevertheless, such persons may find this training and accreditation helpful in preparing them to design or administer asbestos operations and maintenance programs for public and commercial buildings.

The management planner training course shall adequately address the following topics:

(a) *Course overview.* The role and responsibilities of the management planner; operations and maintenance programs; setting work priorities; protection of building occupants.

(b) *Evaluation/interpretation of survey results.* Review of TSCA Title II requirements for inspection and management plans for school buildings as given in section 203(i)(1) of TSCA Title II; interpretation of field data and laboratory results; comparison of field inspector's data sheet with laboratory results and site survey.

(c) *Hazard assessment.* Amplification of the difference between physical assessment and hazard assessment; the role of the management planner in hazard assessment; explanation of significant damage, damage, potential damage, and potential significant damage; use of a description (or decision tree) code for assessment of ACM; assessment of friable ACM; relationship of accessibility, vibration sources, use of adjoining space, and air plenums and other factors to hazard assessment.

(d) *Legal implications.* Liability; insurance issues specific to planners; liabilities associated with interim control measures, in-house maintenance, repair, and removal; use of results from previously performed inspections.

(e) *Evaluation and selection of control options.* Overview of encapsulation, enclosure, interim operations and maintenance, and removal; advantages and disadvantages of each method; response actions described via a decision tree or other appropriate method; work practices for each response action; staging and prioritizing of work in both vacant and occupied buildings; the need for containment barriers and decontamination in response actions.

(f) *Role of other professionals.* Use of industrial hygienists, engineers, and architects in developing technical specifications for response actions; any requirements that may exist for architect sign-off of plans; team approach to design of high-quality job specifications.

(g) *Developing an operations and maintenance (O&M) plan.* Purpose of the plan; discussion of applicable EPA guidance documents; what actions should be taken by custodial staff; proper cleaning procedures; steam cleaning and HEPA vacuuming; reducing disturbance of ACM; scheduling O&M for off-hours; rescheduling or canceling renovation in areas with ACM; boiler room maintenance; disposal of ACM; in-house procedures for ACM—bridging and penetrating encapsulants; pipe fittings; metal sleeves; polyvinyl chloride (PVC), canvas, and wet wraps; muslin with straps, fiber mesh cloth; mineral wool, and insulating cement; discussion of employee protection programs and staff training; case study in developing an O&M plan (development, implementation process, and problems that have been experienced).

(h) *Regulatory review.* Focusing on the OSHA Asbestos Construction Standard found at 29 CFR 1926.58; the National Emission Standard for Hazardous Air Pollutants (NESHAP) found at 40 CFR part 61, Subparts A (General Provisions) and M (National Emission Standard for Asbestos); EPA Worker Protection Rule found at 40 CFR part 763, subpart G; TSCA Title II; applicable State regulations.

(i) *Recordkeeping for the management planner.* Use of field inspector's data sheet along with laboratory results; on-going recordkeeping as a means to track asbestos disturbance; procedures for recordkeeping. EPA recommends that States require the use of standardized forms for purposes of management plans and incorporate the use of such forms into the initial training course for management planners.

(j) *Assembling and submitting the management plan.* Plan requirements for schools in TSCA Title II section 203(i)(1); the management plan as a planning tool.

(k) *Financing abatement actions.* Economic analysis and cost estimates; development of cost estimates; present costs of abatement versus future operation and maintenance costs; Asbestos School Hazard Abatement Act grants and loans.

(l) *Course review.* A review of key aspects of the training course.

5. PROJECT DESIGNER

A person must be accredited as a project designer to design any of the following activities with respect to friable ACBM in a school or public and commercial building: (1) A response action other than a SSSD maintenance activity, (2) a maintenance activity that disturbs friable ACBM other than a SSSD maintenance activity, or (3) a response action for a major fiber release episode. All persons seeking accreditation as a project designer shall complete at least a minimum

3–day training course as outlined below. The project designer course shall include lectures, demonstrations, a field trip, course review and a written examination.

EPA recommends the use of audiovisual materials to complement lectures, where appropriate.

The abatement project designer training course shall adequately address the following topics:

(a) *Background information on asbestos.* Identification of asbestos; examples and discussion of the uses and locations of asbestos in buildings; physical appearance of asbestos.

(b) *Potential health effects related to asbestos exposure.* Nature of asbestos-related diseases; routes of exposure; dose-response relationships and the lack of a safe exposure level; the synergistic effect between cigarette smoking and asbestos exposure; the latency period of asbestos-related diseases; a discussion of the relationship between asbestos exposure and asbestosis, lung cancer, mesothelioma, and cancers of other organs.

(c) *Overview of abatement construction projects.* Abatement as a portion of a renovation project; OSHA requirements for notification of other contractors on a multi-employer site (29 CFR 1926.58).

(d) *Safety system design specifications.* Design, construction, and maintenance of containment barriers and decontamination enclosure systems; positioning of warning signs; electrical and ventilation system lockout; proper working techniques for minimizing fiber release; entry and exit procedures for the work area; use of wet methods; proper techniques for initial cleaning; use of negative-pressure exhaust ventilation equipment; use of HEPA vacuums; proper clean-up and disposal of asbestos; work practices as they apply to encapsulation, enclosure, and repair; use of glove bags and a demonstration of glove bag use.

(e) *Field trip.* A visit to an abatement site or other suitable building site, including on-site discussions of abatement design and building walk-through inspection. Include discussion of rationale for the concept of functional spaces during the walk-through.

(f) *Employee personal protective equipment.* Classes and characteristics of respirator types; limitations of respirators; proper selection, inspection; donning, use, maintenance, and storage procedures for respirators; methods for field testing of the facepiece-to-face seal (positive and negative-pressure fit checks); qualitative and quantitative fit testing procedures; variability between field and laboratory protection factors that alter respiratory fit (e.g., facial hair); the components of a proper respiratory protection program; selection and use of personal protective clothing; use, storage, and handling of non-disposable clothing.

(g) *Additional safety hazards.* Hazards encountered during abatement activities and how to deal with them, including electrical hazards, heat stress, air contaminants other than asbestos, fire, and explosion hazards.

(h) *Fiber aerodynamics and control.* Aerodynamic characteristics of asbestos fibers; importance of proper containment barriers; settling time for asbestos fibers; wet methods in abatement; aggressive air monitoring following abatement; aggressive air movement and negative-pressure exhaust ventilation as a clean-up method.

(i) *Designing abatement solutions.* Discussions of removal, enclosure, and encapsulation methods; asbestos waste disposal.

(j) *Final clearance process.* Discussion of the need for a written sampling rationale for aggressive final air clearance; requirements of a complete visual inspection; and the relationship of the visual inspection to final air clearance.

EPA recommends the use of TEM for analysis of final air clearance samples. These samples should be analyzed by laboratories accredited under the NIST NVLAP.

(k) *Budgeting/cost estimating.* Development of cost estimates; present costs of abatement versus future operation and maintenance costs; setting priorities for abatement jobs to reduce costs.

(l) *Writing abatement specifications.* Preparation of and need for a written project design; means and methods specifications versus performance specifications; design of abatement in occupied buildings; modification of guide specifications for a particular building; worker and building occupant health/medical considerations; replacement of ACM with non-asbestos substitutes.

(m) *Preparing abatement drawings.* Significance and need for drawings, use of as-built drawings as base drawings; use of inspection photographs and on-site reports; methods of preparing abatement drawings; diagramming containment barriers; relationship of drawings to design specifications; particular problems related to abatement drawings.

(n) *Contract preparation and administration.*

(o) *Legal/liabilities/defenses.* Insurance considerations; bonding; hold-harmless clauses; use of abatement contractor's liability insurance; claims made versus occurrence policies.

(p) *Replacement.* Replacement of asbestos with asbestos-free substitutes.

(q) *Role of other consultants.* Development of technical specification sections by industrial hygienists or engineers; the multi-disciplinary team approach to abatement design.

(r) *Occupied buildings.* Special design procedures required in occupied buildings; education of occupants; extra monitoring recommendations; staging of work to minimize occupant exposure; scheduling of renovation to minimize exposure.

(s) *Relevant Federal, State, and local regulatory requirements, procedures and standards, including, but not limited to:*

(i) Requirements of TSCA Title II.

(ii) National Emission Standards for Hazardous Air Pollutants, (40 CFR part 61) subparts A (General Provisions) and M (National Emission Standard for Asbestos).

(iii) OSHA Respirator Standard found at 29 CFR 1910.134.

(iv) EPA Worker Protection Rule found at 40 CFR part 763, subpart G.

(v) OSHA Asbestos Construction Standard found at 29 CFR 1926.58.

(vi) OSHA Hazard Communication Standard found at 29 CFR 1926.59.

(t) *Course review*. A review of key aspects of the training course.

6. PROJECT MONITOR

EPA recommends that States adopt training and accreditation requirements for persons seeking to perform work as project monitors. Project monitors observe abatement activities performed by contractors and generally serve as a building owner's representative to ensure that abatement work is completed according to specification and in compliance with all relevant statutes and regulations. They may also perform the vital role of air monitoring for purposes of determining final clearance. EPA recommends that a State seeking to accredit individuals as project monitors consider adopting a minimum 5–day training course covering the topics outlined below. The course outlined below consists of lectures and demonstrations, at least 6 hours of hands-on training, course review, and a written examination. The hands-on training component might be satisfied by having the student simulate participation in or performance of any of the relevant job functions or activities (or by incorporation of the workshop component described in item ''n'' below of this unit).

EPA recommends that the project monitor training course adequately address the following topics:

(a) *Roles and responsibilities of the project monitor*. Definition and responsibilities of the project monitor, including regulatory/specification compliance monitoring, air monitoring, conducting visual inspections, and final clearance monitoring.

(b) *Characteristics of asbestos and asbestos-containing materials*. Typical uses of asbestos; physical appearance of asbestos; review of asbestos abatement and control techniques; presentation of the health effects of asbestos exposure, including routes of exposure, dose-response relationships, and latency periods for asbestos-related diseases.

(c) *Federal asbestos regulations*. Overview of pertinent EPA regulations, including: NESHAP, 40 CFR part 61, subparts A and M; AHERA, 40 CFR part 763, subpart E; and the EPA Worker Protection Rule, 40 CFR part 763, subpart G. Overview of pertinent OSHA regulations, including: Construction Industry Standard for Asbestos, 29 CFR 1926.58; Respirator Standard, 29 CFR 1910.134; and the Hazard Communication Standard, 29 CFR 1926.59. Applicable State and local asbestos regulations; regulatory interrelationships.

(d) *Understanding building construction and building systems*. Building construction basics, building physical plan layout; understanding building systems (HVAC, electrical, etc.); layout and organization, where asbestos is likely to be found on building systems; renovations and the effect of asbestos abatement on building systems.

(e) *Asbestos abatement contracts, specifications, and drawings*. Basic provisions of the contract; relationships between principle parties, establishing chain of command; types of specifications, including means and methods, performance, and proprietary and nonproprietary; reading and interpreting records and abatement drawings; discussion of change orders; common enforcement responsibilities and authority of project monitor.

(f) *Response actions and abatement practices*. Pre-work inspections; pre-work considerations, precleaning of the work area, removal of furniture, fixtures, and equipment; shutdown/modification of building systems; construction and maintenance of containment barriers, proper demarcation of work areas; work area entry/exit, hygiene practices; determining the effectiveness of air filtration equipment; techniques for minimizing fiber release, wet methods, continuous cleaning; abatement methods other than removal; abatement area clean-up procedures; waste transport and disposal procedures; contingency planning for emergency response.

(g) *Asbestos abatement equipment*. Typical equipment found on an abatement project; air filtration devices, vacuum systems, negative pressure differential monitoring; HEPA filtration units, theory of filtration, design/construction of HEPA filtration units, qualitative and quantitative performance of HEPA filtration units, sizing the ventilation requirements, location of HEPA filtration units, qualitative and quantitative tests of containment barrier integrity; best available technology.

(h) *Personal protective equipment*. Proper selection of respiratory protection; classes and characteristics of respirator types, limitations of respirators; proper use of other safety equipment, protective clothing selection, use, and proper handling, hard/bump hats, safety shoes; breathing air systems, high pressure v. low pressure, testing for Grade D air, determining proper backup air volumes.

(i) *Air monitoring strategies*. Sampling equipment, sampling pumps (low v. high volume), flow regulating devices (critical and

limiting orifices), use of fibrous aerosol monitors on abatement projects; sampling media, types of filters, types of cassettes, filter orientation, storage and shipment of filters; calibration techniques, primary calibration standards, secondary calibration standards, temperature/pressure effects, frequency of calibration, recordkeeping and field work documentation, calculations; air sample analysis, techniques available and limitations of AHERA on their use, transmission electron microscopy (background to sample preparation and analysis, air sample conditions which prohibit analysis, EPA's recommended technique for analysis of final air clearance samples), phase contrast microscopy (background to sample preparation, and AHERA's limits on the use of phase contrast microscopy), what each technique measures; analytical methodologies, AHERA TEM protocol, NIOSH 7400, OSHA reference method (non clearance), EPA recommendation for clearance (TEM); sampling strategies for clearance monitoring, types of air samples (personal breathing zone v. fixed-station area) sampling location and objectives (pre-abatement, during abatement, and clearance monitoring), number of samples to be collected, minimum and maximum air volumes, clearance monitoring (post-visual-inspection) (number of samples required, selection of sampling locations, period of sampling, aggressive sampling, interpretations of sampling results, calculations), quality assurance; special sampling problems, crawl spaces, acceptable samples for laboratory analysis, sampling in occupied buildings (barrier monitoring).

(j) *Safety and health issues other than asbestos.* Confined-space entry, electrical hazards, fire and explosion concerns, ladders and scaffolding, heat stress, air contaminants other than asbestos, fall hazards, hazardous materials on abatement projects.

(k) *Conducting visual inspections.* Inspections during abatement, visual inspections using the ASTM E1368 document; conducting inspections for completeness of removal; discussion of ''how clean is clean?''

(l) *Legal responsibilities and liabilities of project monitors.* Specification enforcement capabilities; regulatory enforcement; licensing; powers delegated to project monitors through contract documents.

(m) *Recordkeeping and report writing.* Developing project logs/daily logs (what should be included, who sees them); final report preparation; recordkeeping under Federal regulations.

(n) *Workshops (6 hours spread over 3 days).* Contracts, specifications, and drawings: This workshop could consist of each participant being issued a set of contracts, specifications, and drawings and then being asked to answer questions and make recommendations to a project architect, engineer or to the building owner based on given conditions and these documents.

Air monitoring strategies/asbestos abatement equipment: This workshop could consist of simulated abatement sites for which sampling strategies would have to be developed (i.e., occupied buildings, industrial situations). Through demonstrations and exhibition, the project monitor may also be able to gain a better understanding of the function of various pieces of equipment used on abatement projects (air filtration units, water filtration units, negative pressure monitoring devices, sampling pump calibration devices, etc.).

Conducting visual inspections: This workshop could consist, ideally, of an interactive video in which a participant is ''taken through'' a work area and asked to make notes of what is seen. A series of questions will be asked which are designed to stimulate a person's recall of the area. This workshop could consist of a series of two or three videos with different site conditions and different degrees of cleanliness.

C. Examinations

1. Each State shall administer a closed book examination or designate other entities such as State-approved providers of training courses to administer the closed-book examination to persons seeking accreditation who have completed an initial training course. Demonstration testing may also be included as part of the examination. A person seeking initial accreditation in a specific discipline must pass the examination for that discipline in order to receive accreditation. For example, a person seeking accreditation as an abatement project designer must pass the State's examination for abatement project designer.

States may develop their own examinations, have providers of training courses develop examinations, or use standardized examinations developed for purposes of accreditation under TSCA Title II. In addition, States may supplement standardized examinations with questions about State regulations. States may obtain commercially developed standardized examinations, develop standardized examinations independently, or do so in cooperation with other States, or with commercial or non-profit providers on a regional or national basis. EPA recommends the use of standardized, scientifically-validated testing instruments, which may be beneficial in terms of both promoting competency and in fostering accreditation reciprocity between States.

Each examination shall adequately cover the topics included in the training course for that discipline. Each person who completes a

training course, passes the required examination, and fulfills whatever other requirements the State imposes must receive an accreditation certificate in a specific discipline. Whether a State directly issues accreditation certificates, or authorizes training providers to issue accreditation certificates, each certificate issued to an accredited person must contain the following minimum information:

a. A unique certificate number

b. Name of accredited person

c. Discipline of the training course completed.

d. Dates of the training course.

e. Date of the examination.

f. An expiration date of 1 year after the date upon which the person successfully completed the course and examination.

g. The name, address, and telephone number of the training provider that issued the certificate.

h. A statement that the person receiving the certificate has completed the requisite training for asbestos accreditation under TSCA Title II.

States or training providers who reaccredit persons based upon completion of required refresher training must also provide accreditation certificates with all of the above information, except the examination date may be omitted if a State does not require a refresher examination for reaccreditation.

Where a State licenses accredited persons but has authorized training providers to issue accreditation certificates, the State may issue licenses in the form of photo-identification cards. Where this applies, EPA recommends that the State licenses should include all of the same information required for the accreditation certificates. A State may also choose to issue photo-identification cards in addition to the required accreditation certificates.

Accredited persons must have their initial and current accreditation certificates at the location where they are conducting work.

2. The following are the requirements for examination in each discipline:

a. Worker:

i. 50 multiple-choice questions

ii. Passing score: 70 percent correct

b. Contractor/Supervisor:

i. 100 multiple-choice questions

ii. Passing score: 70 percent correct

c. Inspector:

i. 50 Multiple-choice questions

ii. Passing score: 70 percent correct

d. Management Planner:

i. 50 Multiple-choice questions

ii. Passing score: 70 percent correct

e. Project Designer:

i. 100 multiple-choice questions

ii. Passing score: 70 percent correct

D. Continuing Education

For all disciplines, a State's accreditation program shall include annual refresher training as a requirement for reaccreditation as indicated below:

1. Workers: One full day of refresher training.

2. Contractor/Supervisors: One full day of refresher training.

3. Inspectors: One half-day of refresher training.

4. Management Planners: One half-day of inspector refresher training and one half-day of refresher training for management planners.

5. Project Designers: One full day of refresher training.

The refresher courses shall be specific to each discipline. Refresher courses shall be conducted as separate and distinct courses and not combined with any other training during the period of the refresher course. For each discipline, the refresher course shall review and discuss changes in Federal, State, and local regulations, developments in state-of-the-art procedures, and a review of key aspects of the initial training course as determined by the State. After completing the annual refresher course, persons shall have their accreditation extended for an additional year from the date of the refresher course. A State may consider requiring persons to pass reaccreditation examinations at specific intervals (for example, every 3 years).

EPA recommends that States formally establish a 12-month grace period to enable formerly accredited persons with expired certificates to complete refresher training and have their accreditation status reinstated without having to re-take the initial training course.

E. Qualifications

In addition to requiring training and an examination, a State may require candidates for accreditation to meet other qualification and/or experience standards that the State considers appropriate for some or all disciplines. States may choose to consider requiring qualifications similar to the examples outlined below for inspectors, management planners and project designers. States may modify these examples as appropriate. In addition, States may want to include some requirements based on experience in performing a task directly as a part of a job or in an apprenticeship role. They may also wish to consider additional criteria for the approval of training course instructors beyond those prescribed by EPA.

1. Inspectors: Qualifications - possess a high school diploma. States may want to require an Associate's Degree in specific fields (e.g., environmental or physical sciences).

2. Management Planners: Qualifications - Registered architect, engineer, or certified industrial hygienist or related scientific field.

3. Project Designers: Qualifications - registered architect, engineer, or certified industrial hygienist.

4. Asbestos Training Course Instructor: Qualifications - academic credentials and/or field experience in asbestos abatement.

EPA recommends that States prescribe minimum qualification standards for training instructors employed by training providers.

F. Recordkeeping Requirements for Training Providers

All approved providers of accredited asbestos training courses must comply with the following minimum recordkeeping requirements.

1. Training course materials. A training provider must retain copies of all instructional materials used in the delivery of the classroom training such as student manuals, instructor notebooks and handouts.

2. Instructor qualifications. A training provider must retain copies of all instructors' resumes, and the documents approving each instructor issued by either EPA or a State. Instructors must be approved by either EPA or a State before teaching courses for accreditation purposes. A training provider must notify EPA or the State, as appropriate, in advance whenever it changes course instructors. Records must accurately identify the instructors that taught each particular course for each date that a course is offered.

3. Examinations. A training provider must document that each person who receives an accreditation certificate for an initial training course has achieved a passing score on the examination. These records must clearly indicate the date upon which the exam was administered, the training course and discipline for which the exam was given, the name of the person who proctored the exam, a copy of the exam, and the name and test score of each person taking the exam. The topic and dates of the training course must correspond to those listed on that person's accreditation certificate. States may choose to apply these same requirements to examinations for refresher training courses.

4. Accreditation certificates. The training providers or States, whichever issues the accreditation certificate, shall maintain records that document the names of all persons who have been awarded certificates, their certificate numbers, the disciplines for which accreditation was conferred, training and expiration dates, and the training location. The training provider or State shall maintain the records in a manner that allows verification by telephone of the required information.

5. Verification of certificate information. EPA recommends that training providers of refresher training courses confirm that their students possess valid accreditation before granting course admission. EPA further recommends that training providers offering the initial management planner training course verify that students have met the prerequisite of possessing valid inspector accreditation at the time of course admission.

6. Records retention and access. (a) The training provider shall maintain all required records for a minimum of 3 years. The training provider, however, may find it advantageous to retain these records for a longer period of time.

(b) The training provider must allow reasonable access to all of the records required by the MAP, and to any other records which may be required by States for the approval of asbestos training providers or the accreditation of asbestos training courses, to both EPA and to State Agencies, on request. EPA encourages training providers to make this information equally accessible to the general public.

(c) If a training provider ceases to conduct training, the training provider shall notify the approving government body (EPA or the State) and give it the opportunity to take possession of that providers asbestos training records.

G. Deaccreditation

1. States must establish criteria and procedures for deaccrediting persons accredited as workers, contractor/supervisors, inspectors, management planners, and project designers. States must follow their own administrative procedures in pursuing deaccreditation actions. At a minimum, the criteria shall include:

(a) Performing work requiring accreditation at a job site without being in physical possession of initial and current accreditation certificates;

(b) Permitting the duplication or use of one's own accreditation certificate by another;

(c) Performing work for which accreditation has not been received; or

(d) Obtaining accreditation from a training provider that does not have approval to offer training for the particular discipline from either EPA or from a State that has a contractor accreditation plan at least as stringent as the EPA MAP.

EPA may directly pursue deaccreditation actions without reliance on State deaccreditation or enforcement authority or actions. In addition to the above-listed situations, the Administrator may suspend or revoke the accreditation of persons who have been subject to a final order imposing a civil penalty or convicted under section 16 of TSCA, 15 U.S.C. 2615 or 2647, for violations of 40 CFR part 763, or section 113 of the Clean

Air Act, 42 U.S.C. 7413, for violations of 40 CFR part 61, subpart M.

2. Any person who performs asbestos work requiring accreditation under section 206(a) of TSCA, 15 U.S.C. 2646(a), without such accreditation is in violation of TSCA. The following persons are not accredited for purposes of section 206(a) of TSCA:

(a) Any person who obtains accreditation through fraudulent representation of training or examination documents;

(b) Any person who obtains training documentation through fraudulent means;

(c) Any person who gains admission to and completes refresher training through fraudulent representation of initial or previous refresher training documentation; or

(d) Any person who obtains accreditation through fraudulent representation of accreditation requirements such as education, training, professional registration, or experience.

H. Reciprocity

EPA recommends that each State establish reciprocal arrangements with other States that have established accreditation programs that meet or exceed the requirements of the MAP. Such arrangements might address cooperation in licensing determinations, the review and approval of training programs and/or instructors, candidate testing and exam administration, curriculum development, policy formulation, compliance monitoring, and the exchange of information and data. The benefits to be derived from these arrangements include a potential cost-savings from the reduction of duplicative activity and the attainment of a more professional accredited workforce as States are able to refine and improve the effectiveness of their programs based upon the experience and methods of other States.

I. Electronic Reporting

States that choose to receive electronic documents must include, at a minimum, the requirements of 40 CFR Part 3—(Electronic reporting) in their programs.

II. EPA Approval Process for State Accreditation Programs

A. States may seek approval for a single discipline or all disciplines as specified in the MAP. For example, a State that currently only requires worker accreditation may receive EPA approval for that discipline alone. EPA encourages States that currently do not have accreditation requirements for all disciplines required under section 206(b)(2) of TSCA, 15 U.S.C. 2646(b)(2), to seek EPA approval for those disciplines the State does accredit. As States establish accreditation requirements for the remaining disciplines, the requested information outlined below should be submitted to EPA as soon as possible. Any State that had an accreditation program approved by EPA under an earlier version of the MAP may follow the same procedures to obtain EPA approval of their accreditation program under this MAP.

B. Partial approval of a State Program for the accreditation of one or more disciplines does not mean that the State is in full compliance with TSCA where the deadline for that State to have adopted a State Plan no less stringent than the MAP has already passed. State Programs which are at least as stringent as the MAP for one or more of the accredited disciplines may, however, accredit persons in those disciplines only.

C. States seeking EPA approval or reapproval of accreditation programs shall submit the following information to the Regional Asbestos Coordinator at their EPA Regional office:

1. A copy of the legislation establishing or upgrading the State's accreditation program (if applicable).

2. A copy of the State's accreditation regulations or revised regulations.

3. A letter to the Regional Asbestos Coordinator that clearly indicates how the State meets the program requirements of this MAP. Addresses for each of the Regional Asbestos Coordinators are shown below:

EPA, Region I, (OES05–1) Asbestos Coordinator, 5 Post Office Square—Suite 100, Boston, MA 02109–3912, (617) 918–1016.

EPA, Region II, (MS-500), Asbestos Coordinator, 2890 Woodbridge Ave., Edison, NJ 08837-3679, (908) 321-6671.

EPA, Region III, (3AT-33), Asbestos Coordinator, 841 Chestnut Bldg., Philadelphia, PA 19107, (215) 597-3160.

EPA, Region IV, Asbestos Coordinator, 345 Courtland St., N.E., Atlanta, GA 30365, (404) 347-5014.

EPA, Region V, (SP-14J), Asbestos Coordinator, 77 W. Jackson Blvd., Chicago, IL 60604-3590, (312) 886-6003.

EPA, Region VI, (6T-PT), Asbestos Coordinator, 1445 Ross Ave. Dallas, TX 75202-2744, (214) 655-7244.

EPA, Region VII, (WWPD/TOPE), Asbestos Coordinator, U.S. Environmental Protection Agency, 11201 Renner Boulevard, Lenexa, Kansas 66219. (800) 223–0425 or (913) 551–7122.

EPA, Region VIII, (8AT-TS), Asbestos Coordinator, 1 Denver Place, Suite 500 999 - 18th St., Denver, CO 80202-2405, (303) 293-1442.

EPA, Region IX, Asbestos NESHAPs Contact, Air Division (A–5), 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3989.

EPA, Region X, (AT-083), Asbestos Coordinator, 1200 Sixth Ave., Seattle, WA 98101, (206) 553-4762.

EPA maintains a listing of all those States that have applied for and received EPA approval for having accreditation requirements that are at least as stringent as the MAP for

one or more disciplines. Any training courses approved by an EPA-approved State Program are considered to be EPA-approved for purposes of accreditation.

III. Approval of Training Courses

Individuals or groups wishing to sponsor training courses for disciplines required to be accredited under section 206(b)(1)(A) of TSCA, 15 U.S.C. 2646(b)(1)(A), may apply for approval from States that have accreditation program requirements that are at least as stringent as this MAP. For a course to receive approval, it must meet the requirements for the course as outlined in this MAP, and any other requirements imposed by the State from which approval is being sought. Courses that have been approved by a State with an accreditation program at least as stringent as this MAP are approved under section 206(a) of TSCA, 15 U.S.C. 2646(a), for that particular State, and also for any other State that does not have an accreditation program as stringent as this MAP.

A. Initial Training Course Approval

A training provider must submit the following minimum information to a State as part of its application for the approval of each training course:

1. The course provider's name, address, and telephone number.

2. A list of any other States that currently approve the training course.

3. The course curriculum.

4. A letter from the provider of the training course that clearly indicates how the course meets the MAP requirements for:

a. Length of training in days.

b. Amount and type of hands-on training.

c. Examination (length, format, and passing score).

d. Topics covered in the course.

5. A copy of all course materials (student manuals, instructor notebooks, handouts, etc.).

6. A detailed statement about the development of the examination used in the course.

7. Names and qualifications of all course instructors. Instructors must have academic and/or field experience in asbestos abatement.

8. A description of and an example of the numbered certificates issued to students who attend the course and pass the examination.

B. Refresher Training Course Approval

The following minimum information is required for approval of refresher training courses by States:

1. The length of training in half-days or days.

2. The topics covered in the course.

3. A copy of all course materials (student manuals, instructor notebooks, handouts, etc.).

4. The names and qualifications of all course instructors. Instructors must have academic and/or field experience in asbestos abatement.

5. A description of and an example of the numbered certificates issued to students who complete the refresher course and pass the examination, if required.

C. Withdrawal of Training Course Approval

States must establish criteria and procedures for suspending or withdrawing approval from accredited training programs. States should follow their own administrative procedures in pursuing actions for suspension or withdrawal of approval of training programs. At a minimum, the criteria shall include:

(1) Misrepresentation of the extent of a training course's approval by a State or EPA;

(2) Failure to submit required information or notifications in a timely manner;

(3) Failure to maintain requisite records;

(4) Falsification of accreditation records, instructor qualifications, or other accreditation information; or

(5) Failure to adhere to the training standards and requirements of the EPA MAP or State Accreditation Program, as appropriate.

In addition to the criteria listed above, EPA may also suspend or withdraw a training course's approval where an approved training course instructor, or other person with supervisory authority over the delivery of training has been found in violation of other asbestos regulations administered by EPA. An administrative or judicial finding of violation, or execution of a consent agreement and order under 40 CFR 22.18, constitutes evidence of a failure to comply with relevant statutes or regulations. States may wish to adopt this criterion modified to include their own asbestos statutes or regulations. EPA may also suspend or withdraw approval of training programs where a training provider has submitted false information as a part of the self-certification required under Unit V.B. of the revised MAP.

Training course providers shall permit representatives of EPA or the State which approved their training courses to attend, evaluate, and monitor any training course without charge. EPA or State compliance inspection staff are not required to give advance notice of their inspections. EPA may suspend or withdraw State or EPA approval of a training course based upon the criteria specified in this Unit III.C.

IV. EPA Procedures for Suspension or Revocation of Accreditation or Training Course Approval.

A. If the Administrator decides to suspend or revoke the accreditation of any person or suspend or withdraw the approval of a training course, the Administrator will notify the affected entity of the following:

1. The grounds upon which the suspension, revocation, or withdrawal is based.

2. The time period during which the suspension, revocation, or withdrawal is effective, whether permanent or otherwise.

3. The conditions, if any, under which the affected entity may receive accreditation or approval in the future.

4. Any additional conditions which the Administrator may impose.

5. The opportunity to request a hearing prior to final Agency action to suspend or revoke accreditation or suspend or withdraw approval.

B. If a hearing is requested by the accredited person or training course provider pursuant to the preceding paragraph, the Administrator will:

1. Notify the affected entity of those assertions of law and fact upon which the action to suspend, revoke, or withdraw is based.

2. Provide the affected entity an opportunity to offer written statements of facts, explanations, comments, and arguments relevant to the proposed action.

3. Provide the affected entity such other procedural opportunities as the Administrator may deem appropriate to ensure a fair and impartial hearing.

4. Appoint an EPA attorney as Presiding Officer to conduct the hearing. No person shall serve as Presiding Officer if he or she has had any prior connection with the specific case.

C. The Presiding Officer appointed pursuant to the preceding paragraph shall:

1. Conduct a fair, orderly, and impartial hearing, without unnecessary delay.

2. Consider all relevant evidence, explanation, comment, and argument submitted pursuant to the preceding paragraph.

3. Promptly notify the affected entity of his or her decision and order. Such an order is a final Agency action.

D. If the Administrator determines that the public health, interest, or welfare warrants immediate action to suspend the accreditation of any person or the approval of any training course provider, the Administrator will:

1. Notify the affected entity of the grounds upon which the emergency suspension is based;

2. Notify the affected entity of the time period during which the emergency suspension is effective.

3. Notify the affected entity of the Administrator's intent to suspend or revoke accreditation or suspend or withdraw training course approval, as appropriate, in accordance with Unit IV.A. above. If such suspension, revocation, or withdrawal notice has not previously been issued, it will be issued at the same time the emergency suspension notice is issued.

E. Any notice, decision, or order issued by the Administrator under this section, and any documents filed by an accredited person or approved training course provider in a hearing under this section, shall be available to the public except as otherwise provided by section 14 of TSCA or by 40 CFR part 2. Any such hearing at which oral testimony is presented shall be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow presentation of information which may be entitled to confidential treatment under section 14 of TSCA or 40 CFR part 2.

V. Implementation Schedule

The various requirements of this MAP become effective in accordance with the following schedules:

A. Requirements applicable to State Programs

1. Each State shall adopt an accreditation plan that is at least as stringent as this MAP within 180 days after the commencement of the first regular session of the legislature of the State that is convened on or after April 4, 1994.

2. If a State has adopted an accreditation plan at least as stringent as this MAP as of April 4, 1994, the State may continue to:

a. Conduct TSCA training pursuant to this MAP.

b. Approve training course providers to conduct training and to issue accreditation that satisfies the requirements for TSCA accreditation under this MAP.

c. Issue accreditation that satisfies the requirements for TSCA accreditation under this MAP.

3. A State that had complied with an earlier version of the MAP, but has not adopted an accreditation plan at least as stringent as this MAP by April 4, 1994, may:

a. Conduct TSCA training which remains in compliance with the requirements of Unit V.B. of this MAP. After such training has been self-certified in accordance with Unit V.B. of this MAP, the State may issue accreditation that satisfies the requirement for TSCA accreditation under this MAP.

b. Sustain its approval for any training course providers to conduct training and issue TSCA accreditation that the State had approved before April 4, 1994, and that remain in compliance with Unit V.B. of this MAP.

c. Issue accreditation pursuant to an earlier version of the MAP that provisionally

satisfies the requirement for TSCA accreditation until October 4, 1994.

Such a State may not approve new TSCA training course providers to conduct training or to issue TSCA accreditation that satisfies the requirements of this MAP until the State adopts an accreditation plan that is at least as stringent as this MAP.

4. A State that had complied with an earlier version of the MAP, but fails to adopt a plan as stringent as this MAP by the deadline established in Unit V.A.1., is subject to the following after that deadline date:

a. The State loses any status it may have held as an EPA-approved State for accreditation purposes under section 206 of TSCA, 15 U.S.C. 2646.

b. All training course providers approved by the State lose State approval to conduct training and issue accreditation that satisfies the requirements for TSCA accreditation under this MAP.

c. The State may not:

i. Conduct training for accreditation purposes under section 206 of TSCA, 15 U.S.C. 2646.

ii. Approve training course providers to conduct training or issue accreditation that satisfies the requirements for TSCA accreditation; or

iii. Issue accreditation that satisfies the requirement for TSCA accreditation.

EPA will extend EPA-approval to any training course provider that loses State approval because the State does not comply with the deadline, so long as the provider is in compliance with Unit V.B. of this MAP, and the provider is approved by a State that had complied with an earlier version of the MAP as of the day before the State loses its EPA approval.

5. A State that does not have an accreditation program that satisfies the requirements for TSCA accreditation under either an earlier version of the MAP or this MAP, may not:

a. Conduct training for accreditation purposes under section 206 of TSCA, 15 U.S.C. 2646;

b. Approve training course providers to conduct training or issue accreditation that satisfies the requirements for TSCA accreditation; or

c. Issue accreditation that satisfies the requirement for TSCA accreditation.

B. Requirements applicable to Training Courses and Providers

As of October 4, 1994, an approved training provider must certify to EPA and to any State that has approved the provider for TSCA accreditation, that each of the provider's training courses complies with the requirements of this MAP. The written submission must document in specific detail the changes made to each training course in order to comply with the requirements of this MAP and clearly state that the provider is also in compliance with all other requirements of this MAP, including the new recordkeeping and certificate provisions. Each submission must include the following statement signed by an authorized representative of the training provider: ''Under civil and criminal penalties of law for the making or submission of false or fraudulent statements or representations (18 U.S.C. 1001 and 15 U.S.C. 2615), I certify that the training described in this submission complies with all applicable requirements of Title II of TSCA, 40 CFR part 763, Appendix C to subpart E, as revised, and any other applicable Federal, state, or local requirements.'' A consolidated self-certification submission from each training provider that addresses all of its approved training courses is permissible and encouraged.

The self-certification must be sent via registered mail, to EPA Headquarters at the following address: Attn. Self-Certification Program, Field Programs Branch, Chemical Management Division (7404), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. A duplicate copy of the complete submission must also be sent to any States from which approval had been obtained.

The timely receipt of a complete self-certification by EPA and all approving States shall have the effect of extending approval under this MAP to the training courses offered by the submitting provider. If a self-certification is not received by the approving government bodies on or before the due date, the affected training course is not approved under this MAP. Such training providers must then reapply for approval of these training courses pursuant to the procedures outlined in Unit III.

C. Requirements applicable to Accredited Persons.

Persons accredited by a State with an accreditation program no less stringent than an earlier version of the MAP or by an EPA-approved training provider as of April 3, 1994, are accredited in accordance with the requirements of this MAP, and are not required to retake initial training. They must continue to comply with the requirements for annual refresher training in Unit I.D. of the revised MAP.

D. Requirements applicable to Non-Accredited Persons.

In order to perform work requiring accreditation under TSCA Title II, persons who are not accredited by a State with an accreditation program no less stringent than an earlier version of the MAP or by an EPA-approved training provider as of April 3, 1994,

must comply with the upgraded training requirements of this MAP by no later than October 4, 1994. Non-accredited persons may obtain initial accreditation on a provisional basis by successfully completing any of the training programs approved under an earlier version of the MAP, and thereby perform work during the first 6 months after this MAP takes effect. However, by October 4, 1994, these persons must have successfully completed an upgraded training program that fully complies with the requirements of this MAP in order to continue to perform work requiring accreditation under section 206 of TSCA, 15 U.S.C. 2646.

[59 FR 5251, Feb. 3, 1994, as amended at 60 FR 31922, June 19, 1995; 70 FR 59889, Oct. 13, 2005; 75 FR 69353, Nov. 12, 2010; 76 FR 49674, Aug. 11, 2011; 78 FR 37978, June 25, 2013]

APPENDIX D TO SUBPART E OF PART 763—TRANSPORT AND DISPOSAL OF ASBESTOS WASTE

For the purposes of this appendix, transport is defined as all activities from receipt of the containerized asbestos waste at the generation site until it has been unloaded at the disposal site. Current EPA regulations state that there must be no visible emissions to the outside air during waste transport. However, recognizing the potential hazards and subsequent liabilities associated with exposure, the following additional precautions are recommended.

Recordkeeping. Before accepting wastes, a transporter should determine if the waste is properly wetted and containerized. The transporter should then require a chain-of-custody form signed by the generator. A chain-of-custody form may include the name and address of the generator, the name and address of the pickup site, the estimated quantity of asbestos waste, types of containers used, and the destination of the waste. The chain-of-custody form should then be signed over to a disposal site operator to transfer responsibility for the asbestos waste. A copy of the form signed by the disposal site operator should be maintained by the transporter as evidence of receipt at the disposal site.

Waste handling. A transporter should ensure that the asbestos waste is properly contained in leak-tight containers with appropriate labels, and that the outside surfaces of the containers are not contaminated with asbestos debris adhering to the containers. If there is reason to believe that the condition of the asbestos waste may allow significant fiber release, the transporter should not accept the waste. Improper containerization of wastes is a violation of the NESHAPs regulation and should be reported to the appropriate EPA Regional Asbestos NESHAPs contact below:

Region I

Asbestos NESHAPs Contact, Office of Environmental Stewardship, USEPA, Region I, 5 Post Office Square—Suite 100, Boston, MA 02109–3912, (617) 918–1551.

Region II

Asbestos NESHAPs Contact, Air & Waste Management Division, USEPA, Region II, 26 Federal Plaza, New York, NY 10007, (212) 264–6770.

Region III

Asbestos NESHAPs Contact, Air Management Division, USEPA, Region III, 841 Chestnut Street, Philadelphia, PA 19107, (215) 597–9325.

Region IV

Asbestos NESHAPs Contact, Air, Pesticide & Toxic Management, USEPA, Region IV, 345 Courtland Street, NE., Atlanta, GA 30365, (404) 347–4298.

Region V

Asbestos NESHAPs Contact, Air Management Division, USEPA, Region V, 77 West Jackson Boulevard, Chicago, IL 60604, (312) 353–6793.

Region VI

Asbestos NESHAPs Contact, Air & Waste Management Division, USEPA, Region VI, 1445 Ross Avenue, Dallas, TX 75202, (214) 655–7229.

Region VII

Asbestos NESHAPs Contact, Air and Waste Management Division, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219. (800) 223–0425 or (913) 551–7122.

Region VIII

Asbestos NESHAPs Contact, Air & Waste Management Division, USEPA, Region VIII, 999 18th Street, Suite 500, Denver, CO 80202, (303) 293–1814.

Region IX

Asbestos NESHAPs Contact, Air Division, USEPA, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3989.

Region X

Asbestos NESHAPs Contact, Air & Toxics Management Division, USEPA, Region X, 1200 Sixth Avenue, Seattle, WA 98101, (206) 442–2724.

Once the transporter is satisfied with the condition of the asbestos waste and agrees to handle it, the containers should be loaded into the transport vehicle in a careful manner to prevent breaking of the containers.

Similarly, at the disposal site, the asbestos waste containers should be transferred carefully to avoid fiber release.

Waste transport. Although there are no regulatory specifications regarding the transport vehicle, it is recommended that vehicles used for transport of containerized asbestos waste have an enclosed carrying compartment or utilize a canvas covering sufficient to contain the transported waste, prevent damage to containers, and prevent fiber release. Transport of large quantities of asbestos waste is commonly conducted in a 20-cubic-yard ''roll off'' box, which should also be covered. Vehicles that use compactors to reduce waste volume should not be used because these will cause the waste containers to rupture. Vacuum trucks used to transport waste slurry must be inspected to ensure that water is not leaking from the truck.

Disposal involves the isolation of asbestos waste material in order to prevent fiber release to air or water. Landfilling is recommended as an environmentally sound isolation method because asbestos fibers are virtually immobile in soil. Other disposal techniques such as incineration or chemical treatment are not feasible due to the unique properties of asbestos. EPA has established asbestos disposal requirements for active and inactive disposal sites under NESHAPs (40 CFR Part 61, subpart M) and specifies general requirements for solid waste disposal under RCRA (40 CFR Part 257). Advance EPA notification of the intended disposal site is required by NESHAPs.

Selecting a disposal facility. An acceptable disposal facility for asbestos wastes must adhere to EPA's requirements of no visible emissions to the air during disposal, or minimizing emissions by covering the waste within 24 hours. The minimum required cover is 6 inches of nonasbestos material, normally soil, or a dust-suppressing chemical. In addition to these Federal requirements, many state or local government agencies require more stringent handling procedures. These agencies usually supply a list of ''approved'' or licensed asbestos disposal sites upon request. Solid waste control agencies are listed in local telephone directories under state, county, or city headings. A list of state solid waste agencies may be obtained by calling the RCRA hotline: 1–800–424–9346 (382–3000 in Washington, DC). Some landfill owners or operators place special requirements on asbestos waste, such as placing all bagged waste into 55-gallon metal drums. Therefore, asbestos removal contractors should contact the intended landfill before arriving with the waste.

Receiving asbestos waste. A landfill approved for receipt of asbestos waste should require notification by the waste hauler that the load contains asbestos. The landfill operator should inspect the loads to verify that asbestos waste is properly contained in leak-tight containers and labeled appropriately. The appropriate EPA Regional Asbestos NESHAPs Contact should be notified if the landfill operator believes that the asbestos waste is in a condition that may cause significant fiber release during disposal. In situations when the wastes are not properly containerized, the landfill operator should thoroughly soak the asbestos with a water spray prior to unloading, rinse out the truck, and immediately cover the wastes with nonasbestos material prior to compacting the waste in the landfill.

Waste deposition and covering. Recognizing the health dangers associated with asbestos exposure, the following procedures are recommended to augment current federal requirements:

• Designate a separate area for asbestos waste disposal. Provide a record for future landowners that asbestos waste has been buried there and that it would be hazardous to attempt to excavate that area. (Future regulations may require property deeds to identify the location of any asbestos wastes and warn against excavation.)

• Prepare a separate trench to receive asbestos wastes. The size of the trench will depend upon the quantity and frequency of asbestos waste delivered to the disposal site. The trenching technique allows application of soil cover without disturbing the asbestos waste containers. The trench should be ramped to allow the transport vehicle to back into it, and the trench should be as narrow as possible to reduce the amount of cover required. If possible, the trench should be aligned perpendicular to prevailing winds.

• Place the asbestos waste containers into the trench carefully to avoid breaking them. Be particularly careful with plastic bags because when they break under pressure asbestos particles can be emitted.

• Completely cover the containerized waste within 24 hours with a minimum of 6 inches of nonasbestos material. Improperly containerized waste is a violation of the NESHAPs and EPA should be notified.

However, if improperly containerized waste is received at the disposal site, it should be covered immediately after unloading. Only after the wastes, including properly containerized wastes, are completely covered, can the wastes be compacted or other heavy equipment run over it. During compacting, avoid exposing wastes to the air or tracking asbestos material away from the trench.

• For final closure of an area containing asbestos waste, cover with at least an additional 30 inches of compacted nonasbestos material to provide a 36-inch final cover. To control erosion of the final cover, it should be properly graded and vegetated. In areas of the United States where excessive soil erosion may occur or the frost line exceeds 3 feet, additional final cover is recommended.

In desert areas where vegetation would be difficult to maintain, 3–6 inches of well graded crushed rock is recommended for placement on top of the final cover.

Controlling public access. Under the current NESHAPs regulation, EPA does not require that a landfill used for asbestos disposal use warning signs or fencing if it meets the requirement to cover asbestos wastes. However, under RCRA, EPA requires that access be controlled to prevent exposure of the public to potential health and safety hazards at the disposal site. Therefore, for liability protection of operators of landfills that handle asbestos, fencing and warning signs are recommended to control public access when natural barriers do not exist. Access to a landfill should be limited to one or two entrances with gates that can be locked when left unattended. Fencing should be installed around the perimeter of the disposal site in a manner adequate to deter access by the general public. Chain-link fencing, 6-ft high and topped with a barbed wire guard, should be used. More specific fencing requirements may be specified by local regulations. Warning signs should be displayed at all entrances and at intervals of 330 feet or less along the property line of the landfill or perimeter of the sections where asbestos waste is deposited. The sign should read as follows:

ASBESTOS WASTE DISPOSAL SITE
BREATHING ASBESTOS DUST MAY CAUSE LUNG DISEASE AND CANCER

Recordkeeping. For protection from liability, and considering possible future requirements for notification on disposal site deeds, a landfill owner should maintain documentation of the specific location and quantity of the buried asbestos wastes. In addition, the estimated depth of the waste below the surface should be recorded whenever a landfill section is closed. As mentioned previously, such information should be recorded in the land deed or other record along with a notice warning against excavation of the area.

[52 FR 41897, Oct. 30, 1987, as amended at 62 FR 1834, Jan. 14, 1997; 75 FR 69353, Nov. 12, 2010; 76 FR 49674, Aug. 11, 2011; 78 FR 37978, June 25, 2013]

APPENDIX E TO SUBPART E OF PART 763—INTERIM METHOD OF THE DETERMINATION OF ASBESTOS IN BULK INSULATION SAMPLES

SECTION 1. POLARIZED LIGHT MICROSCOPY

1.1 Principle and Applicability

Bulk samples of building materials taken for asbestos identification are first examined for homogeneity and preliminary fiber identification at low magnification. Positive identification of suspect fibers is made by analysis of subsamples with the polarized light microscope.

The principles of optical mineralogy are well established.[1] [2] A light microscope equipped with two polarizing filters is used to observe specific optical characteristics of a sample. The use of plane polarized light allows the determination of refractive indices along specific crystallographic axes. Morphology and color are also observed. A retardation plate is placed in the polarized light path for determination of the sign of elongation using orthoscopic illumination. Orientation of the two filters such that their vibration planes are perpendicular (crossed polars) allows observation of the birefringence and extinction characteristics of anisotropic particles.

Quantitative analysis involves the use of point counting. Point counting is a standard technique in petrography for determining the relative areas occupied by separate minerals in thin sections of rock. Background information on the use of point counting[2] and the interpretation of point count data[3] is available.

This method is applicable to all bulk samples of friable insulation materials submitted for identification and quantitation of asbestos components.

1.2 Range

The point counting method may be used for analysis of samples containing from 0 to 100 percent asbestos. The upper detection limit is 100 percent. The lower detection limit is less than 1 percent.

1.3 Interferences

Fibrous organic and inorganic constituents of bulk samples may interfere with the identification and quantitation of the asbestos mineral content. Spray-on binder materials may coat fibers and affect color or obscure optical characteristics to the extent of masking fiber identity. Fine particles of other materials may also adhere to fibers to an extent sufficient to cause confusion in identification. Procedures that may be used for the removal of interferences are presented in Section 1.7.2.2.

1.4 Precision and Accuracy

Adequate data for measuring the accuracy and precision of the method for samples with various matrices are not currently available. Data obtained for samples containing a single asbestos type in a simple matrix are available in the EPA report *Bulk Sample Analysis for Asbestos Content: Evaluation of the Tentative Method.*[4]

1.5 Apparatus

1.5.1 Sample Analysis

A low-power binocular microscope, preferably stereoscopic, is used to examine the bulk insulation sample as received.

- *Microscope:* binocular, 10–45X (approximate).
- *Light Source:* incandescent or fluorescent.
- *Forceps, Dissecting Needles, and Probes*
- *Glassine Paper or Clean Glass Plate*

Compound microscope requirements: A polarized light microscope complete with polarizer, analyzer, port for wave retardation plate, 360° graduated rotating stage, substage condenser, lamp, and lamp iris.

- *Polarized Light Microscope:* described above.
- *Objective Lenses:* 10X, 20X, and 40X or near equivalent.
- *Dispersion Staining Objective Lens* (optional)
- *Ocular Lens:* 10X minimum.
- *Eyepiece Reticle:* cross hair or 25 point Chalkley Point Array.
- *Compensator Plate:* 550 millimicron retardation.

1.5.2 Sample Preparation

Sample preparation apparatus requirements will depend upon the type of insulation sample under consideration. Various physical and/or chemical means may be employed for an adequate sample assessment.

- *Ventilated Hood* or negative pressure glove box.
- *Microscope Slides*
- *Coverslips*
- *Mortar and Pestle:* agate or porcelain. (optional)
- *Wylie Mill* (optional)
- *Beakers and Assorted Glassware* (optional)
- *Certrifuge* (optional)
- *Filtration apparatus* (optional)
- *Low temperature asher* (optional)

1.6 Reagents

1.6.1 Sample Preparation

- *Distilled Water (optional)*
- *Dilute CH_3COOH:* ACS reagent grade (optional)
- *Dilute HCl:* ACS reagent grade (optional)
- *Sodium metaphosphate* $(NaPO_3)_6$ (optional)

1.6.2 Analytical Reagents

Refractive Index Liquids: 1.490–1.570, 1.590–1.720 in increments of 0.002 or 0.004.

- *Refractive Index Liquids for Dispersion Staining:* high-dispersion series, 1.550, 1.605, 1.630 (optional).
- *UICC Asbestos Reference Sample Set:* Available from: UICC MRC Pneumoconiosis Unit, Llandough Hospital, Penarth, Glamorgan CF6 1XW, UK, and commercial distributors.
- *Tremolite-asbestos* (source to be determined)
- *Actinolite-asbestos* (source to be determined)

1.7 Procedures

NOTE: Exposure to airborne asbestos fibers is a health hazard. Bulk samples submitted for analysis are usually friable and may release fibers during handling or matrix reduction steps. All sample and slide preparations should be carried out in a ventilated hood or glove box with continuous airflow (negative pressure). Handling of samples without these precautions may result in exposure of the analyst and contamination of samples by airborne fibers.

1.7.1 Sampling

Samples for analysis of asbestos content shall be taken in the manner prescribed in Reference 5 and information on design of sampling and analysis programs may be found in Reference 6. If there are any questions about the representative nature of the sample, another sample should be requested before proceeding with the analysis.

1.7.2 Analysis

1.7.2.1 Gross Examination

Bulk samples of building materials taken for the identification and quantitation of asbestos are first examined for homogeneity at low magnification with the aid of a stereomicroscope. The core sample may be examined in its container or carefully removed from the container onto a glassine transfer paper or clean glass plate. If possible, note is made of the top and bottom orientation. When discrete strata are identified, each is treated as a separate material so that fibers are first identified and quantified in that layer only, and then the results for each layer are combined to yield an estimate of asbestos content for the whole sample.

1.7.2.2 Sample Preparation

Bulk materials submitted for asbestos analysis involve a wide variety of matrix materials. Representative subsamples may not be readily obtainable by simple means in heterogeneous materials, and various steps may be required to alleviate the difficulties encountered. In most cases, however, the best preparation is made by using forceps to sample at several places from the bulk material. Forcep samples are immersed in a refractive index liquid on a microscope slide, teased apart, covered with a cover glass, and observed with the polarized light microscope.

Alternatively, attempts may be made to homogenize the sample or eliminate interferences before further characterization. The selection of appropriate procedures is dependent upon the samples encountered and personal preference. The following are presented as possible sample preparation steps.

A mortar and pestle can sometimes be used in the size reduction of soft or loosely bound

materials though this may cause matting of some samples. Such samples may be reduced in a Wylie mill. Apparatus should be clean and extreme care exercised to avoid cross-contamination of samples. Periodic checks of the particle sizes should be made during the grinding operation so as to preserve any fiber bundles present in an identifiable form. These procedures are not recommended for samples that contain amphibole minerals or vermiculite. Grinding of amphiboles may result in the separation of fiber bundles or the production of cleavage fragments with aspect ratios greater than 3:1. Grinding of vermiculite may also produce fragments with aspect ratios greater than 3:1.

Acid treatment may occasionally be required to eliminate interferences. Calcium carbonate, gypsum, and bassanite (plaster) are frequently present in sprayed or trowelled insulations. These materials may be removed by treatment with warm dilute acetic acid. Warm dilute hydrochloric acid may also be used to remove the above materials. If acid treatment is required, wash the sample at least twice with distilled water, being careful not to lose the particulates during decanting steps. Centrifugation or filtration of the suspension will prevent significant fiber loss. The pore size of the filter should be 0.45 micron or less. Caution: prolonged acid contact with the sample may alter the optical characteristics of chrysotile fibers and should be avoided.

Coatings and binding materials adhering to fiber surfaces may also be removed by treatment with sodium metaphosphate.[7] Add 10 mL of 10g/L sodium metaphosphate solution to a small (0.1 to 0.5 mL) sample of bulk material in a 15-mL glass centrifuge tube. For approximately 15 seconds each, stir the mixture on a vortex mixer, place in an ultrasonic bath and then shake by hand. Repeat the series. Collect the dispersed solids by centrifugation at 1000 rpm for 5 minutes. Wash the sample three times by suspending in 10 mL distilled water and recentrifuging. After washing, resuspend the pellet in 5 mL distilled water, place a drop of the suspension on a microscope slide, and dry the slide at 110 °C.

In samples with a large portion of cellulosic or other organic fibers, it may be useful to ash part of the sample and view the residue. Ashing should be performed in a low temperature asher. Ashing may also be performed in a muffle furnace at temperatures of 500 °C or lower. Temperatures of 550 °C or higher will cause dehydroxylation of the asbestos minerals, resulting in changes of the refractive index and other key parameters. If a muffle furnace is to be used, the furnace thermostat should be checked and calibrated to ensure that samples will not be heated at temperatures greater than 550 °C.

Ashing and acid treatment of samples should not be used as standard procedures. In order to monitor possible changes in fiber characteristics, the material should be viewed microscopically before and after any sample preparation procedure. Use of these procedures on samples to be used for quantitation requires a correction for percent weight loss.

1.7.2.3 Fiber Identification

Positive identification of asbestos requires the determination of the following optical properties.

- Morphology
- Color and pleochroism
- Refractive indices
- Birefringence
- Extinction characteristics
- Sign of elongation

Table 1–1 lists the above properties for commercial asbestos fibers. Figure 1–1 presents a flow diagram of the examination procedure. Natural variations in the conditions under which deposits of asbestiform minerals are formed will occasionally produce exceptions to the published values and differences from the UICC standards. The sign of elongation is determined by use of the compensator plate and crossed polars. Refractive indices may be determined by the Becke line test. Alternatively, dispersion staining may be used. Inexperienced operators may find that the dispersion staining technique is more easily learned, and should consult Reference 9 for guidance. Central stop dispersion staining colors are presented in Table 1–2. Available high-dispersion (HD) liquids should be used.

TABLE 1–1—OPTICAL PROPERTIES OF ASBESTOC FIBERS

Mineral	Morphology, color[a]	Refractive indices[b]		Birefringence	Extinction	Sign of elonation
		α	γ			
Chrysotile (asbestiform serpentine).	Wavy fibers. Fiber bundles have splayed ends and "kinks". Aspect ratio typically >10:1. Colorless[3], nonpleochroic.	1.493–1.560	1.517–1.562[f] (normally 1.556).	.008	∥ to fiber length.	+ (length slow)

TABLE 1–1—OPTICAL PROPERTIES OF ASBESTOC FIBERS—Continued

Mineral	Morphology, color [a]	Refractive indices [b]		Birefringence	Extinction	Sign of elonation
		α	γ			
Amosite (asbestiform grunerite).	Straight, rigid fibers. Aspect ratio typically >10:1. Colorless to brown, nonpleochroic or weakly so. Opaque inclusions may be present.	1.635–1.696	1.655–1.729[f] (normally 1.696–1.710.	.020–.033	| to fiber length.	+ (length slow)
Crocidolite (asbestiform Riebeckite).	Straight, rigid fibers. Thick fibers and bundles common, blue to purple-blue in color. Pleochroic. Birefringence is generally masked by blue color.	1.654–1.701	1.668–1.717[3e] (normally close to 1.700).	.014–.016	| to fiber length.	– (length fast)
Anthophyllite-asbestos.	Straight fibers and acicular cleavage fragments.[d] Some composite fibers. Aspect ratio <10:1. Colorless to light brown.	1.596–1.652	1.615–1.676[f].	.019–.024	| to fiber length.	+ (length slow)
Tremolite-actinolite-asbestos.	Normally present as acicular or prismatic cleavage fragments.[d] Single crystals predominate, aspect ratio <10:1. Colorless to pale green.	1.599–1.668	1.622–1.688[f].	.023–.020	Oblique extinction, 10–20° for fragments. Composite fibers show | extinction.	+ (length slow)

[a] From reference 5; colors cited are seen by observation with plane polarized light.
[b] From references 5 and 8.
[c] Fibers subjected to heating may be brownish.
[d] Fibers defined as having aspect ratio >3:1.
[e] to fiber length.
[f] |To fiber length.

Polarized light microscopy analysis: For each type of material identified by examination of sample at low magnification. Mount spacially dispersed sample in 1.550 RI liquid. (If using dispersion staining, mount in 1.550 HD.) View at 100X with both plane polarized light and crossed polars. More than one fiber type may be present.

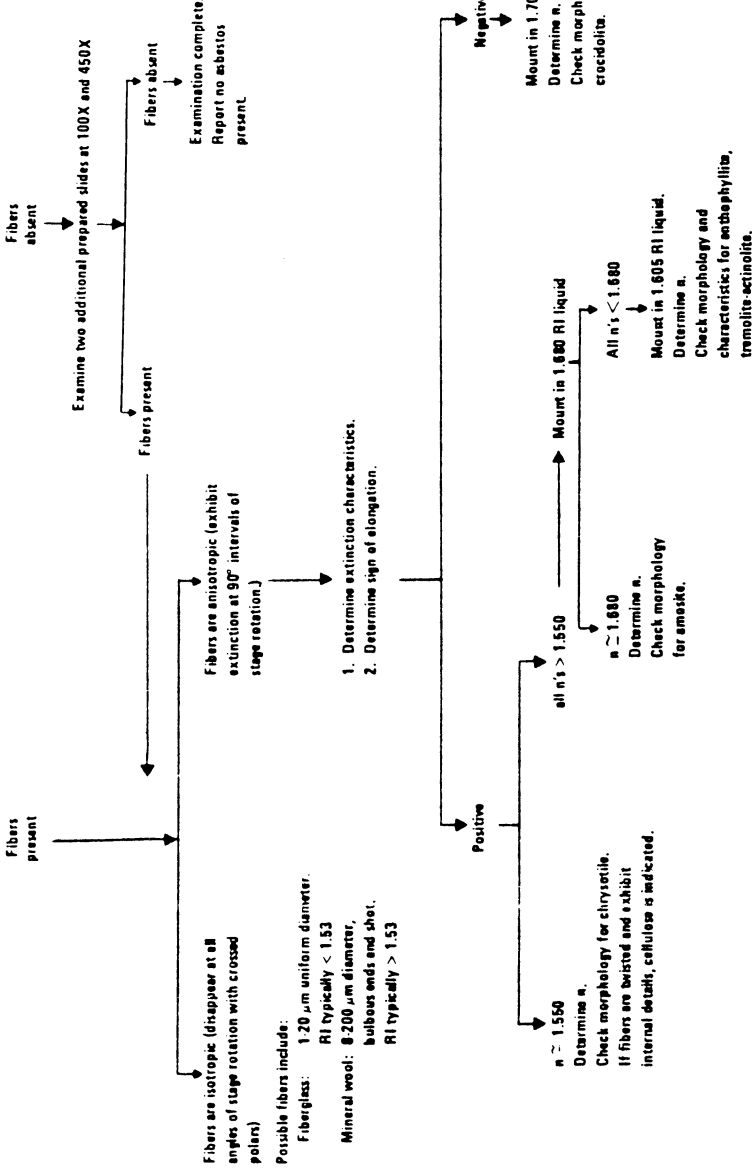


Figure 1-1. Flow chart for analysis of bulk samples by polarized light microscopy.

TABLE 1–2—CENTRAL STOP DISPERSION STAINING COLORS [A]

Mineral	RI Liquid	η	η|
Chrysotile	1.550 HD	Blue	Blue-magenta
Amosite	1.680	Blue-magenta to pale blue.	Golden-yellow
	1.550HD	Yellow to white.	Yellow to white
Crocidolite [b] ..	1.700	Red magenta	Blue-magenta
	1.550HD	Yellow to white.	Yellow to white
Anthophyllite	1.605HD	Blue	Gold to gold-magenta
Tremolite	1.605HD [c]	Pale blue	Gold
Actinolite	1.605HD	Gold-magenta to blue.	Gold
	1.630HD [c]	Magenta	Golden-yellow

[a] From reference 9.
[b] Blue absorption color.
[c] Oblique extinction view.

1.7.2.4 Quantitation of Asbestos Content

Asbestos quantitation is performed by a point-counting procedure or an equivalent estimation method. An ocular reticle (cross-hair or point array) is used to visually superimpose a point or points on the microscope field of view. Record the number of points positioned directly above each kind of particle or fiber of interest. Score only points directly over asbestos fibers or nonasbestos matrix material. Do not score empty points for the closest particle. If an asbestos fiber and a matrix particle overlap so that a point is superimposed on their visual intersection, a point is scored for both categories. Point counting provides a determination of the area percent asbestos. Reliable conversion of area percent to percent of dry weight is not currently feasible unless the specific gravities and relative volumes of the materials are known.

For the purpose of this method, ''asbestos fibers'' are defined as having an aspect ratio greater than 3:1 and being positively identified as one of the minerals in Table 1–1.

A total of 400 points superimposed on either asbestos fibers or nonasbestos matrix material must be counted over at least eight different preparations of representative subsamples. Take eight forcep samples and mount each separately with the appropriate refractive index liquid. The preparation should not be heavily loaded. The sample should be uniformly dispersed to avoid overlapping particles and allow 25–50 percent empty area within the fields of view. Count 50 nonempty points on each preparation, using either

- A cross-hair reticle and mechanical stage; or
- A reticle with 25 points (Chalkley Point Array) and counting at least 2 randomly selected fields.

For samples with mixtures of isotropic and anisotropic materials present, viewing the sample with slightly uncrossed polars or the addition of the compensator plate to the polarized light path will allow simultaneous discrimination of both particle types. Quantitation should be performed at 100X or at the lowest magnification of the polarized light microscope that can effectively distinguish the sample components. Confirmation of the quantitation result by a second analyst on some percentage of analyzed samples should be used as standard quality control procedure.

The percent asbestos is calculated as follows:

% asbestos = (a/n) 100%

where

a = number of asbestos counts,
n = number of nonempty points counted (400).

If a = 0, report ''No asbestos detected.'' If $0<a\leq3$, report ''<1% asbestos''.

The value reported should be rounded to the nearest percent.

1.8 References

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SECTION 2. X-RAY POWDER DIFFRACTION

2.1 Principle and Applicability

The principle of X-ray powder diffraction (XRD) analysis is well established.[1 2] Any solid, crystalline material will diffract an impingent beam of parallel, monochromatic X-rays whenever Bragg's Law,

$\lambda = 2d \sin \theta$,

is satisfied for a particular set of planes in the crystal lattice, where

λ = the X-ray wavelength, Å;
d = the interplanar spacing of the set of reflecting lattice planes, Å; and
θ = the angle of incidence between the X-ray beam and the reflecting lattice planes.

By appropriate orientation of a sample relative to the incident X-ray beam, a diffraction pattern can be generated that, in most cases, will be uniquely characteristic of both the chemical composition and structure of the crystalline phases present.

Unlike optical methods of analysis, however, XRD cannot determine crystal morphology. Therefore, in asbestos analysis, XRD does not distinguish between fibrous and nonfibrous forms of the serpentine and amphibole minerals (Table 2–1). However, when used in conjunction with optical methods such as polarized light microscopy (PLM), XRD techniques can provide a reliable analytical method for the identification and characterization of asbestiform minerals in bulk materials.

For *qualitative analysis* by XRD methods, samples are initially scanned over limited diagnostic peak regions for the serpentine (~7.4 Å) and amphibole (8.2–8.5 Å) minerals (Table 2–2). Standard slow-scanning methods for bulk sample analysis may be used for materials shown by PLM to contain significant amounts of asbestos (>5–10 percent). Detection of minor or trace amounts of asbestos may require special sample preparation and step-scanning analysis. All samples that exhibit diffraction peaks in the diagnostic regions for asbestiform minerals are submitted to a full (5°–60° 2θ; 1° 2θ/min) qualitative XRD scan, and their diffraction patterns are compared with standard reference powder diffraction patterns[3] to verify initial peak assignments and to identify possible matrix interferences when subsequent quantitative analysis will be performed.

TABLE 2–1—THE ASBESTOS MINERALS AND THEIR NONASBESTIFORM ANALOGS

Asbestiform	Nonasbestiform
SERPENTINE	
Chrysotile	Antigorite, lizardite
AMPHIBOLE	
Anthophyllite asbestos	Anthophyllite
Cummingtonite-grunerite asbestos ("Amosite")	Cummingtonite-grunerite
Crocidolite	Riebeckite
Tremolite asbestos	Tremolite
Actinolite asbestos	Actinolite

TABLE 2–2—PRINCIPAL LATTICE SPACINGS OF ASBESTIFORM MINERALS[A]

Minerals	Principal d-spacings (Å) and relative intensities			JCPDS Powder diffraction file[3] number
Chrysotile	7.37_{100}	3.65_{70}	4.57_{50}	21–543[b]
	7.36_{100} ..	3.66_{80}	2.45_{65}	25–645
	7.10_{100} ..	2.33_{80}	3.55_{70}	22–1162 (theoretical)
"Amosite"	8.33_{100}	3.06_{70}	2.756_{70}	17–745 (nonfibrous)
	8.22_{100} ..	3.060_{85}	3.25_{70}	27–1170 (UICC)
Anthophyllite	3.05_{100}	3.24_{60}	8.26_{55}	9–455
	3.06_{100} ..	8.33_{70}	3.23_{50}	16–401 (synthetic)
Anthophyllite	2.72_{100}	2.54_{100}	3.480_{80}	25–157
Crocidolite	8.35_{100}	3.10_{55}	2.720_{35}	27–1415 (UICC)
Tremolite	8.38_{100}	3.12_{100}	2.705_{90}	13–437[b]
	2.706_{100}	3.14_{95}	8.43_{40}	20–1310[b] (synthetic)
	3.13_{100} ..	2.706_{60}	8.44_{40}	23–666 (synthetic mixture with richterite)

[a] This information is intended as a guide, only. Complete powder diffraction data, including mineral type and source, should be referred to, to ensure comparability of sample and reference materials where possible. Additional precision XRD data on amosite, crocidolite, tremolite, and chrysotile are available from the U.S. Bureaus of Mines.[4]
[b] Fibrosity questionable.

Accurate *quantitative analysis* of asbestos in bulk samples by XRD is critically dependent on particle size distribution, crystallite size, preferred orientation and matrix absorption effects, and comparability of standard reference and sample materials. The most intense diffraction peak that has been shown to be free from interference by prior qualitative XRD analysis is selected for quantitation of each asbestiform mineral. A ''thin-layer'' method of analysis[5 6] is recommended in which, subsequent to comminution of the bulk material to ~10 μm by suitable cryogenic milling techniques, an accurately known amount of the sample is deposited on a silver membrane filter. The

mass of asbestiform material is determined by measuring the integrated area of the selected diffraction peak using a step-scanning mode, correcting for matrix absorption effects, and comparing with suitable calibration standards. Alternative ''thick-layer'' or bulk methods,[7 8] may be used for *semi-quantitative analysis*.

This XRD method is applicable as a confirmatory method for identification and quantitation of asbestos in bulk material samples that have undergone prior analysis by PLM or other optical methods.

2.2 Range and Sensitivity

The range of the method has not been determined.

The sensitivity of the method has not been determined. It will be variable and dependent upon many factors, including matrix effects (absoprtion and interferences), diagnostic reflections selected, and their relative intensities.

2.3 Limitations

2.3.1 Interferences

Since the fibrous and nonfibrous forms of the serpentine and amphibole minerals (Table 2–1) are indistinguishable by XRD techniques unless special sample preparation techniques and instrumentation are used,[9] the presence of nonasbestiform serpentines and amphiboles in a sample will pose severe interference problems in the identification and quantitative analysis of their asbestiform analogs.

The use of XRD for identification and quantitation of asbestiform minerals in bulk samples may also be limited by the presence of other interfering materials in the sample. For naturally occurring materials the commonly associated asbestos-related mineral interferences can usually be anticipated. However, for fabricated materials the nature of the interferences may vary greatly (Table 2–3) and present more serious problems in identification and quantitation.[10] Potential interferences are summarized in Table 2–4 and include the following:

- *Chlorite* has major peaks at 7.19 Å and 3.58 Å That interfere with both the primary (7.36 Å) and secondary (3.66 Å) peaks for chrysotile. Resolution of the primary peak to give good quantitative results may be possible when a step-scanning mode of operation is employed.
- *Halloysite* has a peak at 3.63 Å that interferes with the secondary (3.66 Å) peak for chrysotile.
- *Kaolinite* has a major peak at 7.15 Å that may interfere with the primary peak of chrysotile at 7.36 Å when present at concentrations of >10 percent. However, the secondary chrysotile peak at 3.66 Å may be used for quantitation.
- *Gypsum* has a major peak at 7.5 Å that overlaps the 7.36 Å peak of chrysotile when present as a major sample constituent. This may be removed by careful washing with distilled water, or be heating to 300 °C to convert gypsum to plaster of paris.
- *Cellulose* has a broad peak that partially overlaps the secondary (3.66 Å) chrysotile peak.[8]
- Overlap of major diagnostic peaks of the amphibole asbestos minerals, amosite, anthophyllite, crocidolite, and tremolite, at approximately 8.3 Å and 3.1 Å causes mutual interference when these minerals occur in the presence of one another. In some instances, adequate resolution may be attained by using step-scanning methods and/or by decreasing the collimator slit width at the X-ray port.

TABLE 2–3—COMMON CONSTITUENTS IN INSULATION AND WALL MATERIALS

A. Insulation materials

Chrysotile
''Amosite''
Crocidolite
*Rock wool
*Slag wool
*Fiber glass
Gypsum ($CaSO_4 \cdot 2H_2O$)
Vermiculite (micas)
*Perlite
Clays (kaolin)
*Wood pulp
*Paper fibers (talc, clay, carbonate fillers)
Calcium silicates (synthetic)
Opaques (chromite, magnetite inclusions in serpentine)
Hematite (inclusions in ''amosite'')
Magnesite
*Diatomaceous earth

B. Spray finishes or paints

Bassanite
Carbonate minerals (calcite, dolomite, vaterite)
Talc
Tremolite
Anthophyllite
Serpentine (including chrysotile)
Amosite
Crocidolite
*Mineral wool
*Rock wool
*Slag wool
*Fiber glass
Clays (kaolin)
Micas
Chlorite
Gypsum ($CaSO_4 \cdot 2H_2O$)
Quartz
*Organic binders and thickeners
Hyrdomagnesite
Wollastonite
Opaques (chromite, magnetite inclusions in serpentine)
Hematite (inclusions in ''amosite'')

*Amorphous materials___contribute only to overall scattered radiation and increased background radiation.

TABLE 2–4—INTERFERENCES IN XRD ANALYSIS ASBESTIFORM MINERALS

Asbestiform mineral	Primary diagnostic peaks (approximate d-spacings, in A)	Interference
Serpentine		
Chrysotile	7.4	Nonasbestiform serpentines (antigorite, lizardite)
		Chlorite
		Kaolinite
		Gypsum
	3.7	Chlorite
		Halloysite
		Cellulose
Amphibole		
"Amosite" Anthophyllite Crocidolite Tremolite	3.1	Nonasbestiform amphiboles (cummingtonite-grunerite, anthophyllite, riebeckite, tremolite)
		Mutual interferences
		Carbonates
		Talc
	8.3	Mutual interferences

- *Carbonates* may also interfere with quantitative analysis of the amphibole asbestos minerals, amosite, anthophyllite, crocidolite, and tremolite. Calcium carbonate ($CaCO_3$) has a peak at 3.035 Å that overlaps major amphibole peaks at approximately 3.1 Å when present in concentrations of >5 percent. Removal of carbonates with a dilute acid wash is possible; however, if present, chrysotile may be partially dissolved by this treatment.[11]
- A major *talc* peak at 3.12 Å interferes with the primary tremolite peak at this same position and with secondary peaks of crocidolite (3.10 Å), amosite (3.06 Å), and anthophyllite (3.05 Å). In the presence of talc, the major diagnostic peak at approximately 8.3 Å should be used for quantitation of these asbestiform minerals.

The problem of intraspecies and matrix interferences is further aggravated by the variability of the silicate mineral powder diffraction patterns themselves, which often makes definitive identification of the asbestos minerals by comparison with standard reference diffraction patterns difficult. This variability results from alterations in the crystal lattice associated with differences in isomorphous substitution and degree of crystallinity. This is especially true for the amphiboles. These minerals exhibit a wide variety of very similar chemical compositions, with the result being that their diffraction patterns are chracterized by having major (110) reflections of the monoclinic amphiboles and (210) reflections of the orthorhombic anthophyllite separated by less than 0.2 Å.[12]

2.3.2 Matrix Effects

If a copper X-ray source is used, the presence of iron at high concentrations in a sample will result in significant X-ray fluorescence, leading to loss of peak intensity along with increased background intensity and an overall decrease in sensitivity. This situation may be corrected by choosing an X-ray source other than copper; however, this is often accompanied both by loss of intensity and by decreased resolution of closely spaced reflections. Alternatively, use of a diffracted beam monochromator will reduce background fluorescent raditation, enabling weaker diffraction peaks to be detected.

X-ray absorption by the sample matrix will result in overall attenuation of the diffracted beam and may seriously interfere with quantitative analysis. Absorption effects may be minimized by using sufficiently "thin" samples for analysis.[5 13 14] However, unless absorption effects are known to be the same for both samples and standards, appropriate corrections should be made by referencing diagnostic peak areas to an internal standard[7 8] or filter substrate (Ag) peak.[5 6]

2.3.3 Particle Size Dependence

Because the intensity of diffracted X-radiation is particle-size dependent, it is essential for accurate quantitative analysis that both sample and standard reference materials have similar particle size distributions. The optimum particle size range for quantitative analysis of asbestos by XRD has been reported to be 1 to 10 μm.[15] Comparability of sample and standard reference material particle size distributions should be verified by optical microscopy (or another suitable method) prior to analysis.

2.3.4 Preferred Orientation Effects

Preferred orientation of asbestiform minerals during sample preparation often poses a serious problem in quantitative analysis by XRD. A number of techniques have been developed for reducing preferred orientation effects in "thick layer" samples.[7 8 15] However, for "thin" samples on membrane filters, the preferred orientation effects seem to be both reproducible and favorable to enhancement of the principal diagnostic reflections of asbestos minerals, actually increasing the overall sensitivity of the method.[12 14] (Further investigation into preferred orientation effects in both thin layer and bulk samples is required.)

2.3.5 Lack of Suitably Characterized Standard Materials

The problem of obtaining and characterizing suitable reference materials for asbestos analysis is clearly recognized. NIOSH has

recently directed a major research effort toward the preparation and characterization of analytical reference materials, including asbestos standards;[16] [17] however, these are not available in large quantities for routine analysis.

In addition, the problem of ensuring the comparability of standard reference and sample materials, particularly regarding crystallite size, particle size distribution, and degree of crystallinity, has yet to be adequately addressed. For example, Langer et al.[18] have observed that in insulating matrices, chrysotile tends to break open into bundles more frequently than amphiboles. This results in a line-broadening effect with a resultant decrease in sensitivity. Unless this effect is the same for both standard and sample materials, the amount of chrysotile in the sample will be underestimated by XRD analysis. To minimize this problem, it is recommended that standardized matrix reduction procedures be used for both sample and standard materials.

2.4 Precision and Accuracy

Precision of the method has not been determined.

Accuracy of the method has not been determined.

2.5 Apparatus

2.5.1 Sample Preparation

Sample preparation apparatus requirements will depend upon the sample type under consideration and the kind of XRD analysis to be performed.

- *Mortar and Pestle:* Agate or porcelain.
- *Razor Blades*
- *Sample Mill:* SPEX, Inc., freezer mill or equivalent.
- *Bulk Sample Holders*
- *Silver Membrane Filters:* 25-mm diameter, 0.45-μm pore size. Selas Corp. of America, Flotronics Div., 1957 Pioneer Road, Huntington Valley, PA 19006.
- *Microscope Slides*
- *Vacuum Filtration Apparatus:* Gelman No. 1107 or equivalent, and side-arm vacuum flask.
- *Microbalance*
- *Ultrasonic Bath or Probe:* Model W140, Ultrasonics, Inc., operated at a power density of approximately 0.1 W/mL, or equivalent.
- *Volumetric Flasks:* 1–L volume.
- *Assorted Pipettes*
- *Pipette Bulb*
- *Nonserrated Forceps*
- *Polyethylene Wash Bottle*
- *Pyrex Beakers:* 50-mL volume.
- *Desiccator*
- *Filter Storage Cassettes*
- *Magnetic Stirring Plate and Bars*
- *Porcelain Crucibles*
- *Muffle Furnace or Low Temperature Asher*

2.5.2 Sample Analysis

Sample analysis requirements include an X-ray diffraction unit, equipped with:

- *Constant Potential Generator; Voltage and mA Stabilizers*
- *Automated Diffractometer with Step-Scanning Mode*
- *Copper Target X-Ray Tube:* High intensity, fine focus, preferably.
- *X-Ray Pulse Height Selector*
- *X-Ray Detector* (with high voltage power supply): Scintillation or proportional counter.
- *Focusing Graphite Crystal Monochromator;* or *Nickel Filter* (if copper source is used, and iron fluorescence is not a serious problem).
- *Data Output Accessories:*
  - *Strip Chart Recorder*
  - *Decade Scaler/Timer*
  - *Digital Printer*
- *Sample Spinner* (optional).
- *Instrument Calibration Reference Specimen:* α-quartz reference crystal (Arkansas quartz standard, #180–147–00, Philips Electronics Instruments, Inc., 85 McKee Drive, Mahwah, NJ 07430) or equivalent.

2.6 Reagents

2.6.1 Standard Reference Materials

The reference materials listed below are intended to serve as a guide. Every attempt should be made to acquire pure reference materials that are comparable to sample materials being analyzed.

- *Chrysotile:* UICC Canadian, or NIEHS Plastibest. (UICC reference materials available from: UICC, MRC Pneumoconiosis Unit, Llandough Hospital, Penarth, Glamorgan, CF61XW, UK).
- *Crocidolite:* UICC
- *Amosite:* UICC
- *Anthophyllite:* UICC
- *Tremolite Asbestos:* Wards Natural Science Establishment, Rochester, N.Y.; Cyprus Research Standard, Cyprus Research, 2435 Military Ave., Los Angeles, CA 90064 (washed with dilute HCl to remove small amount of calcite impurity); India tremolite, Rajasthan State, India.
- *Actinolite Asbestos*

2.6.2 Adhesive

Tape, petroleum jelly, etc. (for attaching silver membrane filters to sample holders).

2.6.3 Surfactant

1 percent aerosol OT aqueous solution or equivalent.

2.6.4 Isopropanol

ACS Reagent Grade.

2.7 Procedure

2.7.1 Sampling

Samples for analysis of asbestos content shall be collected as specified in EPA Guidance Document #C0090, *Asbestos-Containing Materials in School Buildings.*[10]

2.7.2 Analysis

All samples must be analyzed initially for asbestos content by PLM. XRD should be used as an auxiliary method when a second, independent analysis is requested.

NOTE: Asbestos is a toxic substance. All handling of dry materials should be performed in an operating fume hood.

2.7.2.1 Sample Preparation

The method of sample preparation required for XRD analysis will depend on: (1) The condition of the sample received (sample size, homogeneity, particle size distribution, and overall composition as determined by PLM); and (2) the type of XRD analysis to be performed (qualitative, quantitative, thin layer or bulk).

Bulk materials are usually received as inhomogeneous mixtures of complex composition with very wide particle size distributions. Preparation of a homogeneous, representative sample from asbestos-containing materials is particularly difficult because the fibrous nature of the asbestos minerals inhibits mechanical mixing and stirring, and because milling procedures may cause adverse lattice alterations.

A discussion of specific matrix reduction procedures is given below. Complete methods of sample preparation are detailed in Sections 2.7.2.2 and 2.7.2.3.

NOTE: All samples should be examined microscopically before and after each matrix reduction step to monitor changes in sample particle size, composition, and crystallinity, and to ensure sample representativeness and homogeneity for analysis.

2.7.2.1.1 *Milling*— Mechanical milling of asbestos materials has been shown to decrease fiber crystallinity, with a resultant decrease in diffraction intensity of the specimen; the degree of lattice alteration is related to the duration and type of milling process.[19 22] Therefore, all milling times should be kept to a minimum.

For *qualitative analysis,* particle size is not usually of critical importance and initial characterization of the material with a minimum of matrix reduction is often desirable to document the composition of the sample as received. Bulk samples of very large particle size (>2–3 mm) should be comminuted to ~100 μm. A mortar and pestle can sometimes be used in size reduction of soft or loosely bound materials though this may cause matting of some samples. Such samples may be reduced by cutting with a razor blade in a mortar, or by grinding in a suitable mill (e.g., a microhammer mill or equivalent). When using a mortar for grinding or cutting, the sample should be moistened with ethanol, or some other suitable wetting agent, to minimize exposures.

For accurate, reproducible *quantitative analysis,* the particle size of both sample and standard materials should be reduced to ~10 μm (see Section 2.3.3). Dry ball milling at liquid nitrogen temperatures (e.g., Spex Freezer Mill, or equivalent) for a maximum time of 10 min. is recommended to obtain satisfactory particle size distributions while protecting the integrity of the crystal lattice.[5] Bulk samples of very large particle size may require grinding in two stages for full matrix reduction to <10 μm.[8 16]

Final particle size distributions should always be verified by optical microscopy or another suitable method.

2.7.2.1.2 *Low temperature ashing*—For materials shown by PLM to contain large amounts of gypsum, cellulosic, or other organic materials, it may be desirable to ash the samples prior to analysis to reduce background radiation or matrix interference. Since chrysotile undergoes dehydroxylation at temperatures between 550 °C and 650 °C, with subsequent transformation to forsterite,[23 24] ashing temperatures should be kept below 500 °C. Use of a low temperature asher is recommended. In all cases, calibration of the oven is essential to ensure that a maximum ashing temperature of 500 °C is not exceeded.

2.7.2.1.3 *Acid leaching*—Because of the interference caused by gypsum and some carbonates in the detection of asbestiform minerals by XRD (see Section 2.3.1), it may be necessary to remove these interferents by a simple acid leaching procedure prior to analysis (see Section 1.7.2.2).

2.7.2.2 Qualitative Analysis

2.7.2.2.1 *Initial screening of bulk material*— Qualitative analysis should be performed on a representative, homogeneous portion of the sample with a minimum of sample treatment.

1. Grind and mix the sample with a mortar and pestle (or equivalent method, see Section 2.7.2.1.1.) to a final particle size sufficiently small (~100 μm) to allow adequate packing into the sample holder.

2. Pack the sample into a standard bulk sample holder. Care should be taken to ensure that a representative portion of the milled sample is selected for analysis. Particular care should be taken to avoid possible size segregation of the sample. (Note: Use of a back-packing method[25] of bulk sample preparation may reduce preferred orientation effects.)

3. Mount the sample on the diffractometer and scan over the diagnostic peak regions for

the serpentine (~67.4 Å) and amphibole (8.2–8.5 Å) minerals (see Table 2–2). The X-ray diffraction equipment should be optimized for intensity. A slow scanning speed of 1° 2θ/min is recommended for adequate resolution. Use of a sample spinner is recommended.

4. Submit all samples that exhibit diffraction peaks in the diagnostic regions for asbestiform minerals to a full qualitative XRD scan (5°–60° 2θ; 1°2θ/min) to verify initial peak assignments and to identify potential matrix interferences when subsequent quantitative analysis is to be performed.

5. Compare the sample XRD pattern with standard reference powder diffraction patterns (i.e., JCPDS powder diffraction data[3] or those of other well-characterized reference materials). Principal lattice spacings of asbestiform minerals are given in Table 2–2; common constituents of bulk insulation and wall materials are listed in Table 2–3.

2.7.2.2.2 *Detection of minor or trace constituents*— Routine screening of bulk materials by XRD may fail to detect small concentrations (<5 percent) of asbestos. The limits of detection will, in general, be improved if matrix absorption effects are minimized, and if the sample particle size is reduced to the optimal 1 to 10 μm range, provided that the crystal lattice is not degraded in the milling process. Therefore, in those instances where confirmation of the presence of an asbestiform mineral at very low levels is required, or where a negative result from initial screening of the bulk material by XRD (see Section 2.7.2.2.1) is in conflict with previous PLM results, it may be desirable to prepare the sample as described for quantitative analysis (see Section 2.7.2.3) and step-scan over appropriate 2θ ranges of selected diagnostic peaks (Table 2–2). Accurate transfer of the sample to the silver membrane filter is not necessary unless subsequent quantitative analysis is to be performed.

2.7.2.3 Quantitative Analysis

The proposed method for quantitation of asbestos in bulk samples is a modification of the NIOSH-recommended thin-layer method for chrysotile in air.[5] A thick-layer or bulk method involving pelletizing the sample may be used for semiquantitative analysis;[7 8] however, this method requires the addition of an internal standard, use of a specially fabricated sample press, and relatively large amounts of standard reference materials. Additional research is required to evaluate the comparability of thin- and thick-layer methods for quantitative asbestos analysis.

For quantitative analysis by thin-layer methods, the following procedure is recommended:

1. Mill and size all or a substantial representative portion of the sample as outlined in Section 2.7.2.1.1.

2. Dry at 100 °C for 2 hr; cool in a desiccator.

3. Weigh accurately to the nearest 0.01 mg.

4. Samples shown by PLM to contain large amounts of cellulosic or other organic materials, gypsum, or carbonates, should be submitted to appropriate matrix reduction procedures described in Sections 2.7.2.1.2 and 2.7.2.1.3. After ashing and/or acid treatment, repeat the drying and weighing procedures described above, and determine the percent weight loss; L.

5. Quantitatively transfer an accurately weighed amount (50–100 mg) of the sample to a 1–L volumetric flask with approximately 200 mL isopropanol to which 3 to 4 drops of surfactant have been added.

6. Ultrasonicate for 10 min at a power density of approximately 0.1 W/mL, to disperse the sample material.

7. Dilute to volume with isopropanol.

8. Place flask on a magnetic stirring plate. Stir.

9. Place a silver membrane filter on the filtration apparatus, apply a vacuum, and attach the reservoir. Release the vacuum and add several milliliters of isopropanol to the reservoir. Vigorously hand shake the asbestos suspension and immediately withdraw an aliquot from the center of the suspension so that total sample weight, W_T, on the filter will be approximately 1 mg. Do not adjust the volume in the pipet by expelling part of the suspension; if more than the desired aliquot is withdrawn, discard the aliquot and resume the procedure with a clean pipet. Transfer the aliquot to the reservoir. Filter rapidly under vacuum. Do not wash the reservoir walls. Leave the filter apparatus under vacuum until dry. Remove the reservoir, release the vacuum, and remove the filter with forceps. (Note: Water-soluble matrix interferences such as gypsum may be removed at this time by careful washing of the filtrate with distilled water. Extreme care should be taken not to disturb the sample.)

10. Attach the filter to a flat holder with a suitable adhesive and place on the diffractometer. Use of a sample spinner is recommended.

11. For each asbestos mineral to be quantitated select a reflection (or reflections) that has been shown to be free from interferences by prior PLM or qualitative XRD analysis and that can be used unambiguously as an index of the amount of material present in the sample (see Table 2–2).

12. Analyze the selected diagnostic reflection(s) by step scanning in increments of 0.02° 2θ for an appropriate fixed time and integrating the counts. (A fixed count scan may be used alternatively; however, the method chosen should be used consistently for all samples and standards.) An appropriate scanning interval should be selected for each peak, and background corrections made. For a fixed time scan, measure the

background on each side of the peak for one-half the peak-scanning time. The net intensity, I_a, is the difference between the peak integrated count and the total background count.

13. Determine the net count, I_{Ag}, of the filter 2.36 Å silver peak following the procedure in step 12. Remove the filter from the holder, reverse it, and reattach it to the holder. Determine the net count for the unattenuated silver peak, $I_{\mathring{A}g}$. Scan times may be *less* for measurement of silver peaks than for sample peaks; however, they should be *constant* throughout the analysis.

14. Normalize all raw, net intensities (to correct for instrument instabilities) by referencing them to an external standard (e.g., the 3.34 Å peak of an α-quartz reference crystal). After each unknown is scanned, determine the net count, I_r, of the reference specimen following the procedure in step 12. Determine the normalized intensities by dividing the peak intensities by I_r:

$$\hat{I}_a = \frac{I_a}{I_r^\circ}, \quad \hat{I}_{Ag} = \frac{I_{Ag}}{I_r^\circ}, \quad \text{and} \quad \hat{I}_{Ag}^\circ = \frac{I_{Ag}^\circ}{I_r^\circ}$$

2.8 Calibration

2.8.1 Preparation of Calibration Standards

1. Mill and size standard asbestos materials according to the procedure outlined in Section 2.7.2.1.1. *Equivalent, standardized matrix reduction and sizing techniques should be used for both standard and sample materials.*

2. Dry at 100 °C for 2 hr; cool in a desiccator.

3. Prepare two suspensions of each standard in isopropanol by weighing approximately 10 and 50 mg of the dry material to the nearest 0.01 mg. Quantitatively transfer each to a 1–L volumetric flask with approximately 200 mL isopropanol to which a few drops of surfactant have been added.

4. Ultrasonicate for 10 min at a power density of approximately 0.1 W/mL, to disperse the asbestos material.

5. Dilute to volume with isopropanol.

6. Place the flask on a magnetic stirring plate. Stir.

7. Prepare, in triplicate, a series of at least five standard filters to cover the desired analytical range, using appropriate aliquots of the 10 and 50 mg/L suspensions and the following procedure.

Mount a silver membrane filter on the filtration apparatus. Place a few milliliters of isopropanol in the reservoir. Vigorously hand shake the asbestos suspension and immediately withdraw an aliquot from the center of the suspension. Do not adjust the volume in the pipet by expelling part of the suspension; if more than the desired aliquot is withdrawn, discard the aliquot and resume the procedure with a clean pipet. Transfer the aliquot to the reservoir. Keep the tip of the pipet near the surface of the isopropanol. Filter rapidly under vacuum. Do not wash the sides of the reservoir. Leave the vacuum on for a time sufficient to dry the filter. Release the vacuum and remove the filter with forceps.

2.8.2 Analysis of Calibration Standards

1. Mount each filter on a flat holder. Perform step scans on selected diagnostic reflections of the standards and reference specimen using the procedure outlined in Section 2.7.2.3, step 12, and the same conditions as those used for the samples.

2. Determine the normalized intensity for each peak measured, $\hat{I}_{std}$, as outlined in Section 2.7.2.3, step 14.

2.9 Calculations

For each asbestos reference material, calculate the exact weight deposited on each standard filter from the concentrations of the standard suspensions and aliquot volumes. Record the weight, w, of each standard. Prepare a calibration curve by regressing $\hat{I}2_{std}$ on w. Poor reproducibility (±15 percent RSD) at any given level indicates problems in the sample preparation technique, and a need for new standards. The data should fit a straight line equation.

Determine the slope, m, of the calibration curve in counts/microgram. The intercept, b, of the line with the $\hat{I}_{std}$ axis should be approximately zero. A large negative intercept indicates an error in determining the background. This may arise from incorrectly measuring the baseline or from interference by another phase at the angle of background measurement. A large positive intercept indicates an error in determining the baseline or that an impurity is included in the measured peak.

Using the normalized intensity, $\hat{I}_{Ag}$, for the attenuated silver peak of a sample, and the corresponding normalized intensity from the unattenuated silver peak, $\hat{I}_{\mathring{A}g}$, of the sample filter, calculate the transmittance, T, for each sample as follows:[26 27]

$$T = \frac{\hat{I}_{Ag}}{\hat{I}_{Ag}^\circ}$$

Determine the correction factor, f(T), for each sample according to the formula:

$$f(T) = \frac{-R\,(\ln T)}{1 - T^R}$$

where

$$R = \frac{\sin \Theta_{Ag}}{\sin \Theta_a}$$

θ_{Ag} = angular position of the measured silver peak (from Bragg's Law), and

θ_a = angular position of the diagnostic asbestos peak.

Calculate the weight, W_a, in micrograms, of the asbestos material analyzed for in each sample, using the appropriate calibration data and absorption corrections:

$$W_a = \frac{\hat{I}_a f(t) - b}{m}$$

Calculate the percent composition, P_a, of each asbestos mineral analyzed for in the parent material, from the total sample weight, W_T, on the filter:

$$P_a = \frac{W_a(1-.01L)}{W_T} \times 100$$

where

P_a = percent asbestos mineral in parent material;

W_a = mass of asbestos mineral on filter, in µg;

W_T = total sample weight on filter, in µg;

L = percent weight loss of parent material on ashing and/or acid treatment (see Section 2.7.2.3).

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Subpart F [Reserved]

Subpart G—Asbestos Worker Protection

SOURCE: 65 FR 69216, Nov. 15, 2000, unless otherwise noted.

§ 763.120 What is the purpose of this subpart?

This subpart protects certain State and local government employees who are not protected by the Asbestos Standards of the Occupational Safety and Health Administration (OSHA). This subpart applies the OSHA Asbestos Standards in 29 CFR 1910.1001 and 29 CFR 1926.1101 to these employees.

§ 763.121 Does this subpart apply to me?

If you are a State or local government employer and you are not subject to a State asbestos standard that OSHA has approved under section 18 of the Occupational Safety and Health Act or a State asbestos plan that EPA has exempted from the requirements of this subpart under § 763.123, you must follow the requirements of this subpart to protect your employees from occupational exposure to asbestos.

§ 763.122 What does this subpart require me to do?

If you are a State or local government employer whose employees perform:

(a) Construction activities identified in 29 CFR 1926.1101(a), you must:

(1) Comply with the OSHA standards in 29 CFR 1926.1101.

(2) Submit notifications required for alternative control methods to the Director, National Program Chemicals Division (7404), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(b) Custodial activities not associated with the construction activities identified in 29 CFR 1926.1101(a), you must comply with the OSHA standards in 29 CFR 1910.1001.

(c) Repair, cleaning, or replacement of asbestos-containing clutch plates and brake pads, shoes, and linings, or removal of asbestos-containing residue from brake drums or clutch housings, you must comply with the OSHA standards in 29 CFR 1910.1001.

§ 763.123 May a State implement its own asbestos worker protection plan?

This section describes the process under which a State may be exempted from the requirements of this subpart.

(a) *States seeking an exemption.* If your State wishes to implement its own asbestos worker protection plan, rather than complying with the requirements of this subpart, your State must apply for and receive an exemption from EPA.

(1) *What must my State do to apply for an exemption?* To apply for an exemption from the requirements of this subpart, your State must send to the Director of EPA's Office of Pollution Prevention and Toxics (OPPT) a copy of its asbestos worker protection regulations and a detailed explanation of how your State's asbestos worker protection plan meets the requirements of TSCA section 18 (15 U.S.C. 2617).

(2) *What action will EPA take on my State's application for an exemption?* EPA will review your State's application and make a preliminary determination whether your State's asbestos worker protection plan meets the requirements of TSCA section 18.

(i) If EPA's preliminary determination is that your State's plan does meet the requirements of TSCA section 18, EPA will initiate a rulemaking, including an opportunity for public comment, to exempt your State from the requirements of this subpart. After considering any comments, EPA will issue a final rule granting or denying the exemption.

(ii) If EPA's preliminary determination is that the State plan does not meet the requirements of TSCA section 18, EPA will notify your State in writing and will give your State a reasonable opportunity to respond to that determination.

(iii) If EPA does not grant your State an exemption, then the State and local government employers in your State are subject to the requirements of this subpart.

(b) *States that have been granted an exemption.* If EPA has exempted your State from the requirements of this subpart, your State must update its asbestos worker protection regulations as necessary to implement changes to meet the requirements of this subpart, and must apply to EPA for an amendment to its exemption.

(1) *What must my State do to apply for an amendment to its exemption?* To apply for an amendment to its exemption, your State must send to the Director of OPPT a copy of its updated asbestos worker protection regulations and a detailed explanation of how your State's updated asbestos worker protection plan meets the requirements of TSCA section 18. Your State must submit its application for an amendment within 6 months of the effective date of any changes to the requirements of this subpart, or within a reasonable time agreed upon by your State and OPPT.

(2) *What action will EPA take on my State's application for an amendment?* EPA will review your State's application for an amendment and make a preliminary determination whether your State's updated asbestos worker protection plan meets the requirements of TSCA section 18.

(i) If EPA determines that the updated State plan does meet the requirements of TSCA section 18, EPA will issue your State an amended exemption.

(ii) If EPA determines that the updated State plan does not meet the requirements of TSCA section 18, EPA will notify your State in writing and will give your State a reasonable opportunity to respond to that determination.

(iii) If EPA does not grant your State an amended exemption, or if your State does not submit a timely request for amended exemption, then the State and local government employers in your State are subject to the requirements of this subpart.

Subpart H [Reserved]

Subpart I—Prohibition of the Manufacture, Importation, Processing, and Distribution in Commerce of Certain Asbestos-Containing Products; Labeling Requirements

SOURCE: 54 FR 29507, July 12, 1989, unless otherwise noted.

§ 763.160 Scope.

This subpart prohibits the manufacture, importation, processing, and distribution in commerce of the asbestos-containing products identified and at the dates indicated in §§ 763.165, 763.167, and 763.169. This subpart requires that products subject to this rule's bans, but not yet subject to a ban on distribution in commerce, be labeled. This subpart also includes general exemptions and procedures for requesting exemptions from the provisions of this subpart.

§ 763.163 Definitions.

For purposes of this subpart:

Act means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

Agency means the United States Environmental Protection Agency.

Asbestos means the asbestiform varieties of: chrysotile (serpentine); crocidolite (riebeckite); amosite (cummingtonite-grunerite); tremolite; anthophyllite; and actinolite.

Asbestos-containing product means any product to which asbestos is deliberately added in any concentration or which contains more than 1.0 percent asbestos by weight or area.

Chemical substance, has the same meaning as in section 3 of the Act.

Commerce has the same meaning as in section 3 of the Act.

Commercial paper means an asbestos-containing product which is made of paper intended for use as general insulation paper or muffler paper. Major applications of commercial papers are insulation against fire, heat transfer, and corrosion in circumstances that require a thin, but durable, barrier.

Corrugated paper means an asbestos-containing product made of corrugated paper, which is often cemented to a flat backing, may be laminated with foils or other materials, and has a corrugated surface. Major applications of asbestos corrugated paper include: thermal insulation for pipe coverings; block insulation; panel insulation in elevators; insulation in appliances; and insulation in low-pressure steam, hot water, and process lines.

Customs territory of the United States means the 50 States, Puerto Rico, and the District of Columbia.

Distribute in commerce has the same meaning as in section 3 of the Act, but the term does not include actions taken with respect to an asbestos-containing product (to sell, resale, deliver, or hold) in connection with the end use of the product by persons who are users (persons who use the product for its intended purpose after it is manufactured or processed). The term also does not include distribution by manufacturers, importers, and processors, and other persons solely for purposes of disposal of an asbestos-containing product.

Flooring felt means an asbestos-containing product which is made of paper felt intended for use as an underlayer for floor coverings, or to be bonded to the underside of vinyl sheet flooring.

Import means to bring into the customs territory of the United States, except for: (1) Shipment through the customs territory of the United States for export without any use, processing, or disposal within the customs territory of the United States; or (2) entering the customs territory of the United States as a component of a product during normal personal or business activities involving use of the product.

Importer means anyone who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. *Importer* includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term includes as appropriate:

(1) The consignee.

(2) The importer of record.

(3) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20.

(4) The transferee, if the right to withdraw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR part 144.

Manufacture means to produce or manufacture in the United States.

Manufacturer means a person who produces or manufactures in the United States.

New uses of asbestos means commercial uses of asbestos not identified in § 763.165 the manufacture, importation or processing of which would be initiated for the first time after August 25, 1989.

Person means any natural person, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof, or any municipality; any interstate body and any department, agency, or instrumentality of the Federal Government.

Process has the same meaning as in section 3 of the Act.

Processor has the same meaning as in section 3 of the Act.

Rollboard means an asbestos-containing product made of paper that is produced in a continuous sheet, is flexible, and is rolled to achieve a desired thickness. Asbestos rollboard consists of two sheets of asbestos paper

laminated together. Major applications of this product include: office partitioning; garage paneling; linings for stoves and electric switch boxes; and fire-proofing agent for security boxes, safes, and files.

Specialty paper means an asbestos-containing product that is made of paper intended for use as filters for beverages or other fluids or as paper fill for cooling towers. Cooling tower fill consists of asbestos paper that is used as a cooling agent for liquids from industrial processes and air conditioning systems.

State has the same meaning as in section 3 of the Act.

Stock-on-hand means the products which are in the possession, direction, or control of a person and are intended for distribution in commerce.

United States has the same meaning as in section 3 of the Act.

[59 FR 33208, June 28, 1994]

§ 763.165 Manufacture and importation prohibitions.

(a) After August 27, 1990, no person shall manufacture or import the following asbestos-containing products, either for use in the United States or for export: flooring felt and new uses of asbestos.

(b) After August 26, 1996, no person shall manufacture or import the following asbestos-containing products, either for use in the United States or for export: commercial paper, corrugated paper, rollboard, and specialty paper.

(c) The import prohibitions of this subpart do not prohibit:

(1) The import into the customs territory of the United States of products imported solely for shipment outside the customs territory of the United States, unless further repackaging or processing of the product is performed in the United States; or

(2) Activities involving purchases or acquisitions of small quantities of products made outside the customs territory of the United States for personal use in the United States.

[59 FR 33209, June 28, 1994]

§ 763.167 Processing prohibitions.

(a) After August 27, 1990, no person shall process for any use, either in the United States or for export, any of the asbestos-containing products listed at § 763.165(a).

(b) After August 26, 1996, no person shall process for any use, either in the United States or for export, any of the asbestos-containing products listed at § 763.165(b).

[59 FR 33209, June 28, 1994]

§ 763.169 Distribution in commerce prohibitions.

(a) After August 25, 1992, no person shall distribute in commerce, either for use in the United States or for export, any of the asbestos-containing products listed at § 763.165(a).

(b) After August 25, 1997, no person shall distribute in commerce, either for use in the United States or for export, any of the asbestos-containing products listed at § 763.165(b).

(c) A manufacturer, importer, processor, or any other person who is subject to a ban on distribution in commerce in paragraph (a) or (b) of this section must, within 6 months of the effective date of the ban of a specific asbestos-containing product from distribution in commerce, dispose of all their remaining stock-on-hand of that product, by means that are in compliance with applicable local, State, and Federal restrictions which are current at that time.

[59 FR 33209, June 28, 1994]

§ 763.171 Labeling requirements.

(a) After August 27, 1990, manufacturers, importers, and processors of all asbestos-containing products that are identified in § 763.165(a) shall label the products as specified in this subpart at the time of manufacture, import, or processing. This requirement includes labeling all manufacturers', importers', and processors' stock-on-hand as of August 27, 1990.

(b) After August 25, 1995, manufacturers, importers, and processors of all asbestos-containing products that are identified in § 763.165(b), shall label the products as specified in this subpart at the time of manufacture, import, or processing. This requirement includes

labeling all manufacturers', importers', and processors' stock-on-hand as of August 25, 1995.

(c) The label shall be placed directly on the visible exterior of the wrappings and packaging in which the product is placed for sale, shipment, or storage. If the product has more than one layer of external wrapping or packaging, the label must be attached to the innermost layer adjacent to the product. If the innermost layer of product wrapping or packaging does not have a visible exterior surface larger than 5 square inches, either a tag meeting the requirements of paragraph (d) of this section must be securely attached to the product's innermost layer of product wrapping or packaging, or a label must be attached to the next outer layer of product packaging or wrapping. Any products that are distributed in commerce to someone other than the end user, shipped, or stored without packaging or wrapping must be labeled or tagged directly on a visible exterior surface of the product as described in paragraph (d) of this section.

(d)(1) Labels must be either printed directly on product packaging or in the form of a sticker or tag made of plastic, paper, metal, or other durable substances. Labels must be attached in such a manner that they cannot be removed without defacing or destroying them. Product labels shall appear as in paragraph (d)(2) of this section and consist of block letters and numerals of color that contrasts with the background of the label or tag. Labels shall be sufficiently durable to equal or exceed the life, including storage and disposal, of the product packaging or wrapping. The size of the label or tag must be at least 15.25 cm (6 inches) on each side. If the product packaging is too small to accommodate a label of this size, the label may be reduced in size proportionately to the size of the product packaging or wrapping down to a minimum 2.5 cm (1 inch) on each side if the product wrapping or packaging has a visible exterior surface larger than 5 square inches.

(2) Products subject to this subpart shall be labeled in English as follows:

NOTICE

This product contains *ASBESTOS*. The U.S. Environmental Protection Agency has banned the distribution in U.S. commerce of this product under section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) as of (insert effective date of ban on distribution in commerce). Distribution of this product in commerce after this date and intentionally removing or tampering with this label are *violations of Federal law*.

(e) No one may intentionally remove, deface, cover, or otherwise obscure or tamper with a label or sticker that has been applied in compliance with this section, except when the product is used or disposed of.

[59 FR 33209, June 28, 1994]

§ 763.173 Exemptions.

(a) Persons who are subject to the prohibitions imposed by § 763.165, § 763.167, or § 763.169 may file an application for an exemption. Persons whose exemption applications are approved by the Agency may manufacture, import, process, or distribute in commerce the banned product as specified in the Agency's approval of the application. No applicant for an exemption may continue the banned activity that is the subject of an exemption application after the effective date of the ban unless the Agency has granted the exemption or the applicant receives an extension under paragraph (b)(4) or (5) of this section.

(b) Application filing dates. (1) Applications for products affected by the prohibitions under §§ 763.165(a) and 763.167(a) may be submitted at any time and will be either granted or denied by EPA as soon as is feasible.

(2) Applications for products affected by the ban under § 763.169(a) may be submitted at any time and will be either granted or denied by EPA as soon as is feasible.

(3) Applications for products affected by the ban under §§ 763.165(b) and 763.167(b) may not be submitted prior to February 27, 1995. Complete applications received after that date, but before August 25, 1995, will be either granted or denied by the Agency prior to the effective date of the ban for the product. Applications received after August 25, 1995, will be either granted or denied by EPA as soon as is feasible.

(4) Applications for products affected by the ban under § 763.169(b) may not be submitted prior to February 26, 1996. Complete applications received after that date, but before August 26, 1996, will be either granted or denied by the Agency prior to the effective date of the ban for the product. Applications received after August 26, 1996, will be either granted or denied by EPA as soon as is feasible.

(5) The Agency will consider an application for an exemption from a ban under § 763.169 for a product at the same time the applicant submits an application for an exemption from a ban under § 763.165 or § 763.167 for that product. EPA will grant an exemption at that time from a ban under § 763.169 if the Agency determines it appropriate to do so.

(6) If the Agency denies an application less than 30 days before the effective date of a ban for a product, the applicant can continue the activity for 30 days after receipt of the denial from the Agency.

(7) If the Agency fails to meet the deadlines stated in paragraphs (b)(3) and (b)(4) of this section for granting or denying a complete application in instances in which the deadline is before the effective date of the ban to which the application applies, the applicant will be granted an extension of 1 year from the Agency's deadline date. During this extension period the applicant may continue the activity that is the subject of the exemption application. The Agency will either grant or deny the application during the extension period. The extension period will terminate either on the date the Agency grants the application or 30 days after the applicant receives the Agency's denial of the application. However, no extension will be granted if the Agency is scheduled to grant or deny an application at some date after the effective date of the ban, pursuant to the deadlines stated in paragraphs (b)(3) and (b)(4) of this section.

(c) Where to file. All applications must be submitted to the following location: TSCA Docket Receipts Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Rm E-G99, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTENTION: Asbestos Exemption. For information regarding the submission of exemptions containing information claimed as confidential business information (CBI), see § 763.179.

(d) Content of application and criteria for decisionmaking.

(1) Content of application. Each application must contain the following:

(i) Name, address, and telephone number of the applicant.

(ii) Description of the manufacturing, import, processing, and/or distribution in commerce activity for which an exemption is requested, including a description of the asbestos-containing product to be manufactured, imported, processed, or distributed in commerce.

(iii) Identification of locations at which the exempted activity would take place.

(iv) Length of time requested for exemption (maximum length of an exemption is 4 years).

(v) Estimated amount of asbestos to be used in the activity that is the subject of the exemption application.

(vi) Data demonstrating the exposure level over the life cycle of the product that is the subject of the application.

(vii) Data concerning:

(A) The extent to which non-asbestos substitutes for the product that is the subject of the application fall significantly short in performance under necessary product standards or requirements, including laws or ordinances mandating product safety standards.

(B) The costs of non-asbestos substitutes relative to the costs of the asbestos-containing product and, in the case in which the product is a component of another product, the effect on the cost of the end use product of using the substitute component.

(C) The extent to which the product or use serves a high-valued use.

(viii) Evidence of demonstrable good faith attempts by the applicant to develop and use a non-asbestos substance or product which may be substituted for the asbestos-containing product or the asbestos in the product or use that is the subject to the application.

(ix) Evidence, in addition to that provided in the other information required with the application, showing that the continued manufacture, importation,

processing, distribution in commerce, and use, as applicable, of the product will not present an unreasonable risk of injury to human health.

(2) Criteria for decision (existing products). After considering all the information provided by an applicant under paragraphs (d)(1) and (e) of this section, and any other information available to EPA, EPA will grant an exemption from the prohibitions in §763.165, §763.167, or §763.169 for an applicant's asbestos-containing product only if EPA determines both of the following:

(i) The applicant has made good faith attempts to develop and use a non-asbestos substance or product which may be substituted for the asbestos-containing product or the asbestos in the product or use, and those attempts have failed to produce a substitute or a substitute that results in a product that can be economically produced.

(ii) Continued manufacturing, processing, distribution in commerce, and use, as applicable, of the product will not present an unreasonable risk of injury to human health.

(3) Criteria for decision (new products). Requests to develop and use an asbestos substance or product will be treated as a petition pursuant to section 21 of TSCA.

(e) The Agency reserves the right to request further information from an exemption applicant if necessary to complete the Agency's evaluation of an application.

(f) Upon receipt of a complete application, the Agency will issue a notice in the FEDERAL REGISTER announcing its receipt and invite public comments on the merits of the application.

(g) If the application does not include all of the information required in paragraph (d) of this section, the Agency will return it to the applicant as incomplete and any resubmission of the application will be considered a new application for purposes of the availability of any extension period. If the application is substantially inadequate to allow the Agency to make a reasoned judgment on any of the information required in paragraph (d) of this section and the Agency chooses to request additional information from the applicant, the Agency may also determine that an extension period provided for in paragraph (b)(5) of this section is unavailable to the applicant.

(h) When denying an application, the Agency will notify the applicant by registered mail of its decision and rationale. Whenever possible, the Agency will send this letter prior to the appropriate ban. This letter will be considered a final Agency action for purposes of judicial review. A notice announcing the Agency's denial of the application will be published in the FEDERAL REGISTER.

(i) If the Agency proposes to approve an exemption, it will issue a notice in the FEDERAL REGISTER announcing this intent and invite public comments. If, after considering any timely comments received, the Agency approves an exemption, its decision will be published in the FEDERAL REGISTER. This notice will be considered a final Agency action for purposes of judicial review.

(j) The length of an exemption period will be specified by the agency when it approves the exemption. To extend an exemption period beyond the period stipulated by EPA, applicants must submit a new application to the Agency, following the application procedures described in this section. Applications may not be submitted prior to 15 months before the expiration of the exemption period, unless stated otherwise in the notice granting the exemption. Applications received between 15 months and 1 year before the end of the exemption period will be either granted or denied by the Agency before the end of the exemption period. Applications received after the date 1 year prior to the end of the exemption period will be either granted or denied by the Agency as soon as is feasible. Applicants may not continue the activity that is the subject of the renewal application after the date of the end of the exemption period.

[54 FR 29507, July 12, 1989; 54 FR 37531, Sept. 11, 1989, as amended at 54 FR 46898, Nov. 8, 1989; 59 FR 33210, June 28, 1994]

§763.175 Enforcement.

(a) Failure to comply with any provision of this subpart is a violation of section 15 of the Act (15 U.S.C. 2614).

(b) Failure or refusal to establish and maintain records, or to permit access

to or copying of records as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(c) Failure or refusal to permit entry or inspection as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(e) The Agency may seek to enjoin the manufacture, import, processing, or distribution in commerce of asbestos-containing products in violation of this subpart, or act to seize any asbestos-containing products manufactured, imported, processed, or distributed in commerce in violation of this subpart, or take any other actions under the authority of section 7 or 17 of the Act (15 U.S.C. 2606 or 2616) that are appropriate.

§ 763.176 Inspections.

The Agency will conduct inspections under section 11 of the Act (15 U.S.C. 2610) to ensure compliance with this subpart.

§ 763.178 Recordkeeping.

(a) *Inventory.* (1) Each person who is subject to the prohibitions imposed by §§ 763.165 and 763.167 must perform an inventory of the stock-on-hand of each banned product as of the effective date of the ban for that product for the applicable activity.

(2) The inventory shall be in writing and shall include the type of product, the number of product units currently in the stock-on-hand of the person performing the inventory, and the location of the stock.

(3) Results of the inventory for a banned product must be maintained by the person for 3 years after the effective date of the § 763.165 or § 763.167 ban on the product.

(b) *Records.* (1) Each person whose activities are subject to the bans imposed by §§ 763.165, 763.167, and 763.169 for a product must, between the effective date of the § 763.165 or § 763.167 ban on the product and the § 763.169 ban on the product, keep records of all commercial transactions regarding the product, including the dates of purchases and sales and the quantities purchased or sold. These records must be maintained for 3 years after the effective date of the § 763.169 ban for the product.

(2) Each person who is subject to the requirements of § 763.171 must, for each product required to be labeled, maintain a copy of the label used in compliance with § 763.171. These records must be maintained for 3 years after the effective date of the ban on distribution in commerce for the product for which the § 763.171 requirements apply.

[54 FR 29507, July 12, 1989, as amended at 54 FR 46898, Nov. 8, 1989; 58 FR 34205, June 23, 1993]

§ 763.179 Confidential business information claims.

(a) Applicants for exemptions under § 763.173 may assert a Confidential Business Information (CBI) claim for information in an exemption application or supplement submitted to the Agency under this subpart only if the claim is asserted in accordance with this section, and release of the information would reveal trade secrets or confidential commercial or financial information, as provided in section 14(a) of the Act. Information covered by a CBI claim will be treated in accordance with the procedures set forth in 40 CFR part 2, subpart B. The Agency will place all information not claimed as CBI in the manner described in this section in a public file without further notice to the applicant.

(b) Applicants may assert CBI claims only at the time they submit a completed exemption application and only in the specified manner. If no such claim accompanies the information when it is received by the Agency, the information may be made available to the public without further notice to the applicant. Submitters that claim information as business confidential must do so by writing the word ''Confidential'' at the top of the page on which the information appears and by underlining, circling, or placing brackets ([ ]) around the information claimed CBI.

(c) Applicants who assert a CBI claim for submitted information must provide the Agency with two copies of their exemption application. The first copy must be complete and contain all

information being claimed as CBI. The second copy must contain only information not claimed as CBI. The Agency will place the second copy of the submission in a public file. Failure to furnish a second copy of the submission when information is claimed as CBI in the first copy will be considered a presumptive waiver of the claim of confidentiality. The Agency will notify the applicant by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The applicant has 30 days from the date of receipt of notification to submit the required second copy. Failure to submit the second copy will cause the Agency to place the first copy in a public file.

(d) Applicants must substantiate all claims of CBI at the time the applicant asserts the claim, i.e., when the exemption application or supplement is submitted, by responding to the questions in paragraph (e) of this section. Failure to provide substantiation of a claim at the time the applicant submits the application will result in a waiver of the CBI claim, and the information may be disclosed to the public without further notice to the applicant.

(e) Applicants who assert any CBI claims must substantiate all claims by providing detailed responses to the following:

(1) Is this information subject to a patent or patent application in the United States or elsewhere? If so, why is confidentiality necessary?

(2) For what period do you assert a claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

(3) Has the information that you are claiming as confidential been disclosed to persons outside of your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

(4) Briefly describe measures taken by your company to guard against undesired disclosure of the information you are claiming as confidential to others.

(5) Does the information claimed as confidential appear or is it referred to in advertising or promotional materials for the product or the resulting end product, safety data sheets or other similar materials for the product or the resulting end product, professional or trade publications, or any other media available to the public or to your competitors? If you answered yes, indicate where the information appears.

(6) If the Agency disclosed the information you are claiming as confidential to the public, how difficult would it be for the competitor to enter the market for your product? Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes.

(7) Has the Agency, another Federal agency, or a Federal court made any confidentiality determination regarding this information? If so, provide copies of such determinations.

(8) How would your company's competitive position be harmed if the Agency disclosed this information? Why should such harm be considered substantial? Describe the causal relationship between the disclosure and harm.

(9) In light of section 14(b) of TSCA, if you have claimed information from a health and safety study as confidential, do you assert that disclosure of this information would disclose a process used in the manufacturing or processing of a product or information unrelated to the effects of asbestos on human health and the environment? If your answer is yes, explain.

PART 766—DIBENZO-PARA-DIOXINS/DIBENZOFURANS

Subpart A—General Provisions

Sec.

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AUTHORITY: 15 U.S.C. 2603 and 2607.

SOURCE: 52 FR 21437, June 5, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 766.1 Scope and purpose.

(a) This part identifies requirements for testing under section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603, to ascertain whether certain specified chemical substances may be contaminated with halogenated dibenzodioxins (HDDs)/dibenzofurans (HDFs) as defined in §766.3, and requirements for reporting under section 8 of TSCA, 15 U.S.C. 2607.

(b) Section 766.35(b) requires manufacturers and processors of chemical substances identified in §766.25 to submit to EPA:

(1) Any existing test data showing analysis of the chemical substances for concentrations of HDDs/HDFs, applicable protocols, and the results of the analysis for HDDs/HDFs, (2) allegations of significant adverse reactions to HDDs/HDFs, compiled in accordance with part 717 of this chapter, and (3) health and safety studies on the HDDs/HDFs, in accordance with applicable provisions of part 716 of this chapter.

(c) Section 766.35(a) requires manufacturers and, under certain circumstances, processors of chemical substances identified in §766.25 to submit letters of intent to test and protocols for the analysis of the chemical substances for the presence of HDDs/HDFs. Section 766.20 requires these manufacturers and processors to test their chemical substances for the presence of HDDs/HDFs. Any submissions must be in accordance with the EPA Procedures Governing Testing Consent Agreements and Test Rules contained in part 790 of this chapter and any modifications to such procedures contained in this part.

(d) Section 766.32 specifies conditions under which persons required to test may request an exclusion or waiver from testing.

(e) Deadlines for submission to EPA of protocols, reports, studies, and test results are specified in part 790, subpart C and §766.35.

(f) Sections 766.10, 766.12, 766.14, 766.16, and 766.18 prescribe analytical methods required; §766.27 prescribes target levels of quantitation (LOQ) for each congener for which quantitation is required.

(g) If results of existing tests or tests performed under this part indicate the presence of HDDs/HDFs in the identified chemical substance above the LOQ specified in §766.27, §766.35(c) requires the following additional reporting on the specified chemicals: production, process, use, exposure and disposal data under section 8(a) of TSCA; health and safety studies under section 8(d) of TSCA; and reports of allegations of significant adverse reactions under section 8(c) of TSCA. In some cases, additional reporting may be required of manufacturers reporting no contamination of the identified chemical substances under §766.35(c)(2).

(h) Section 766.38 requires manufacturers of chemical substances produced from chemical substances identified as possible precursors to HDD/HDF formation, to report on chemical substances produced from such precursors.

§ 766.2 Applicability and duration of this part.

(a) *Chemical substances subject to testing.* (1) This part is applicable to each person who, at any time during the duration of this part, manufactures (and/or imports), or processes, a chemical substance identified under §766.25.

(2) The duration of this part for any testing requirement for any chemical substance is the period commencing with the effective date of this part to the end of the reimbursement period, as defined in §766.3, for each chemical substance. All reporting requirements for any chemical substance listed under §766.25 shall be in effect for the

same period as the testing requirement.

(b) *Precursor chemical substances.* (1) This part is applicable to each person who manufactures (and/or imports) a chemical substance from any precursor chemical substance identified in § 766.38.

(2) The requirement for precursor reporting under § 766.38 shall be in effect until three years after the effective date of this part.

(3) Small manufacturers are exempt from reporting process and reaction condition data on chemical substances made from precursor chemical substances listed under § 766.38.

§ 766.3 Definitions.

The definitions in section 3 of TSCA and the definitions of §§ 704.3, 716.3, 717.3, and 790.3 of this chapter also apply to this part.

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

Chemical Information Submission System or *CISS* means EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information, or its successors.

Congener means any one particular member of a class of chemical substances. A specific congener is denoted by unique chemical structure, for example 2,3,7,8-tetrachlorodibenzofuran.

Dibenzofuran means any of a family of compounds which has as a nucleus a triple-ring structure consisting of two benzene rings connected through a pair of bridges between the benzene rings. The bridges are a carbon-carbon bridge and a carbon-oxygen-carbon bridge at both substitution positions.

Dibenzo-p-dioxin or *dioxin* means any of a family of compounds which has as a nucleus a triple-ring structure consisting of two benzene rings connected through a pair of oxygen atoms.

Guidelines means the Midwest Research Institute (MRI) publication *Guidelines for the Determination of Polyhalogenated Dioxins and Dibenzofurans in Commercial Products*, EPA contract No. 68–02–3938; MRI Project No. 8201–A(41), 1985.

HDD or *2,3,7,8-HDD* means any of the dibenzo-p-dioxins totally chlorinated or totally brominated at the following positions on the molecular structure: 2,3,7,8; 1,2,3,7,8; 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; and 1,2,3,4,7,8,9.

HDF or *2,3,7,8-HDF* means any of the dibenzofurans totally chlorinated or totally brominated at the following positions on the molecular structure: 2,3,7,8; 1,2,3,7,8; 2,3,4,7,8; 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; 2,3,4,6,7,8; 1,2,3,4,6,7,8; and 1,2,3,4,7,8,9.

Homolog means a group of isomers that have the same degree of halogenation. For example, the homologous class of tetrachlorodibenzo-p-dioxins consists of all dibenzo-p-dioxins containing four chlorine atoms. When the homologous classes discussed in this part are referred to, the following abbreviations for the prefix denoting the number of halogens are used:

tetra-, T (4 atoms)
penta-, Pe (5 atoms)
hexa-, Hx (6 atoms)
hepta-, Hp (7 atoms)

HRGC means high resolution gas chromatography.

HRMS means high resolution mass spectrometry.

Level of quantitation or *LOQ* means the lowest concentration at which HDDs/HDFs can be reproducibly measured in a specific chemical substance within specified confidence limits, as described in this part.

Polybrominated dibenzofurans refers to any member of a class of dibenzofurans with two to eight bromine substituents.

Polybrominated dibenzo-p-dioxin or *PBDD* means to any member of a class of dibenzo-p-dioxins with two to eight bromine substituents.

Polychlorinated dibenzofuran means any member of a class of dibenzofurans with two to eight chlorine substituents.

Polychlorinated dibenzo-p-dioxin or *PCDD* means any member of a class of dibenzo-p-dioxins with two to eight chlorine substituents.

Polyhalogenated dibenzofuran or *PHDF* means any member of a class of dibenzofurans containing two to eight chlorine, bromine, or a combination of chlorine and bromine substituents.

Polyhalogenated dibenzo-p-dioxin or *PHDD* means any member of a class of dibenzo-p-dioxins containing two to

eight chlorine substituents or two to eight bromine substituents.

Positive test result means: (1) Any resolvable gas chromatographic peak for any 2,3,7,8-HDD or HDF which exceeds the LOQ listed under § 766.27 for that congener, or (2) exceeds LOQs approved by EPA under § 766.28.

Precursor means a chemical substance which is not contaminated due to the process conditions under which it is manufactured, but because of its molecular structure, and under favorable process conditions, it may cause or aid the formation of HDDs/HDFs in other chemicals in which it is used as a feedstock or intermediate.

QA means quality assurance.

QC means quality control.

Reimbursement period means the period that begins when the data from the last test to be completed under this part for a specific chemical substance listed in § 766.25 is submitted to EPA, and ends after an amount of time equal to that which had been required to develop that data or 5 years, whichever is later.

TSCA means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

[52 FR 21437, June 5, 1987, as amended at 78 FR 72828, Dec. 4, 2013]

§ 766.5 Compliance.

Any person who fails or refuses to comply with any aspect of this part is in violation of section 15 of TSCA. Section 15(1) makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) makes it unlawful for any person to fail or refuse to submit information required under this part. Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Under section 17 of TSCA, the district courts of the United States have jurisdiction to restrain any violation of section 15.

§ 766.7 Submission of information.

(a) All information (including letters of intent, protocols, data, forms, studies, and allegations) submitted to EPA under this part must bear the applicable Code of Federal Regulations (CFR) section number (e.g., § 766.20).

(b) You must use the CISS tool to complete and submit all data, reports, and other information required under this part except for records and reports of allegations of significant adverse reactions, which must be submitted in accordance with paragraph (c) of this section.

(1) Submissions must be submitted to EPA via CDX.

(2) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

(c) You must submit records and reports of allegations of significant adverse reactions and the accompanying cover letters by one of the following methods:

(1) Mail, preferably certified, to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001, ATTN: Dioxin/Furan report part 766, Allegations of significant adverse reactions.

(2) Hand delivery to OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave. NW., Washington, DC, ATTN: Dioxin/Furan report part 766, Allegations of significant adverse reactions. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation.

[78 FR 72828, Dec. 4, 2013]

§ 766.10 Test standards.

Testing required under subpart B of this part must be performed using the protocols submitted to and reviewed by the EPA expert panel established under § 766.28. All new data, documentation, records, protocols, specimens, and reports generated as a result of testing under subpart B of this part must be fully developed and retained in accordance with part 792 of this chapter. These items must be made available during an inspection or submitted to

EPA upon request by EPA or its authorized representative. Laboratories conducting testing for submission to EPA in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA Good Laboratory Practices (GLPs) published in part 792 of this chapter. Sponsors must notify the laboratory that the testing is being conducted pursuant to TSCA section 4. Sponsors are also responsible for ensuring that laboratories conducting the testing abide by the TSCA GLP standards. At the time test data are submitted, manufacturers must submit a certification to EPA that the laboratory performing the testing adhered to the TSCA GLPs.

§ 766.12 Testing guidelines.

Analytical test methods must be developed using methods equivalent to those described or reviewed in *Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products*. Copies are available from the Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, U.S.Environmental Protection Agency, Room E–543B, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 544–0551. Publicly available docket materials are available at the addresses in § 700.17(b)(1) and (2) of this chapter.

[60 FR 34466, July 3, 1995, as amended at 77 FR 46292, Aug. 3, 2012]

§ 766.14 Contents of protocols.

Protocols should include all parts of the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins*, as stated in the Guidelines. For each chemical substance and each process, the manufacturer must submit a statement of how many grades of the chemical substance it produces, a justification for selection of the specific grade of chemical substance for testing, specific plans for collection of samples from the process stream, naming the point of collection, the method of collecting the sample, and an estimate of how well the samples will represent the material to be characterized; a description of how control samples (blanks) and HDD/HDF-reinforced control samples, or isotopically labeled compounds (standards) and duplicate samples will be handled; a description of the chemical extraction and clean up procedures to be used; how extraction efficiency and measurement efficiency will be established; and a description of instrument hardware and operating conditions, including type and source of columns, carrier gas and flow rate, operating temperature range, and ion source temperature.

§ 766.16 Developing the analytical test method.

Because of the matrix differences of the chemicals listed for testing, no one method for sample selection, preparation, extraction and clean up is prescribed. For analysis, High Resolution Gas Chromatography (HRGC) with High Resolution Mass Spectrometry (HRMS) is the method of choice, but other methods may be used if they can be demonstrated to reach the target LOQs as well as HRGC/HRMS.

(a) *Sample selection*. The chemical product to be tested should be sampled so that the specimens collected for analysis are representative of the whole. Additional guidance for sample selection is provided under § 766.12.

(b) *Sample preparation*. The sample must be mechanically homogenized and subsampled as necessary. Subsamples must be spiked or reinforced with surrogate compounds or with standard stock solutions, and the surrogates or standards must be thoroughly incorporated by mechanical agitation. Additional guidance is provided under § 766.12.

(c) *Sample extraction and cleanup*. The spiked samples must be treated to separate the HDDs/HDFs from the sample matrix. Methods are reviewed in the Guidelines under § 766.12, but the final method or methods are left to the discretion of the analyst, provided the instrumental response of the surrogates meets the criteria listed in the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins*, Appendixes B and C of the Guidelines. Cleanup techniques are described in the Guidelines. These

are chosen at the discretion of the analyst to meet the requirements of the chemical matrix.

(d) *Analysis.* The method of choice is High Resolution Gas Chromatographic/High Resolution Mass Spectrometric Determination, (HRGC/HRMS) but alternate methods may be used if the manufacturer can demonstrate that the method will reach the target LOQs as well as HRGC/HRMS. Specific operating requirements are found in the Guidelines.

§ 766.18 Method sensitivity.

The target level of quantitation required under § 766.27 for each HDD/HDF congener is the level which must be attempted for each resolved HRGC peak for that congener. For at least one product sample, at least two analyses of the same isotopically labeled HDD/HDF internal calibration standards spiked to a final product concentration equal to the LOQ for that congener must be reproducibly extracted, cleaned up, and quantified to within ±20 percent of each other. For each spiked product sample, the signal to noise ratio for the calibration standard peaks after complete extraction and cleanup must be 10:1 or greater. The recovery of the internal calibration standards in the extracted and cleaned up product samples must be within 50 to 150 percent of the amount spiked, and the results must be corrected for recovery.

Subpart B—Specific Chemical Testing/Reporting Requirements

§ 766.20 Who must test.

(a) Any person who manufactures, imports, or processes a chemical substance listed in § 766.25 must test that chemical substance and must submit appropriate information to EPA according to the schedules described in § 766.35. Chemical substances manufactured, imported or processed between January 1, 1984 and the date of promulgation of this part are subject to testing upon the effective date of this part. All other chemical substances are subject to testing immediately upon manufacture, import or processing. EPA expects that only manufacturers and importers will perform testing, and that the cost of testing will be passed on to processors through the pricing mechanism, thereby enabling them to share in the cost of testing. However, processors will be called upon to sponsor testing should manufacturers and importers fail to do so. A processor may apply for an exemption from testing upon certification to EPA that a manufacturer or importer is testing the chemical substance which that person processes.

(b) If no manufacturer or importer described in § 766.20 submits a letter of intent to perform testing within the period described under § 766.35(a), or an exemption application under § 790.45(a), or a request for an exclusion or waiver under § 766.32, EPA will issue a notice in the FEDERAL REGISTER to notify all processors of that chemical substance. The notice will state that EPA has not received any of the documents described in the previous sentence, and that current processors will have 30 days to submit either a letter of intent to perform the test or submit an exemption application.

(c) If no manufacturer, importer or processor submits a letter of intent to perform testing of a specific chemical substance produced by a specific process, EPA will notify all manufacturers, importers, and processors, either by notice in the FEDERAL REGISTER or by letter, that all exemption applications will be denied and that within 30 days all manufacturers, importers, and processors will be in violation of this part until a proposed study plan is submitted for required testing.

(d) Manufacturers, importers, and processors who are subject to this part must comply with the test rule development and exemption procedures in part 790 of this chapter, except as modified in this part.

§ 766.25 Chemical substances for testing.

(a) *Listing of chemical substances.* Chemical substances required to be tested for HDDs/HDFs under this rule are listed in this section. The listing is by Chemical Abstracts Service (CAS) Number and common name.

NOTE: For purposes of guidance only, EPA lists the chemical substances subject to testing under this part in two classes—those

known to be manufactured or imported between January 1, 1984, and promulgation of this part, and those not known to be manufactured or imported at the time of promulgation of this part.

(1) *Chemicals substances known to be manufactured between January 1, 1984 and date of promulgation of this part.*

CAS No.	Chemical name
79–94–7	Tetrabromobisphenol-A.
118–75–2	2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione.
118–79–6	2,4,6-Tribromophenol.
120–83–2	2,4-Dichlorophenol.
1163–19–5	Decabromodiphenyloxide.
4162–45–2	Tetrabromobisphenol-A-bisethoxylate.
21850–44–2	Tetrabromobisphenol-A-bis-2,3-dibromopropyl ether.
25327–89–3	Allyl ether of tetrabromobisphenol-A.
32534–81–9	Pentabromodiphenyloxide.
32536–52–0	Octabromodiphenyloxide.
37853–59–1	1,2-Bis(tribromophenoxy)-ethane.
55205–38–4	Tetrabromobisphenol-A diacrylate.

(2) *Chemicals not known to be manufactured between January 1, 1984 and the date of promulgation of this part.*

CAS No.	Chemical name
79–95–8	Tetrachlorobisphenol-A.
87–10–5	3,4′,5-Tribromosalicylanilide.
87–65–0	2,6-Dichlorophenol.
95–77–2	3,4-Dichlorophenol.
95–95–4	2,4,5-Trichlorophenol.
99–28–5	2,6-Dibromo-4-nitrophenol.
120–36–5	2[2,4-(Dichlorophenoxy)]-propionic acid.
320–72–9	3,5-Dichlorosalicyclic acid.
488–47–1	Tetrabromocatechol.
576–24–9	2,3-Dichlorophenol.
583–78–8	2,5-Dichlorophenol.
608–71–9	Pentabromophenol.
615–58–7	2,4-Dibromophenol.
933–75–5	2,3,6-Trichlorophenol.
1940–42–7	4-Bromo-2,5-dichlorophenol.
2577–72–2	3,5-Dibromosalicylanilide.
3772–94–9	Pentachlorophenyl laurate.
37853–61–5	Bismethylether of tetrabromobisphenol-A.
	Alkylamine tetrachlorophenate.
	Tetrabromobisphenol-B.

(b) *Grade to be tested.* If the same process is used to manufacture all grades of the same chemical substance, only one grade need be tested. The grade to be tested must be the grade subject to the most intense heat and alkalinity for the longest duration of time, manufactured under each different process. If the heat, alkalinity and duration of reaction do not differ for various grades, the test substance must be the grade of chemical substance with the highest volume of sales.

§ 766.27 Congeners and LOQs for which quantitation is required.

Quantitation at the target LOQ shown for each of the following HDDs/HDFs which may be present in the chemical substances is required for the chemical substances listed under § 766.25. Analysis must take place for either chlorinated or brominated dibenzodioxins or dibenzofurans, whichever is predominantly expected to occur in the chemical substance to be tested. Only chlorinated and brominated congeners need be quantified; for chemical substances containing predominantly chlorine atoms, only congeners totally chlorinated at the numbered positions need be quantified; for chemical substances containing predominantly bromine atoms, only congeners totally brominated at the numbered positions need be quantified.

Chlorinated dioxins	Brominated dioxins	LOQ
2,3,7,8-TCDD	2,3,7,8-TBDD	0.1 ppb.
1,2,3,7,8-PeCDD	1,2,3,7,8-PeBDD	0.5 ppb.
1,2,3,4,7.8-HxCDD	1,2,3,4,7,8-HxBDD	2.5 ppb.
1,2,3,6,7,8-HxCDD	1,2,3,6,7,8-HxBDD	2.5 ppb.
1,2,3,7,8,9-HxCDD	1,2,3,7,8,9-HxBDD	2.5 ppb.
1,2,3,4,6,7,8-HpCDD	1,2,3,4,6,7,8-HpBDD	100 ppb.
2,3,7,8-TCDF	2,3,7,8-TBDF	1 ppb.
1,2,3,7,8-PeCDF	1,2,3,7,8-PeBDF	5 ppb.
2,3,4,7,8-PeCDF	2,3,4,7,8-PeBDF	5 ppb.
1,2,3,4,7,8-HxCDF	1,2,3,4,7,8-HxBDF	25 ppb.
1,2,3,6,7,8-HxCDF	1,2,3,6,7,8-HxBDF	25 ppb.
1,2,3,7,8,9-HxCDF	1,2,3,7,8,9-HxBDF	25 ppb.
2,3,4,6,7,8-HxCDF	2,3,4,6,7,8-HxBDF	25 ppb.
1,2,3,4,6,7,8-HpCDF	1,2,3,4,6,7,8-HpBDF	1 ppm.
1,2,3,4,7,8,9-HpCDF	1,2,3,4,7,8,9-HpBDF	1 ppm.

§ 766.28 Expert review of protocols.

EPA will gather a panel of experts in analysis of chemical matrices for HDDs/HDFs to review the protocols for testing submitted to EPA. The panel members will be employees of EPA and/or of other U.S. Government agencies who have had experience in analysis of chemical matrices and/or chemical wastes for HDDs/HDFs. The panel will recommend to the Director, EPA Office of Pollution Prevention and Toxics, whether the protocol submitted is likely to allow analysis down to the target LOQs, or if not, whether the protocol represents a good faith effort on the part of the tester to achieve the

lowest possible LOQs. The final determination to accept or reject the protocol will be made by the Director, Office of Pollution Prevention and Toxics. EPA will review the submitted protocols as rapidly as possible and will complete the review within 90 days after receipt. EPA may require submission of revised protocols. Comments and recommendations will be transmitted to the submitter, and if revisions are required, a final protocol must be submitted to EPA within 90 days after EPA transmits such recommendations.

§ 766.32 Exclusions and waivers.

(a) *Reasons for exclusions and waivers.* Any person subject to the testing requirements of this part may request an exclusion or waiver from testing for any one of the following reasons:

(1) *Exclusions may be granted if.* (i) Testing of the appropriate grade of the chemical substance has already been carried out, either analytical testing at the lowest LOQ possible, with appropriate QA/QC, or a well-designed bioassay with appropriate QA/QC or;

(ii) Process and reaction conditions of the chemical substance such that no HDDs/HDFs could be produced under those conditions;

(2) *Waivers may be granted if.* (i) A responsible company official certifies that the chemical substance is produced only in quantities of 100 kilograms or less per year, only for research and development purposes; or

(ii) In the judgement of EPA, the cost of testing would drive the chemical substance off the market, or prevent resumption of manufacture or import of the chemical substance, if it is not currently manufactured, and the chemical substance will be produced so that no unreasonable risk will occur due to its manufacture, import, processing, distribution, use, or disposal. (In this case, the manufacturer must submit to EPA all data supporting the determination.)

(iii) Waivers may be appropriately conditioned with respect to such factors as time and conditions of manufacture or use. The grade of decabromodiphenyl oxide produced by Dow Chemical Company (Dow) for the National Toxicology Program (NTP) bioassay on that chemical is excluded from the testing requirement under this part. Provided, however, that this exclusion will not apply if Dow fails to supply to EPA within 60 days of the effective date of this section evidence showing which grade was used for the NTP bioassay.

(b) *Timing.* Exclusion or waiver requests and detailed supporting data must be submitted to EPA within 60 days from the effective date of this part for persons manufacturing, importing or processing a chemical substance as of the date of promulgation, or 60 days prior to the date of resumption of manufacture or import for a chemical substance produced by a specific process if the chemical substance is not manufactured, imported or processed as of the date of promulgation.

(c) *Publication.* Within 10 days of receipt of any exclusion or waiver request, EPA will issue in the FEDERAL REGISTER a notice of such receipt. EPA will also issue a notice of its decision on each exclusion or waiver request within 60 days of receipt.

(d) *Decision.* The EPA Director of the Office of Pollution Prevention and Toxics will make the decision to grant or deny waivers or exclusions.

§ 766.35 Reporting requirements.

(a) *Letters of intent, exemption applications, and protocols*—(1) *Letters of intent.* (i) Persons who have manufactured or imported chemical substances listed under § 766.25 between January 1, 1984, and the effective date of this part are required to submit under § 790.45 of this chapter a letter of intent to test or an exemption application. These letters must be submitted no later than September 3, 1987.

(ii) Persons who commence manufacture, import or processing of a chemical substance listed under § 766.25 that has not been manufactured, imported or processed between January 1, 1984 and the effective date of this part must submit under § 790.45 of this chapter, within 60 days after the commencement of manufacture, import, or processing of the chemical substance, a letter of intent to test or an exemption application.

(iii) Persons who commence manufacture, import or processing of a

chemical substance listed under § 766.25 between the effective date of this part and the end of the reimbursement period for that particular chemical substance produced by a specific process must submit under § 790.45 of this chapter, within 60 days after the commencement of manufacture, import or processing of the chemical substance, a letter of intent to test or an exemption application.

(2) *Protocols.* (i) Each person who is manufacturing or processing a chemical substance listed in § 766.25 as of the effective date of this part who submits a notice of intent to test under § 766.35(a)(1) must submit a protocol for the test as follows:

(A) The protocols for each chlorinated chemical substance produced by each process to be tested must be submitted to EPA no later than 12 months after the effective date of this part.

(B) The protocol for each brominated chemical substance produced by each process to be tested must be submitted to EPA no later than 24 months after the effective date of this part except for the following chemicals.

(*1*) The deadline for submitting the protocols for tetrabromobisphenol-A (CAS No. 79–94–7); 2,4,6 tribromophenol (CAS. No. 118–79–6); decabromodiphenyloxide (CAS No. 1163–19–5); and 1,2-bis(tribromophenoxy)-ethane (CAS No. 37853–59–1) is January 31, 1991.

(*2*) The deadline for submitting protocols for octabromodiphenyloxide (CAS No. 32536–52–0) and allyl ether of tetrabromobisphenol-A (CAS No. 25327–89–3) is January 31, 1991.

(*3*) The deadline for submitting protocols for pentabromodiphenyloxide (CAS No. 32534–81–9) is February 6, 1995. The deadline for submitting tetrabromobisphenol-A-bisethoxylate (CAS No. 4126–45–2) is January 31, 1991.

(*4*) The deadline for submitting protocols for 3,4′,5-tribromosalicylanilide (CAS No. 87–10–5) is September 5, 1990.

(ii) For chemical substances produced by a specific process not manufactured or processed as of the effective date of this part, a person who begins manufacture and submits a notice of intent to test must submit protocols for the test as follows:

(A) Except as noted for the submitter and substance specified in the following table, protocols for testing must be submitted 12 months after manufacture or importation begins for chlorinated chemical substances.

CAS No.	Submitter	Chemical	Due date
118–75–2	Rhone-Poulenc	2,3,5,6-tetrachloro-2,5-cyclohexaniene-1,4-dione	March 4, 1994

(B) Protocols for testing must be submitted 24 months after manufacture begins for brominated chemical substances.

(iii) For persons who have been granted exemptions, waivers or exclusions from testing, protocols must be submitted 12 months after expiration of the exemption, waiver or exclusion for chlorinated chemical substances, and 24 months after expiration of the exemption, waiver or exclusion for brominated chemical substances.

(b) *Information that must be submitted to EPA.* (1) Persons who manufacture or import a chemical substance listed under § 766.25 must report no later than October 5, 1987 or 90 days after the person first manufactures or imports the chemical substance, whichever is later, the results of all existing test data which show that chemical substance has been tested for the presence of HDDs/HDFs.

(2) Any manufacturer or importer of a chemical substance listed in § 766.25 in possession of unpublished health and safety studies on HDDs/HDFs is required to submit copies of such studies to EPA no later than October 5, 1987 or 90 days after the person first manufactures or imports the chemical substance, whichever is later. The following provisions of part 716 of this chapter apply to submission of these studies: §§ 716.3, 716.10(a) (1) and (4); 716.20(a) (1), (2), (3), (4), (7), (8) and (10); 716.25; 716.30; 716.35(a) (1), (2), and (4) [if applicable]; 716.35 (b) and (c); 716.40 (a) and (b); 716.50; 716.55; and 716.60(a)(2).

(3) No later than October 5, 1987 or 90 days after the person first manufactures or imports the substance listed in § 766.25, any manufacturer or importer of a chemical substance listed in § 766.25 must submit records required to be held under part 717 of this chapter on any HDDs/HDFs.

(4) *Test results.* (i) Test results must be submitted to EPA not later than 270 days after EPA's transmission of comments or 180 days after a final protocol is submitted to EPA, whichever is shorter, except as noted for the submitters and substances specified in the following table:

CAS No.	Submitter	Chemical	Due Date	Effective Date
79–94–7	Great Lakes	Tetrabromobisphenol-A	May 26, 1992	May 28, 1993
79–94–7	Ethyl	Tetrabromobisphenol-A	August 10, 1992	May 28, 1993
79–94–7	Ameribrom	Tetrabromobisphenol-A	April 15, 1994	September 29, 1995
87–10–5	Pfister	3,4′,5-tribromosalicylanilide	45 days after protocol approval	May 28, 1993
118–75–2	Rhone-Poulenc Inc.	2,3,5,6-tetrachloro-2,5-cyclohexadiene-1,4-dione	July 5, 1996	June 30, 1997
118–79–6	Great Lakes	2,4,6-Tribromophenol	May 26, 1992	May 28, 1993
1163–19–5	Ameribrom	Decabromodiphenyloxide	April 15, 1994	September 29, 1995
1163–19–5	Ethyl	Decabromodiphenyloxide	May 26, 1992	May 28, 1993
1163–19–5	Great Lakes	Decabromodiphenyloxide	May 26, 1992	May 28, 1993
4162–45–2	Great Lakes	Tetrabromobisphenol-A-bisethoxylate	June 2, 1993	September 8, 1994
25327–89–3	Great Lakes	Allyl Ether of Tetrabromobisphenol-A	August 10, 1992	May 28, 1993
32534–81–9	Great Lakes	Pentabromodiphenyloxide	March 22, 1993	September 8, 1994
32534–81–9	Akzo Chemicals Inc.	Pentabromodiphenyloxide	February 6, 1995	September 29, 1995
32534–81–9	Ameribrom	Pentabromodiphenyloxide	March 22, 1993	September 8, 1994
32536–52–0	Ameribrom	Octabromodiphenyloxide	January 8, 1993	September 29, 1995
32536–52–0	Ethyl	Octabromodiphenyloxide	May 15, 1994	May 28, 1993
32536–52–0	Great Lakes	Octabromodiphenyloxide	May 26, 1992	May 28, 1993
37853–59–1	Great Lakes	1,2-bis(tribromophenoxy)ethane	January 24, 1995	September 29, 1995

(ii) For purposes of reporting test results to EPA, and for further reporting triggered by a positive test result under § 766.35(c), a positive test result is defined at § 766.3.

(iii) Reporting of test results must follow procedures set out in part 790 of this chapter, except as modified in this part.

(c) *Information required to be submitted to EPA after submission of a positive test result.* (1) Any person who submits a positive test result for a specific chemical substance listed under § 766.25 must submit to EPA no later than 90 days after the date of submission of the positive test result the following:

(i) A completed form (EPA 7710–51) for that chemical substance. The form and instructions are available online at *http://www.epa.gov/oppt/chemtest/ereporting/index.html*. One form must be submitted for each chemical substance for which a positive test result has been submitted.

(ii) Health and safety studies for the chemical substance for which a positive test result has been reported. The following provisions of part 716 of this chapter apply to submission of these studies: §§ 716.3; 716.10 (a) (1), (2), (3) and (4); 716.20; 716.25; 716.30; 716.35(a) (1), (2), and (4), [if applicable]; 716.35 (b) and (c); 716.40 (a) and (b); 716.50; 716.55; 716.60(a)(2).

(iii) Copies of records on the chemical substances required to be held under part 717 of this chapter.

(2) If a positive test result on a chemical substance is received from one person but not from others, EPA may issue a notice in the FEDERAL REGISTER listing that chemical substance and requiring any person manufacturing, importing or processing that chemical substance who has not submitted a positive test result to submit the information required in Part II of EPA Form 7710–51. Such a notice will be published only if EPA needs additional

process data to make a determination of unreasonable risk.

(d)–(e) [Reserved]

(f) *Effective date.* (1) The effective date of this final rule is July 6, 1987, except for paragraphs (a)(2)(i)(B) introductory text, (a)(2)(i)(B)(*1*), (a)(2)(i)(B)(*2*), (a)(2)(i)(B)(*3*), (a)(2)(i)(B)(*4*), the table in paragraph (a)(2)(ii)(A), and the table in paragraph (b)(4)(i) of this section.

(2) The effective date for paragraph (a)(2)(i)(B) introductory text, (a)(2)(i)(B)(*1*), (a)(2)(i)(B)(*2*), and (a)(2)(i)(B)(*4*), is May 21, 1991. The effective date of paragraphs (a)(2)(i)(B)(*3*), and the table in paragraph (a)(2)(ii)(A) is September 29, 1995. The effective date of paragraph (b)(4)(i) introductory text is May 28, 1993, and the effective date of the entries in the table in paragraph (b)(4)(i) is shown in the effective dates column of the table.

(3) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

[52 FR 21437, June 5, 1987, as amended at 56 FR 23229, May 21, 1991; 57 FR 24960, June 12, 1992; 58 FR 30991, May 28, 1993, 58 FR 34205, June 23, 1993; 59 FR 46356, Sept. 8, 1994; 60 FR 31922, June 19, 1995; 60 FR 50433, Sept. 29, 1995; 60 FR 56955, Nov. 13, 1995; 62 FR 35105, June 30, 1997; 78 FR 72829, Dec. 4, 2013]

§ 766.38 Reporting on precursor chemical substances.

(a) *Identification of precursor chemical substances.* Precursor chemical substances are produced under conditions that will not yield HDDs and HDFs, but their molecular structure is conducive to HDD/HDF formation under favorable reaction conditions when they are used to produce other chemicals or products. The following precursor chemical substances are identified by Chemical Abstract Service (CAS) number and name.

CAS No.	Chemical name
85–22–3 ...	Pentabromoethylbenzene.
87–61–6 ...	1,2,3-Trichlorobenzene.
87–84–3 ...	1,2,3,4,5-Pentabromo-6-chloro-cyclohexane.
89–61–2 ...	1,4-Dichloro-2-nitrobenzene.
89–64–5 ...	4-Chloro-2-nitrophenol.
89–69–0 ...	2,4,5-Trichloronitrobenzene.
92–04–6 ...	2-Chloro-4-phenylphenol.
94–74–6 ...	4-Chloro-o-toloxy acetic acid.
94–81–5 ...	4-(2-Methyl-4-chlorophenoxy) butyric acid.
95–50–1 ...	o-Dichlorobenzene.
95–56–7 ...	o-Bromophenol.
95–57–8 ...	o-Chlorophenol.
95–88–5 ...	4-Chlororesorcinol.
95–94–3 ...	1,2,4,5-Tetrachlorobenzene.
97–50–7 ...	5-Chloro-2,4-dimethoxyaniline.
99–30–9 ...	2,6-Dichloro-4-nitroaniline.
99–54–7 ...	1,2-Dichloro-4-nitrobenzene.
106–46–7	p-Dichlorobenzene.
108–70–3	1,3,5-Trichlorobenzene.
108–86–1	Bromobenzene.
108–90–7	Chlorobenzene.
117–18–0	1,2,4,5-Tetrachloro-3-nitrobenzene.
120–82–1	1,2,4-Trichlorobenzene.
348–51–6	o-Chorofluorobenzene.
350–30–1	3-Chloro-4-fluoronitrobenzene.
615–67–8	Chlorohydroquinone.
626–39–1	1,3,5-Tribromobenzene.
827–94–1	2,6-Dibromo-4-nitroaniline.

(b) *Persons required to report.* All persons who manufacture or import a chemical product produced using any of the chemical substances listed in paragraph (a) of this section as feedstocks or intermediates must report no later than September 29, 1987. Small manufacturers and those manufacturers and importers who produce the precursor chemical substances in quantities of 100 kilograms or less per year only for research and development purposes are not required to report under this section

(c) *Data to be reported.* Manufacturers and importers of chemical products made from precursor chemical substances identified in paragraph (a) of this section must report process and reaction condition data on Part II of EPA Form 7710–51 for each chemical product. A separate EPA Form 7710–51 must be submitted for each chemical product reported, and the precursor chemical substance used must be identified. All forms must be submitted to EPA no later than September 29, 1987.

[52 FR 21437, June 5, 1987, as amended at 60 FR 31922, June 19, 1995]

PARTS 767–769 [RESERVED]

PART 770—FORMALDEHYDE STANDARDS FOR COMPOSITE WOOD PRODUCTS

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Subpart D—Incorporation by Reference

770.99 Incorporation by reference.

AUTHORITY: 15 U.S.C. 2697(d).

SOURCE: 81 FR 89724, Dec. 12, 2016, unless otherwise noted.

Subpart A—General Provisions

§ 770.1 Scope and applicability.

(a) This part contains formaldehyde emission standards, testing and certification provisions, and other requirements for the manufacture (including import), distribution, and sale of composite wood products, component parts that contain composite wood products, and finished goods that contain composite wood products.

(b) This part applies to:

(1) Laboratory Accreditation Bodies (ABs) and Product ABs that are accrediting third-party certifiers (TPCs) for TSCA Title VI (15 U.S.C. 2697(d)) purposes and those that wish to commence accrediting TPCs for TSCA Title VI purposes.

(2) TPCs that are certifying composite wood products for TSCA Title VI compliance and those that wish to commence certifying composite wood products for TSCA Title VI compliance.

(3) Any composite wood products, and component parts or finished goods containing these materials, that are sold, supplied, offered for sale, or manufactured (including imported) in the United States, including composite wood products used or installed in manufactured housing.

(c) Subparts B, C, and D of this part do not apply to the following:

(1) Any finished good that has previously been sold or supplied to an end user, an individual or entity that purchased or acquired the finished good in good faith for purposes other than resale. For example, subparts B, C, and D of this part do not apply to antiques or secondhand furniture.

(2) Hardboard.

(3) Structural plywood, as specified in PS 1–09, Structural Plywood (incorporated by reference, see § 770.99).

(4) Structural panels, as specified in PS 2–10, Performance Standard for Wood-Based Structural-Use Panels (incorporated by reference, see § 770.99).

(5) Structural composite lumber, as specified in ASTM D5456–14b, Standard Specification for Evaluation of Structural Composite Lumber Products (incorporated by reference, see § 770.99).

(6) Oriented strand board.

(7) Glued laminated lumber, as specified in ANSI A190.1–2017, Standard for Wood Products—Structural Glued Laminated Timber (incorporated by reference, see § 770.99).

(8) Prefabricated wood I-joists, as specified in ASTM D5055–16, Standard Specification for Establishing and Monitoring Structural Capacities of Prefabricated Wood I-Joists (incorporated by reference, see § 770.99).

(9) Finger-jointed lumber.

(10) Wood packaging, including pallets, crates, spools, and dunnage.

(11) Composite wood products used inside the following:

(i) New vehicles (other than recreational vehicles) that are constructed entirely from new parts and that have never been the subject of a retail sale or registered with the applicable State or other governmental agency.

(ii) New rail cars.

(iii) New boats.

(iv) New aerospace craft.

(v) New aircraft.

(d) The emission standards in § 770.10 do not apply to windows that contain composite wood products, if the windows contain less than five percent by volume of composite wood products, combined, in relation to the total volume of the finished window.

(e) The emission standards in § 770.10 do not apply to exterior doors and garage doors that contain composite wood products, if:

(1) The doors are made from composite wood products manufactured with no-added formaldehyde-based resins or ultra low-emitting formaldehyde resins; or

(2) The doors contain less than three percent by volume of composite wood products, combined, in relation to the total volume of the finished exterior door or garage door.

[81 FR 89724, Dec. 12, 2016, as amended at 83 FR 5345, Feb. 7, 2018]

§ 770.2 Applicability and compliance dates.

(a) [Reserved]

(b) Laboratory and Product ABs that wish to accredit TPCs for TSCA Title VI purposes may apply to EPA beginning May 22, 2017, to become recognized. Laboratory and Product ABs must be recognized by EPA before they begin to provide and at all times while providing TSCA Title VI accreditation services.

(c) TPCs that are not approved by the California Air Resources Board (CARB) that wish to provide TSCA Title VI certification services may apply to EPA beginning May 22, 2017, to become recognized. TPCs must be recognized by EPA and comply with all of the applicable requirements of this part before they begin to provide and at all times while providing TSCA Title VI certification services.

(d) Notwithstanding any other provision of this part, TPCs that are approved by CARB to certify composite wood products have until March 22, 2019, to become accredited by an EPA TSCA Title VI AB(s) pursuant to the requirements of this part. During this two-year transition period, existing CARB-approved TPCs that are recognized by EPA and CARB TPCs approved during this transition period may carry out certification activities under TSCA Title VI, provided that they remain approved by CARB and comply with all aspects of this part other than the requirements of § 770.7(c)(1)(i) and (ii) and (c)(2)(iii) and (iv). After the two-year transition period, CARB-approved TPCs may continue to certify composite wood products under TSCA Title VI provided the TPC maintains its CARB approval, follows the requirements under this part, submits to EPA documentation from CARB supporting their eligibility for reciprocity and has received EPA recognition as an EPA TSCA Title VI TPC. All TPCs that are certifying products as compliant with TSCA Title VI, both during and after the transition period, are subject to enforcement actions for any violations of TSCA Title VI or these regulations.

(e) Beginning December 12, 2018, all manufacturers (including importers), fabricators, suppliers, distributors, and retailers of composite wood products, and component parts or finished goods containing these materials, must comply with this part, subject to the following:

(1) Beginning December 12, 2018, laminated product producers must comply with the requirements of this part that are applicable to fabricators.

(2) Beginning March 22, 2024, producers of laminated products must comply with the requirements of this part that are applicable to hardwood plywood panel producers (in addition to the requirements of this part that are applicable to fabricators) except as provided at § 770.4.

(3) Beginning March 22, 2024, producers of laminated products that, as provided at § 770.4, are exempt from the definition of ''hardwood plywood'' must comply with the recordkeeping requirements in § 770.40(c) and (d) (in addition to the requirements of this part that are applicable to fabricators).

(4) Composite wood products manufactured (including imported) before December 12, 2018 may be sold, supplied, offered for sale, or used to fabricate component parts or finished goods at any time.

[82 FR 44536, Sept. 25, 2017]

§ 770.3 Definitions.

For the purposes of this part, the following definitions apply:

Accreditation Body or *AB* means an organization that provides an impartial verification of the competency of conformity assessment bodies or TPCs.

Agent for Service means an entity designated by a TPC or AB to receive legal documents on their behalf.

Article means a manufactured item which:

(1) Is formed to a specific shape or design during manufacture;

(2) Has end use functions dependent in whole or in part upon its shape or design during the end use; and

(3) Has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in 19 CFR 12.120(a)(2), except that fluids and particles are not considered articles regardless of shape or design.

Assessment means a process to include an on-site review undertaken by an AB to assess the competence of all operations of a conformity assessment body and TPC, based on particular standard(s) and/or other normative documents for a defined scope of accreditation, as defined in ISO/IEC 17011:2004(E) (incorporated by reference, see § 770.99).

Bundle means more than one composite wood product, component part, or finished good fastened together for transportation or sale.

Combination core means a platform for making hardwood plywood or laminated products that consists of a combination of layers of veneer and particleboard or medium density fiberboard.

Component part means an object other than a panel that contains one or more composite wood products and is used in the construction or assembly of finished goods. Component parts that are sold directly to consumers are considered finished goods.

Composite core means a platform for making hardwood plywood or laminated products that consists of particleboard and/or medium density fiberboard, or combination core.

Composite wood product means hardwood plywood made with a veneer or composite core, medium-density fiberboard, and particleboard.

Distributor means any person or entity to whom a composite wood product, component part, or finished good is sold or supplied for the purposes of resale or distribution in commerce, except that manufacturers and retailers are not distributors.

Engineered veneer means a type of veneer that is created by dyeing and gluing together leaves of veneer in a mold to produce a block. The block is then sliced into leaves of veneer with a designed appearance that is highly repeatable.

EPA TSCA Title VI Laboratory Accreditation Body or *EPA TSCA Title VI Laboratory AB* means an AB that has a recognition agreement with EPA under the EPA TSCA Title VI Third-Party Certification Program, accredits a TPC's testing laboratory or contract testing laboratory to ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99) with a scope of accreditation to include this part and the formaldehyde test methods used to comply with this part, and assesses the testing laboratory's conformance to ISO/IEC 17020:2012(E) (incorporated by reference, see § 770.99) in order to perform laboratory testing services.

EPA TSCA Title VI Product Accreditation Body or *EPA TSCA Title VI Product AB* means an AB that has a recognition agreement with EPA under the EPA TSCA Title VI Third-Party Certification Program, accredits a TPC to ISO/IEC 17065:2012(E) (incorporated by reference, see § 770.99) with a scope of accreditation to include composite wood products and this part, and assesses the TPC's conformance to ISO/IEC 17020:2012(E) (incorporated by reference, see § 770.99) in order to perform product certification.

EPA TSCA Title VI Third-Party Certifier or *EPA TSCA Title VI TPC* means a conformity assessment body that provides both product certification services and laboratory testing services (either directly or through contracted services), is accredited by an EPA TSCA Title VI Product AB and an EPA TSCA Title VI Laboratory AB (unless the laboratory testing services are contracted to a laboratory accredited by an EPA TSCA Title VI Laboratory

AB), and is recognized by EPA pursuant to § 770.7(c).

Fabricator means a person or entity who incorporates composite wood products into component parts or into finished goods. This includes laminated product producers, but persons or entities in the construction trades are not fabricators by renovating or remodeling buildings.

Finished good means any good or product, other than a panel, that contains hardwood plywood (with a veneer or composite core), particleboard, or medium-density fiberboard and that is not a component part or other part used in the assembly of a finished good. Site-built buildings or other site-built real property improvements are not considered finished goods.

Hardboard means a composite panel composed of cellulosic fibers, consolidated under heat and pressure in a hot press by: A wet process; or a dry process that uses a phenolic resin, or a resin system in which there is no formaldehyde as part of the resin crosslinking structure; or a wet formed/dry pressed process; and that is commonly or commercially known, or sold, as hardboard, including any product conforming to one of the following ANSI standards: Basic Hardboard (ANSI A135.4–2012) (incorporated by reference, see § 770.99), Prefinished Hardboard Paneling (ANSI A135.5–2012) (incorporated by reference, see § 770.99), Engineered Wood Siding (ANSI A135.6–2012) (incorporated by reference, see § 770.99), or Engineered Wood Trim (ANSI A135.7–2012) (incorporated by reference, see § 770.99). There is a rebuttable presumption that products emitting more than 0.06 ppm formaldehyde as measured by ASTM E1333–14 (incorporated by reference, see § 770.99) or ASTM D6007–14 (incorporated by reference, see § 770.99) are not hardboard.

Hardwood plywood means a hardwood or decorative panel that is intended for interior use and composed of (as determined under ANSI/HPVA HP–1–2016 (incorporated by reference, see § 770.99)) an assembly of layers or plies of veneer, joined by an adhesive with a lumber core, a particleboard core, a medium-density fiberboard core, a hardboard core, a veneer core, or any other special core or special back material. Hardwood plywood does not include military-specified plywood, curved plywood, or any plywood specified in PS 1–09, Structural Plywood (incorporated by reference, see § 770.99), or PS 2–10, Performance Standard for Wood-Based Structural-Use Panels (incorporated by reference, see § 770.99). In addition, hardwood plywood includes laminated products except as provided at § 770.4.

Importer means any person or entity who imports composite wood products, component parts, or finished goods into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedules of the United States pursuant to 15 U.S.C. 2612(a)(1)). Importer includes:

(1) The entity primarily liable for the payment of any duties on the products; or

(2) An authorized agent acting on the entity's behalf.

Intended for interior use means intended for use or storage inside a building or recreational vehicle, or constructed in such a way that it is not suitable for long-term use in a location exposed to the elements. Windows, doors, and garage doors with at least one interior-facing side are intended for interior use.

Laboratory Accreditation Body or *Laboratory AB* means an AB that accredits conformity assessment body testing laboratories.

Laminated product means a product in which a wood or woody grass veneer is affixed to a particleboard core or platform, a medium-density fiberboard core or platform, or a veneer core or platform. A laminated product is a component part used in the construction or assembly of a finished good. In addition, a laminated product is produced by either the fabricator of the finished good in which the product is incorporated or a fabricator who uses the laminated product in the further construction or assembly of a component part.

Laminated product producer means a manufacturing plant or other facility that manufactures (excluding facilities that solely import products) laminated products on the premises. Laminated product producers are fabricators and, beginning March 22, 2024, laminated product producers are also hardwood

plywood panel producers except as provided at § 770.4.

Lot means the panels produced from the beginning of production of a product type until the first quality control test; between one quality control test and the next; or from the last quality control test to the end of production for a particular product type.

Medium-density fiberboard means a panel composed of cellulosic fibers made by dry forming and pressing a resinated fiber mat (as determined under ANSI A208.2–2016 (incorporated by reference, see § 770.99)).

No-added formaldehyde-based resin means a resin formulated with no added formaldehyde as part of the resin crosslinking structure in a composite wood product that meets the emission standards in § 770.17(c).

Non-complying lot means any lot of composite wood product represented by a quarterly test value or quality control test result that indicates that the lot exceeds the applicable standard for the particular composite wood product in § 770.10(b). A quality control test result that exceeds the QCL is considered a test result that indicates that the lot exceeds the applicable standard. Future production of the product type(s) represented by a failed quarterly test are not considered certified and must be treated as a non-complying lot until the product type(s) are re-qualified through a successful quarterly test.

Panel means a thin (usually less than two inches thick), flat, usually rectangular piece of particleboard, medium-density fiberboard or hardwood plywood. Embossing or imparting of an irregular surface on the composite wood products by the original panel producer during pressing does not remove the product from this definition. Cutting a panel into smaller pieces, without additional fabrication, does not make the panel into a component part or finished good. This does not include items made for the purpose of research and development, provided such items are not sold, supplied, or offered for sale.

Panel producer means a manufacturing plant or other facility that manufactures (excluding facilities that solely import products) composite wood products on the premises.

Particleboard means a panel composed of cellulosic material in the form of discrete particles (as distinguished from fibers, flakes, or strands) that are pressed together with resin (as determined under ANSI A208.1–2016 (incorporated by reference, see § 770.99)). Particleboard does not include any product specified in PS 2–10 (incorporated by reference, see § 770.99).

Phenol-formaldehyde resin means a resin that consists primarily of phenol and formaldehyde and does not contain urea-formaldehyde.

Product Accreditation Body or *Product AB* means an AB that accredits conformity assessment bodies who perform product certification.

Product type means a type of composite wood product, or group of composite wood products, made by the same panel producer with the same resin system that differs from another product type based on panel composition and formaldehyde emission characteristics. Grouped products must have similar formaldehyde emission characteristics and their emissions must fit the same correlation curve or linear regression.

Production line means a set of operations and physical industrial or mechanical equipment used to produce a composite wood product in one facility utilizing the same or similar equipment and quality assurance and quality control procedures.

Purchaser means any panel producer, importer, fabricator, distributor, or retailer that acquires composite wood products, component parts, or finished goods for purposes of resale in exchange for money or its equivalent.

Quality control limit or *QCL* means the value from the quality control method test that is the correlative equivalent to the applicable emission standard based on the ASTM E1333–14 method (incorporated by reference, see § 770.99) or, upon showing equivalence in accordance with § 770.20(d), the ASTM D6007–14 method (incorporated by reference, see § 770.99).

Reassessment means an assessment, as described in sections 7.5 to 7.11 of ISO/IEC 17011:2004(E) (incorporated by reference, see § 770.99), except that experience gained during previous assessments shall be taken into account.

Recreational vehicle means a vehicle which is:

(1) Built on a single chassis;

(2) Four hundred square feet or less when measured at the largest horizontal projections;

(3) Self-propelled or permanently towable by a light duty truck; and

(4) Designed primarily not for use as a permanent dwelling but as temporary living quarters for recreational, camping, travel, or seasonal use.

Resin system means type of resin used, including but not limited to urea-formaldehyde, soy, phenol-formaldehyde, or melamine-urea-formaldehyde.

Retailer means any person or entity that sells, offers for sale, or supplies directly to consumers composite wood products, component parts or finished goods that contain composite wood products, except that persons or entities in the construction trades are not considered retailers by selling, renovating, or remodeling buildings.

Scavenger means a chemical or chemicals that can be applied to resins or composite wood products either during or after manufacture and that react with residual or excess formaldehyde to reduce the amount of formaldehyde that can be emitted from composite wood products.

Shipping quality control limit means a quality control limit that is developed in conjunction with an EPA TSCA Title VI TPC that is based on panels prior to shipment rather than immediately after manufacturing.

Stockpiling means manufacturing or purchasing composite wood products, whether in the form of panels or incorporated into component parts or finished goods, between July 7, 2010 and June 12, 2017 at an average rate at least 20% greater than the average rate of manufacture or purchase during the 2009 calendar year for the purpose of circumventing the emission standards and other requirements of this subpart.

Thin medium-density fiberboard means medium-density fiberboard that has a thickness less than or equal to 8 millimeters or 0.315 inches.

Third-party certifier or *TPC* means a conformity assessment body that provides both product certification services and laboratory testing services (either directly or through contracted services).

TPC laboratory means a laboratory or contract laboratory of an EPA TSCA Title VI TPC that is accredited by an EPA TSCA Title VI Laboratory AB to ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99), and whose inspection activities are in conformance with ISO/IEC 17020:2012(E) (incorporated by reference, see § 770.99).

Surveillance On-Site Assessment means a set of on-site activities that are less comprehensive than reassessment, to monitor the continued fulfilment by accredited conformance assessment bodies of requirements for accreditation, as described in sections 7.5 to 7.11 of ISO/IEC 17011:2004(E) (incorporated by reference, see § 770.99).

Ultra low-emitting formaldehyde resin means a resin in a composite wood product that meets the emission standards in § 770.18(c).

Veneer means a sheet of wood or woody grass with a maximum thickness of 6.4 millimeters (¼ inch) that is rotary cut, sliced, or sawed from a log, bolt, flitch, block, or culm; including engineered veneer.

Veneer core means a platform for making hardwood plywood or laminated products that consists of veneer.

Woody grass means a plant of the family *Poaceae* (formerly *Gramineae*) with hard lignified tissues or woody parts.

[81 FR 89724, Dec. 12, 2016, as amended at 82 FR 44537, Sept. 25, 2017; 83 FR 5345, Feb. 7, 2018]

§ 770.4 Exemption from the hardwood plywood definition for certain laminated products.

(a) *Current exemptions.* The definition of the term ''hardwood plywood'' in § 770.3 does not include:

(1) Laminated products made by attaching a wood or woody grass veneer with a phenol-formaldehyde resin to a platform that has been manufactured in compliance with this part (including either certified in accordance with § 770.15, manufactured with no-added formaldehyde-based resins under § 770.17, or manufactured with ultra low-emitting formaldehyde-based resins under § 770.18).

(2) Laminated products made by attaching a wood or woody grass veneer with a resin formulated with no-added formaldehyde as part of the resin crosslinking structure to a platform that has been manufactured in compliance with this part (including either certified in accordance with § 770.15, manufactured with no-added formaldehyde-based resins under § 770.17, or manufactured with ultra low-emitting formaldehyde-based resins under § 770.18).

(b) *Rulemaking petitions for exemption.* (1) Any person may petition the Agency to initiate a rulemaking for additional exemptions for laminated products from the definition of the term ''hardwood plywood,'' pursuant to 15 U.S.C. 2697(a)(3)(C)(i)(I).

(2) Each petition should provide all available and relevant information, including studies conducted and formaldehyde emissions data, and should be submitted to: Director, National Program Chemicals Division, Office of Pollution Prevention and Toxics (MC 7404T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave NW., Washington, DC 20460–001.

(3) EPA will promptly review each submitted petition and, where appropriate, publish a proposed rule in the FEDERAL REGISTER based on the petition and provide a public comment period of generally 30 days before taking a final action.

§ 770.5 Prohibited acts.

(a) Failure or refusal to comply with any requirement of TSCA section 601 (15 U.S.C. 2697) or this part is a violation of TSCA section 15 (15 U.S.C. 2614).

(b) Failure or refusal to establish and maintain records or to make available or permit access to or copying of records, as required by this part, is a violation of TSCA section 15 (15 U.S.C. 2614).

(c) Making false or misleading statements in any statement, certification, or record required by this part is a violation of TSCA section 15 (15 U.S.C. 2614).

(d) Violators may be subject to civil and criminal sanctions pursuant to TSCA section 16 (15 U.S.C. 2615) for each violation.

Subpart B—EPA TSCA Title VI Third-Party Certification Program

§ 770.7 Third-party certification.

(a) *EPA TSCA Title VI Product ABs.* To participate in the EPA TSCA Title VI Third-Party Certification Program as an EPA TSCA Title VI Product AB, a Product AB must have the qualifications described in this section, submit an application and enter into a recognition agreement with EPA as described in this section, and, upon recognition from EPA, impartially perform the responsibilities described in this section.

(1) *Qualifications.* To qualify for recognition by EPA in the EPA TSCA Title VI Third-Party Certification Program as an EPA TSCA Title VI Product AB, an applicant Product AB must:

(i) Be a signatory to the International Accreditation Forum, Inc.'s (IAF) Multilateral Recognition Arrangement (MLA) through level three, or have membership in one of the IAF recognized regional accreditation cooperations, or an equivalent organization as determined by EPA;

(ii) Be in conformance with ISO/IEC 17011:2004(E) (incorporated by reference, see § 770.99); and

(iii) Be competent to perform accreditation activities for product certification according to ISO/IEC 17065:2012(E) (incorporated by reference, see § 770.99).

(2) *Application.* To be recognized by EPA under the EPA TSCA Title VI Third-Party Certification Program, a Product AB must submit an application to EPA in accordance with § 770.8 that contains the following:

(i) Name, address, telephone number, and email address of the organization or primary contact;

(ii) Documentation of IAF MLA signatory status, membership in one of the IAF recognized regional accreditation cooperations, or an equivalent organization as determined by EPA;

(iii) Description of any other qualifications related to the Product AB's experience in performing product accreditation of TPCs for manufactured products including an affirmation that assessors will be technically competent to assess a TPC's ability to perform

their activities under paragraph (c)(4) of this section; and

(iv) If not a domestic entity, name and address of an agent for service located in the United States. Service on this agent constitutes service on the AB or any of its officers or employees for any action by EPA or otherwise by the United States related to the requirements of this part. ABs may share an agent for service.

(3) *Recognition agreement.* To be recognized by EPA under the EPA TSCA Title VI Third-Party Certification Program, a Product AB must enter into a recognition agreement with EPA that describes the EPA TSCA Title VI Product AB's responsibilities under this subpart.

(i) Each recognition agreement will be valid for three years.

(ii) Each recognition agreement will identify an EPA Recognition Agreement Implementation Officer and an EPA TSCA Title VI Product AB Implementation Officer that will serve as the point of contact for the EPA TSCA Title VI Third-Party Certification Program.

(iii) To renew a recognition agreement for an additional three-year period, the EPA TSCA Title VI Product AB must submit an application for renewal in accordance with §770.8 before the three-year period of the recognition agreement lapses. The application must indicate any changes from the EPA TSCA Title VI Product AB's initial application or most recent renewal application.

(iv) If an EPA TSCA Title VI Product AB fails to submit an application for renewal prior to the expiration of the previous recognition agreement, its recognition will lapse and the EPA TSCA Title VI Product AB may not provide accreditation services under TSCA Title VI.

(v) If an EPA TSCA Title VI Product AB does submit an application for renewal prior to the expiration of the previous recognition agreement, it may continue to provide TSCA Title VI accreditation services under the terms of its previous recognition agreement until EPA has taken action on its application for renewal of the recognition agreement.

(4) *Impartiality.* EPA TSCA Title VI Product ABs must act impartially when performing activities under the EPA TSCA Title VI Third-Party Certification Program. To demonstrate impartiality, Product ABs must:

(i) Ensure that an accreditation decision regarding a TPC is made by persons different from those who conducted the assessment of the TPC; and

(ii) Ensure that the AB's personnel who assess TPCs or make decisions regarding accreditation do not receive financial benefit from the outcome of an accreditation decision.

(5) *Responsibilities.* Each EPA TSCA Title VI Product AB has the following responsibilities under the EPA TSCA Title VI Third-Party Certification Program:

(i) *Accreditation.* EPA TSCA Title VI Product ABs must determine the accreditation eligibility, and accredit if appropriate, each TPC seeking recognition under the EPA TSCA Title VI Third-Party Certification Program by performing an assessment of each TPC as described in this section. The assessment must include all of the following components:

(A) An on-site assessment by the EPA TSCA Title VI Product AB to determine whether the TPC meets the requirements of ISO/IEC 17065:2012(E), is in conformance with ISO/IEC 17020:2012(E) as required under ISO/IEC 17065:2012(E) section 6.2.1 (incorporated by reference, see §770.99) and the EPA TSCA Title VI TPC requirements under this part. In performing the on-site assessment, the EPA TSCA Title VI Product AB must:

(*1*) Develop a checklist of the EPA TSCA Title VI TPC requirements under paragraph (c)(4) of this section and the key accreditation elements of ISO/IEC 17065:2012(E) (incorporated by reference, see §770.99); and

(*2*) Use the checklist for each on-site assessment.

(B) A review of the approach that the TPC will use to verify the accuracy of the formaldehyde emissions tests conducted by the TPC laboratory and the formaldehyde quality control tests conducted by or for the panel producers producing composite wood products that are subject to the requirements of TSCA Title VI.

(C) A review of the approach that the TPC will use for evaluating a panel producer's quality assurance and quality control processes, the proficiency of the panel producer's quality assurance and quality control personnel, the required elements of a panel producer's quality assurance and quality control manual, and sufficiency of on-site testing facilities as applicable.

(D) A review of the approach that the TPC laboratory will use for establishing correlation or equivalence between ASTM E1333–14 and ASTM D6007–14, if used, (incorporated by reference, see § 770.99) or allowable formaldehyde test methods listed under § 770.20.

(E) A review of the approach that the TPC will use for evaluating the process for sample selection, handling, and shipping procedures that the panel producer will use for quality control testing as applicable.

(F) A review of the accreditation credentials of the TPC laboratory, including a verification that the laboratory has been accredited to ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99) with a scope of accreditation to include this part—Formaldehyde Standards for Composite Wood Products and the formaldehyde test methods ASTM E1333–14 and ASTM D6007–14, if used, by an EPA TSCA Title VI Laboratory AB (incorporated by reference, see § 770.99).

(ii) *Reassessment.* Each EPA TSCA Title VI Product AB must, in accordance with ISO/IEC 17011:2004(E) section 7.11 (incorporated by reference, see § 770.99), conduct an on-site reassessment or surveillance on-site assessment at least every two years of each EPA TSCA Title VI TPC that the AB has accredited.

(iii) *Suspension, reduction, withdrawal.* Each EPA TSCA Title VI Product AB must suspend, reduce, or withdraw the accreditation of an EPA TSCA Title VI TPC that the AB has accredited when circumstances warrant.

(iv) *Notifications.* Each EPA TSCA Title VI Product AB must provide, in accordance with § 770.8, the following notifications to EPA, as applicable:

(A) Notification of the loss of its status as a signatory to the IAF MLA, or loss of membership in one of the IAF recognized regional accreditation cooperations, or an equivalent organization as determined by EPA must be provided within five calendar days of the date that the body receives notification of the loss of its signatory or membership status.

(B) Notification that an EPA TSCA Title VI TPC has failed to comply with any provision of this part must be provided within 72 hours of the time the Product AB identifies the deficiency. The notice must include a description of the steps taken to address the deficiency.

(C) Notification of suspension, reduction or withdrawal of an EPA TSCA Title VI TPC's accreditation must be provided within 72 hours of the time that the suspension, reduction or withdrawal takes effect.

(D) Notification of a change in a nondomestic Product AB's agent for service must be provided within five calendar days.

(v) *Records.* Each EPA TSCA Title VI Product AB must maintain, in electronic form, the checklists and other records documenting compliance with the requirements for assessment, reassessment, and surveillance on-site assessments of EPA TSCA Title VI TPCs for three years.

(vi) *Annual report.* Each EPA TSCA Title VI Product AB must provide, in accordance with § 770.8, an annual report on or before March 1st of each year for the AB services performed during the previous calendar year including the number and locations of assessment, reassessment, and surveillance on-site assessments performed for each EPA TSCA Title VI TPC.

(vii) *EPA meetings.* Each EPA TSCA Title VI Product AB must meet with EPA at least once every two years in person, via teleconference, or through other virtual methods to discuss the implementation of the EPA TSCA Title VI Third-Party Certification Program.

(viii) *Inspections.* Each EPA TSCA Title VI Product AB must allow inspections of the AB's facilities by EPA, at reasonable times, within reasonable limits, and in a reasonable manner, upon the presentation of appropriate credentials and a written notification to the AB.

(b) *EPA TSCA Title VI Laboratory ABs.* To participate in the EPA TSCA Title VI Third-Party Certification Program as an EPA TSCA Title VI Laboratory AB, a Laboratory AB must have the qualifications described in this section, submit an application and enter into a recognition agreement with EPA as described in this section, and, upon recognition from EPA, impartially perform the responsibilities described in this section.

(1) *Qualifications.* To qualify for recognition by EPA under the EPA TSCA Title VI Third-Party Certification Program as an EPA TSCA Title VI Laboratory AB, an applicant Laboratory AB must:

(i) Be a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), or have membership in one of the ILAC recognized regional accreditation cooperations, or an equivalent organization as determined by EPA;

(ii) Be in conformance with ISO/IEC 17011:2004(E) (incorporated by reference, see §770.99);

(iii) Be competent to perform accreditation activities for laboratory accreditation according to ISO/IEC 17025:2005(E) (incorporated by reference, see §770.99); and

(iv) Be competent to ensure EPA TSCA Title VI TPC inspection activities are in conformance with ISO/IEC 17020:2012(E) (incorporated by reference, see §770.99).

(2) *Application.* To be recognized by EPA under the EPA TSCA Title VI Third-Party Certification Program, a Laboratory AB must submit an application to EPA, which may be submitted in conjunction with a Product AB application. For recognition, a Laboratory AB must submit an application in accordance with §770.8 that contains the following:

(i) Name, address, telephone number, and email address of the organization or primary contact;

(ii) Documentation of ILAC MRA signatory status, membership in one of the ILAC recognized regional accreditation cooperations, or an equivalent organization as determined by EPA;

(iii) Description of any other qualifications related to the Laboratory AB's experience in performing laboratory accreditation and inspection certification of TPCs including an affirmation that assessors will be technically competent to assess TPCs ability to perform their activities under paragraph (c)(4) of this section; and

(iv) If not a domestic entity, name and address of an agent for service located in the United States. Service on this agent constitutes service on the AB or any of its officers or employees for any action by EPA or otherwise by the United States related to the requirements of this part. ABs may share an agent for service.

(3) *Recognition agreement.* To be recognized by EPA under the EPA TSCA Title VI Third-Party Certification Program, a Laboratory AB must enter into a recognition agreement with EPA that describes the EPA TSCA Title VI Laboratory AB's responsibilities under this subpart.

(i) Each recognition agreement will be valid for three years.

(ii) Each recognition agreement will identify an EPA Recognition Agreement Implementation Officer and an EPA TSCA Title VI Laboratory AB Implementation Officer that will serve as the point of contact for the EPA TSCA Title VI Third-Party Certification Program.

(iii) To renew a recognition agreement for an additional three-year period, the EPA TSCA Title VI Laboratory AB must submit an application for renewal in accordance with §770.8 before the three-year period of the recognition agreement lapses. The application must indicate any changes from the EPA TSCA Title VI Laboratory AB's initial application or most recent renewal application.

(iv) If an EPA TSCA Title VI Laboratory AB fails to submit an application for renewal prior to the expiration of the previous recognition agreement, its recognition will lapse and the EPA TSCA Title VI Laboratory AB may not provide accreditation services under TSCA Title VI.

(v) If an EPA TSCA Title VI Laboratory AB does submit an application for renewal prior to the expiration of the previous recognition agreement, it may continue to provide TSCA Title VI accreditation services under the terms of

its previous recognition agreement until EPA has taken action on its application for renewal of the recognition agreement.

(4) *Impartiality*. EPA TSCA Title VI Laboratory ABs must act impartially when performing activities under the EPA TSCA Title VI Third-Party Certification Program. To demonstrate impartiality, Laboratory ABs must:

(i) Ensure that an accreditation decision regarding a TPC is made by persons different from those who conducted the assessment of the TPC; and

(ii) Ensure that the AB's personnel who assess TPCs or make decisions regarding accreditation do not receive financial benefit from the outcome of an accreditation decision.

(5) *Responsibilities*. Each EPA TSCA Title VI Laboratory AB has the following responsibilities under the EPA TSCA Title VI Third-Party Certification Program:

(i) *Accreditation*. EPA TSCA Title VI Laboratory ABs must determine the accreditation eligibility, and accredit if appropriate, each TPC seeking recognition under the EPA TSCA Title VI Third-Party Certification Program by performing an assessment of each TPC. The assessment must include an on-site assessment by the EPA TSCA Title VI Laboratory AB to determine whether the laboratory meets the requirements of ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99), is in conformance with ISO/IEC 17020:2012(E) (incorporated by reference, see § 770.99) and the EPA TSCA Title VI TPC requirements under this part including the formaldehyde test methods ASTM E1333–14 and ASTM D6007–14 (incorporated by reference, see § 770.99), if used. In performing the on-site assessment, the EPA TSCA Title VI Laboratory AB must:

(A) Develop a checklist of the TPC requirements under paragraph (c)(4) of this section and the key conformity elements of ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99); and

(B) Use the checklist for each on-site assessment.

(ii) *Reassessment*. Each EPA TSCA Title VI Laboratory AB must, in accordance with ISO/IEC 17011:2004(E) section 7.11 (incorporated by reference, see § 770.99), conduct a follow-up reassessment or surveillance on-site assessment of each TPC laboratory that the AB has accredited.

(iii) *Proficiency*. Each EPA TSCA Title VI Laboratory AB must verify the accuracy of the formaldehyde emissions tests conducted by the TPC laboratory by ensuring the TPC laboratory participates in the CARB interlaboratory comparison for formaldehyde emissions when offered. In lieu of participation in the CARB interlaboratory comparison ensure that the TPC laboratory participates in an EPA-recognized proficiency testing program, if available.

(iv) *Suspension, reduction, withdrawal*. Each EPA TSCA Title VI Laboratory AB must suspend, reduce, or withdraw the accreditation of a TPC laboratory that the AB has accredited when circumstances warrant.

(v) *Notifications*. Each EPA TSCA Title VI Laboratory AB must provide, in accordance with § 770.8, the following notifications to EPA as applicable:

(A) Notification of the loss of its status as a signatory to the ILAC MRA, or loss of membership in one of the ILAC recognized regional accreditation cooperations, or an equivalent organization as determined by EPA, within five calendar days of the date that the body receives notice of the loss of its signatory or membership status.

(B) Notification that a TPC laboratory has failed to comply with any provision of this part within 72 hours of the time the Laboratory AB identifies the deficiency. The notice must include a description of the steps taken to address the deficiency.

(C) Notification of suspension, reduction or withdrawal of a TPC laboratory's accreditation within 72 hours of the time that the suspension, reduction or withdrawal takes effect.

(D) Notification of a change in a nondomestic Laboratory AB's agent for service within five calendar days.

(vi) *Records*. Each EPA TSCA Title VI Laboratory AB must maintain, in electronic form, the checklists and other records documenting compliance with the requirements for assessment, reassessment, and surveillance on-site assessments of TPC laboratories for three years.

(vii) *Annual report.* Each EPA TSCA Title VI Laboratory AB must provide, in accordance with §770.8, an annual report to EPA on or before March 1st of each year for AB services performed during the previous calendar year including the number and locations of assessment, reassessment, and surveillance on-site assessments performed for each TPC laboratory.

(viii) *EPA meetings.* Each EPA TSCA Title VI Laboratory AB must meet with EPA at least once every two years in person, via teleconference, or through other virtual methods to discuss the implementation of the EPA TSCA Title VI Third-Party Certification Program.

(ix) *Inspections.* Each EPA TSCA Title VI Laboratory AB must allow inspections of the AB's facilities by EPA, at reasonable times, within reasonable limits, and in a reasonable manner, upon the presentation of appropriate credentials and a written notification to the AB.

(c) *EPA TSCA Title VI Third-Party Certifiers.* To participate in the EPA TSCA Title VI Third-Party Certification Program as an EPA TSCA Title VI TPC, a TPC must be accredited by an EPA TSCA Title VI Product AB, use a laboratory that is accredited by an EPA TSCA Title VI Laboratory AB, have the other qualifications described in this subsection, submit an application and be recognized by EPA, and, upon recognition from EPA, impartially perform the responsibilities described in this section. Alternatively, CARB-approved TPCs must meet the criteria for reciprocity in paragraph (d) of this section and comply with the requirements of this part in order to be recognized by EPA as an EPA TSCA Title VI TPC.

(1) *Qualifications.* To qualify for recognition by EPA in the EPA TSCA Title VI Third-Party Certification Program as an EPA TSCA Title VI TPC, an applicant TPC must:

(i) Be accredited by an EPA TSCA Title VI Product AB to ISO/IEC 17065:2012(E) (incorporated by reference, see §770.99), with a scope of accreditation that includes include composite wood products and this part—Formaldehyde Standards for Composite Wood Products;

(ii) Be, or have a contract with a laboratory that is, accredited by an EPA TSCA Title VI Laboratory AB to ISO/IEC 17025:2005(E) (incorporated by reference, see §770.99) with a scope of accreditation to include this part—Formaldehyde Standards for Composite Wood Products—and the formaldehyde test methods ASTM E1333–14 and ASTM D6007–14, if used (incorporated by reference, see §770.99);

(iii) Have the ability to conduct inspections of composite wood products and properly train and supervise inspectors to inspect composite wood products in conformance with ISO/IEC 17020:2012(E) as required under ISO/IEC 17065:2012(E) section 6.2.1 (incorporated by reference, see §770.99);

(iv) Have demonstrated experience in the composite wood product industry with at least one type of composite wood product and indicated the specific product(s) the applicant intends to certify; and

(v) Have demonstrated experience in performing or verifying formaldehyde emissions testing on composite wood products, including experience with test method ASTM E1333–14 and ASTM D6007–14, if used, (incorporated by reference, see §770.99), and experience evaluating correlation between test methods. Applicant TPCs that have demonstrated experience with test method ASTM D6007–14 only, must be contracting testing with a laboratory that has a large chamber and demonstrate its experience with ASTM E1333–14.

(2) *Application.* Before certifying any products under this part, a TPC must be recognized by EPA under the EPA TSCA Title VI Third-Party Certification Program. To be recognized by EPA, a TPC must submit an application in accordance with §770.8 and renew that application every two years. The application must contain the following:

(i) Email address of the organization or primary contact, organization name, organization telephone number, and organization address;

(ii) Type of composite wood products that the applicant intends to certify;

(iii) A copy of the TPC's certificate of accreditation from an EPA TSCA Title VI Product AB to ISO/IEC

17065:2012(E) (incorporated by reference, see § 770.99) with a scope of accreditation that includes composite wood products and this part—Formaldehyde Standards for Composite Wood Products;

(iv) A copy of the TPC laboratory's certificate of accreditation from an EPA TSCA Title VI Laboratory AB to ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99) with a scope of accreditation to include this part—Formaldehyde Standards for Composite Wood Products—and the formaldehyde test methods ASTM E1333–14 and ASTM D6007–14 (incorporated by reference, see § 770.99), if used;

(v) An affirmation of the TPC's ability to conduct inspections of composite wood products and properly train and supervise inspectors to inspect composite wood products in conformance with ISO/IEC 17020:2012(E) as required under ISO/IEC 17065:2012(E) section 6.2.1 (incorporated by reference, see § 770.99);

(vi) A description of the TPC's experience in the composite wood product industry with at least one type of composite wood product and indicate the specific product(s) the applicant intends to certify;

(vii) A description of the TPC's experience in performing or verifying formaldehyde emissions testing on composite wood products;

(viii) A description of the TPC's experience with test method ASTM E1333–14 and/or ASTM D6007–14, if used, (incorporated by reference, see § 770.99), and experience evaluating correlation between test methods. Applicant TPCs that have experience with test method ASTM D6007–14 only, must be contracting testing with a laboratory that has a large chamber and describe its experience with ASTM E1333–14; and

(ix) If not a domestic entity, the name and address of an agent for service located in the United States. Service on this agent constitutes service on the TPC or any of its officers or employees for any action by EPA or otherwise by the United States related to the requirements of this part. TPCs may share an agent for service.

(3) *Impartiality*. EPA TSCA Title VI TPCs must act impartially in accordance with their accreditation when performing activities under the EPA TSCA Title VI Third-Party Certification Program. To demonstrate impartiality, TPCs must:

(i) Not also be, or have a financial interest in a panel producer, fabricator, laminated product producer, importer, designer, distributor or retailer of composite wood products;

(ii) Ensure that TPC management personnel and TPC personnel involved in the review and certification decision-making process for composite wood products are not involved in activities within the same or separate legal entity that may compromise the impartiality of its certification decision-making process, such as advocacy or consulting activities;

(iii) Ensure that TPC management personnel and TPC personnel of the same or separate legal entity involved in activities such as advocacy or consulting are not involved in the management of the certification body, the review, or the certification decisions; and

(iv) Ensure that TPC management personnel and TPC personnel certifying composite wood products sign a conflict of interest statement attesting that they will receive no financial benefit from the outcome of certification.

(4) *Responsibilities*. Each EPA TSCA Title VI TPC has the following responsibilities under the EPA TSCA Title VI Third-Party Certification Program:

(i) *Certification*. EPA TSCA Title VI TPCs certify composite wood products that are produced in accordance with this part and that comply with the emission standards of TSCA Title VI and this part, in accordance with ISO/IEC 17065:2012(E) (incorporated by reference, see § 770.99). For each panel producer making composite wood products certified by the TPC, the EPA TSCA Title VI TPC must:

(A) Verify that each panel producer has adequate quality assurance and quality control procedures and is complying with the applicable quality assurance and quality control requirements of this part;

(B) Verify each panel producer's quality control test results compared with test results from ASTM E1333–14 and ASTM D6007–14, if used, (incorporated by reference, see § 770.99) by having the TPC laboratory conduct quarterly

tests and evaluate test method equivalence and correlation as required under § 770.20;

(C) In consultation with the panel producer, establish quality control limits (QCLs) for formaldehyde emissions, and, if applicable, shipping quality control limits or other formaldehyde emission limits, for each panel producer and product type;

(D) Establish, for each panel producer, the process that will be used to determine if products are exceeding the applicable QCL;

(E) Provide its CARB or EPA TPC number to each panel producer for labeling and recordkeeping; and

(F) Inspect each panel producer, its products, and its records at least quarterly in conformance with ISO/IEC 17020:2012(E) as required under ISO/IEC 17065:2012(E) section 6.2.1 (incorporated by reference, see § 770.99).

(ii) *Laboratories.* For quarterly testing, each EPA TSCA Title VI TPC must use only laboratories that have been accredited by an EPA TSCA Title VI Laboratory AB and that either participate in the CARB interlaboratory comparison for formaldehyde emissions when offered or in an EPA-recognized proficiency or interlaboratory program, if available.

(iii) *NAF and ULEF.* For panel producers that do not receive approval for NAF or ULEF third-party certification exemptions or ULEF reduced testing from CARB, EPA TSCA Title VI TPCs must review applications for NAF or ULEF third-party certification exemptions or ULEF reduced testing. Each EPA TSCA Title VI TPC must approve these applications within 90 calendar days of receipt if the panel producer demonstrates that the requirements for third-party certification exemption under § 770.17 or § 770.18 or reduced testing under § 770.18 are met.

(iv) *Reduced testing for medium-density fiberboard or fiberboard.* EPA TSCA Title VI TPCs must review applications from panel producers to reduce the number of quality control tests for particleboard and medium-density fiberboard, and approve these applications within 90 calendar days of receipt if the panel producer demonstrates that the requirements for reduced testing under § 770.20(b)(2)(ii) are met.

(v) *Notifications to EPA.* Each EPA TSCA Title VI TPC must provide, in accordance with § 770.8, the following notifications to EPA, as applicable:

(A) Notification of an approved or rejected application, including a renewal application, for a NAF or ULEF third-party certification exemption or ULEF reduced testing within five calendar days of the approval or rejection with copies of all approved applications forwarded to EPA within 30 calendar days of approval.

(B) Notification of an approved or rejected application, including a renewal application, for reduced testing for medium-density fiberboard or particleboard within five calendar days of the approval or rejection with copies of all approved applications forwarded to EPA within 30 calendar days of approval.

(C) Notification of a panel producer exceeding its established QCL for more than two consecutive quality control tests within 72 hours of the time that the TPC becomes aware of the second exceedance. The notice must include the product type, dates of the quality control tests that exceeded the QCL, quality control test results, ASTM E1333–14 (incorporated by reference, see § 770.99) or ASTM D6007–14 method (incorporated by reference, see § 770.99) correlative equivalent values in accordance with § 770.20(d), the established QCL value(s) and the quality control method used.

(D) Notification of each failed quarterly test, that is any sample that exceeds the applicable formaldehyde emission standard in § 770.10, within 72 hours. Information in this notification is not eligible for treatment as confidential business information.

(E) Notification of a change in a nondomestic TPC's agent for service within five calendar days.

(F) Notification of a loss of accreditation or notification that the TPC has discontinued its participation in the EPA TSCA Title VI Third-Party Certification Program must be provided within 72 hours.

(vi) *Other notifications.* Each EPA TSCA Title VI TPC must provide the following notifications, if applicable:

(A) Notification of each failed quarterly test, that is any sample that exceeds the applicable formaldehyde emission standard in §770.10, to the panel producer in writing within 72 hours. Information in this notification is not eligible for treatment as confidential business information.

(B) Notification of a loss of accreditation or notification that the TPC has discontinued its participation in the EPA TSCA Title VI Third-Party Certification Program within 72 hours to all panel producers for which it provides EPA TSCA Title VI certification services.

(C) Notification of any changes in personnel qualifications, procedures, or laboratories used, to the TPC's EPA TSCA Title VI ABs within 30 calendar days.

(vii) *Records.* Each EPA TSCA Title VI TPC must maintain, in electronic form, the following records for three years from the date the record is created, and provide them to EPA within 30 calendar days of a request from EPA:

(A) A list of panel producers and their respective products and product types, including type of resin systems used, that the EPA TSCA Title VI TPC has certified;

(B) Results of inspections and formaldehyde emissions tests conducted for and linked to each panel producer and product type;

(C) A list of laboratories used by the EPA TSCA Title VI TPC, as well as all test methods used, including test conditions and conditioning time, and quarterly test results;

(D) Methods and results for establishing test method correlations and equivalence;

(E) Documentation for NAF or ULEF third-party certification exemptions or ULEF reduced testing approvals, including the name of the panel producer, facility, products approved, type of resin systems used and dates of approval;

(F) Documentation of reduced testing approval for panel producers of medium-density fiberboard or particleboard, including the name of the panel producer, products approved and dates of approval; and

(G) A copy of the most recent assessment, reassessment, and/or surveillance on-site assessment report provided by its EPA TSCA Title VI ABs.

(viii) *Annual report.* Each EPA TSCA Title VI TPC must provide, in accordance with §770.8, an annual report on or before March 1st of each year for the TPC services performed during the previous calendar year. Quarterly test results, the test method, date of test, and product tested (including the product name or description and panel producer name) are not eligible for treatment as confidential business information. The report must contain all of the following elements, as applicable:

(A) The following information for each panel producer making composite wood products certified by the TPC, the EPA TSCA Title VI TPC:

(*1*) Composite wood products that the EPA TSCA Title VI TPC has certified during the previous calendar year;

(*2*) Types of resin systems used for the composite wood products certified;

(*3*) Dates of quarterly inspections;

(*4*) For each quarterly test, the date, result, test method, and whether a contract laboratory was used;

(*5*) For each failed quarterly test, the product type, the volume of product affected, the results of recertification testing, and a description of the final disposition of the affected product, including how the non-complying lot was addressed;

(*6*) For each non-complying lot resulting from a failed quality control test, the test date, method, product type, volume of product affected, lot numbers, the results of retesting, and a description of the final disposition of the affected product, including how the non-complying lot was addressed; and

(*7*) Any corrective actions that resulted from quarterly tests and inspections.

(B) A list of laboratories and test methods used by the TPC, number and volume (cubic meters) of large and small chambers, date of equivalence determination and equivalence data.

(C) Any non-conformities identified by its EPA TSCA Title VI AB(s) and how they were addressed.

(D) The results compared with the mean of the interlaboratory comparison for all formaldehyde emissions

interlaboratory comparison tests other than the CARB interlaboratory comparison or, if available, the results of an EPA-recognized proficiency testing program.

(ix) *Assessments and inspections.* Upon request, each EPA TSCA Title VI TPC must allow EPA representatives to:

(A) Accompany the TPC's staff during an assessment, reassessment or surveillance on-site assessment of the TPC by its AB(s); and

(B) Inspect the TPC's facilities, at reasonable times, within reasonable limits, and in a reasonable manner, upon the presentation of appropriate credentials and a written notification to the TPC.

(d) *Reciprocity for third-party certifiers approved by the California Air Resources Board (CARB)*—(1) *During transitional period.* The transitional period is defined as the period beginning on December 12, 2016 and ending on March 22, 2019. TPCs already approved by CARB and TPCs subsequently approved by CARB during the transitional period must apply for EPA recognition in accordance with §770.8 before they can certify any products under this part. Once recognized by EPA, CARB-approved TPCs become EPA TSCA Title VI TPCs and may certify composite wood products under TSCA Title VI until March 22, 2019, as long as they:

(i) Remain approved by CARB; and

(ii) Comply with all aspects of this part other than the requirements of paragraphs (c)(1)(i) and (ii) and (c)(2)(iii) and (iv) of this section. This includes:

(A) Provide panel producers with the TPC number issued by CARB; and

(B) Provide the annual report required by paragraph (c)(4)(viii) of this section to CARB and EPA during the two-year transitional period.

(C) Provide notifications required by paragraph (c)(4)(v) to EPA.

(2) *After transition period.* (i) TPCs approved by CARB may continue to certify composite wood products under TSCA Title VI after the two-year transitional period if the TPC:

(A) Maintains its CARB approval;

(B) Complies with the requirements of this part;

(C) Submits to EPA, in accordance with §770.8:

(*1*) Documentation from CARB that specifies eligibility for reciprocity; and

(*2*) A copy of the application submitted to CARB to be recognized as a TPC under the CARB ATCM.

(D) Receives EPA recognition as an EPA TSCA Title VI TPC.

(ii) EPA retains the authority to deny recognition of CARB-approved TPCs who seek recognition through reciprocity in the EPA TSCA Title VI Third-Party Certification Program if EPA has information indicating that the TPC is not qualified.

(e) *Suspension, revocation or modification of recognition*—(1) *Third-party certifiers.* EPA may suspend, revoke or modify the recognition of a TPC, if the TPC:

(i) Fails to comply with any requirement of TSCA Title VI or this part;

(ii) Makes any false or misleading statements on its application, records, or reports; or

(iii) Makes substantial changes to personnel qualifications, procedures, or laboratories that make the TPC or TPC laboratory unable to comply with any applicable requirements of this part.

(2) *ABs.* EPA may suspend, revoke or modify the recognition of an AB if the AB:

(i) No longer maintains signatory status to the IAF MLA or ILAC MRA, membership in one of the IAF/ILAC recognized regional accreditation cooperations, or an equivalent organization as determined by EPA;

(ii) Fails to comply with any requirement of TSCA Title VI or this part;

(iii) Makes any false or misleading statements on its application, records, or reports; or

(iv) Makes substantial changes to personnel qualifications or procedures that make the AB, TPC and/or TPC laboratory unable to comply with any applicable requirements of this part.

(3) *Process for suspending, revoking or modifying recognition.* (i) Prior to taking action to suspend, revoke or modify recognition, EPA will notify the participant AB or the participant TPC in writing of the following:

(A) The legal and factual basis for the proposed suspension, revocation or modification;

(B) The anticipated commencement date and duration of the suspension, revocation or modification;

(C) Actions, if any, which the affected AB or TPC may take to avoid suspension, revocation or modification, or to receive recognition in the future; and

(D) The opportunity and method for requesting a hearing with EPA prior to final suspension, revocation or modification.

(ii) If the affected AB or TPC requests a hearing in writing to EPA within 30 calendar days of receipt of the notification, EPA will:

(A) Provide the affected AB or TPC an opportunity to offer written statements in response to EPA's assertions of the legal and factual basis for the proposed action; and

(B) Appoint an impartial EPA official as Presiding Officer to conduct the hearing. The Presiding Officer will:

(*1*) Conduct a fair, orderly, and impartial hearing within 90 calendar days of the request for a hearing;

(*2*) Consider all relevant evidence, explanations, comments, and arguments submitted; and

(*3*) Notify the affected AB or TPC in writing within calendar 90 days of completion of the hearing of his or her decision and order. Such an order is a final EPA action which may be subject to judicial review. The order must contain the basis, commencement date, and duration of the suspension, revocation or modification.

(iii) If EPA determines that the public health, interest, or welfare warrants immediate action to revoke the recognition of an AB or TPC prior to the opportunity for a hearing, it will notify the affected AB or TPC of its right to request a hearing on the immediate revocation within 15 calendar days of the revocation taking place and the procedures for the conduct of such a hearing.

(iv) Any notification, decision, or order issued by EPA under this section, any transcript or other verbatim record of oral testimony, and any documents filed by a certified individual or firm in a hearing under this section will be available to the public, except as otherwise provided by TSCA section 14. Any such hearing at which oral testimony is presented will be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow presentation of information which may be entitled to confidential treatment under TSCA section 14.

(v) EPA will maintain a publicly available list of ABs on its Web site whose recognition has been suspended, revoked or modified, or reinstated and a publicly available list of TPCs whose recognition has been suspended, revoked, modified, or reinstated.

(vi) Unless the decision and order issued under paragraph (e)(3) of this section specify otherwise, an AB or a TPC whose recognition has been revoked must reapply for recognition in order to become recognized under this part again.

(vii) Unless the decision and order issued under paragraph (e)(3) of this section specify otherwise, an AB whose recognition has been revoked or a TPC whose recognition has been revoked, must immediately notify all TPCs or panel producers to which it provides TSCA Title VI accreditation or certification services of the revocation.

(f) *Effect of the loss of recognition or accreditation.* (1) If an AB is removed or withdraws from the EPA TSCA Title VI Third-Party Certification Program:

(i) For reasons other than fraud or providing false or misleading statements, and other than a reason that implicates a particular TPC in a violation of TSCA Title VI, TPCs accredited by that AB can continue to certify products under TSCA Title VI for 180 calendar days, after which the TPCs must be accredited again by another EPA TSCA Title VI AB and re-recognized by EPA.

(ii) Due to fraud or providing false or misleading statements with respect to a particular TPC, or for any other reason that implicates a particular TPC in a violation of TSCA Title VI, that TPC may not provide any TSCA Title VI certification services until it has been accredited again by another EPA TSCA Title VI AB and re-recognized by EPA.

(2) If a TPC loses its accreditation, or if TPC is removed or withdraws from the EPA TSCA Title VI Third-Party Certification Program:

(i) For reasons other than fraud or providing false or misleading statements, and other than a reason that implicates a particular panel producer in a violation of TSCA Title VI, the panel producers that used the TPC to certify their products must enlist another EPA TSCA Title VI TPC to certify their products within 90 calendar days. If the panel producer is not able to obtain the services of another EPA TSCA Title VI TPC within 90 days, the panel producer may request from EPA a 90 calendar day extension. During the time a panel producer is seeking a new TPC, it must continue to comply with all other requirements of TSCA Title VI, including quality control testing.

(ii) Due to fraud or providing false or misleading statements with respect to a particular panel producer, or for any other reason that implicates a particular panel producer in a violation of TSCA Title VI, that panel producer may not sell, supply, offer for sale, or manufacture composite wood products for sale in the United States until its composite wood products have been recertified by another EPA TSCA Title VI TPC.

(g) *Process for denying EPA TSCA Title VI recognition.* (1) Upon EPA denying a request for recognition of an AB or TPC, EPA will notify the AB or TPC in writing of the following:

(i) The legal and factual basis for the denial; and

(ii) Actions, if any, which the affected AB or TPC may take to receive recognition in the future.

(2) [Reserved]

[81 FR 89724, Dec. 12, 2016, as amended at 82 FR 44537, Sept. 25, 2017; 83 FR 5346, Feb. 7, 2018]

§ 770.8 Applications, notifications, and reports.

(a) All applications, notifications, and reports that are required to be submitted to EPA under this subpart must be submitted via the EPA Central Data Exchange (CDX) found at *https://cdx.epa.gov*.

(b) If the EPA CDX is unavailable, EPA will so inform EPA TSCA Title VI ABs and TPCs and will make electronic applications and reporting forms available online at *http://www.epa.gov/formaldehyde*.

(c)(1) Persons submitting a notice under this rule are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B, except that the certification in paragraph (c)(2) of this section must also be provided when asserting a claim of confidentiality.

(2) In submitting a claim of confidentiality, a person must certify the truth of the following four statements concerning all information which is claimed as confidential:

(i) My company has taken measures to protect the confidentiality of the information.

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law.

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Subpart C—Composite Wood Products

§ 770.10 Formaldehyde emission standards.

(a) Except as otherwise provided in this part, the emission standards in this section apply to composite wood products sold, supplied, offered for sale, or manufactured (including imported) on or after December 12, 2018 in the United States. These emission standards apply regardless of whether the composite wood product is in the form of a panel, a component part, or incorporated into a finished good.

(b) The emission standards are based on test method ASTM E1333–14 (incorporated by reference, see § 770.99), and are as follows:

(1) For hardwood plywood made with a veneer core or a composite core, 0.05 parts per million (ppm) of formaldehyde.

(2) For medium-density fiberboard, 0.11 ppm of formaldehyde.

(3) For thin medium-density fiberboard, 0.13 ppm of formaldehyde.

(4) For particleboard, 0.09 ppm of formaldehyde.

[81 FR 89724, Dec. 12, 2016, as amended at 82 FR 44537, Sept. 25, 2017; 83 FR 5347, Feb. 7, 2018]

§ 770.12 Stockpiling.

(a) The sale of stockpiled inventory of composite wood products, whether in the form of panels or incorporated into component parts or finished goods, is prohibited after December 12, 2018.

(b) To determine whether stockpiling has occurred, the rate of manufacture or purchase is measured as follows:

(1) For composite wood products in the form of panels, the rate is measured in terms of square footage of panels produced.

(2) For composite wood products incorporated into component parts or finished goods, the rate is measured in terms of the square footage of composite wood product panels purchased for the purpose of incorporating them into component parts or finished goods.

(c) Manufacturers or purchasers who have, in an annual year, a greater than 20% increase in manufacturing or purchasing composite wood products relative to annual year 2009 for some reason other than circumventing the emission standards would not be in violation of this section. Such reasons may include, but are not limited to:

(1) A quantifiable immediate increase in customer demand or sales.

(2) A documented and planned business expansion.

(3) The manufacturer or purchaser was not in business at the beginning of calendar year 2009.

(4) An increase in production to meet increased demand resulting from an emergency event or natural disaster.

(d) In order to be found to be stockpiling an entity must be increasing the rate of manufacturing or purchasing for the purpose of circumventing the emission standards.

[81 FR 89724, Dec. 12, 2016, as amended at 82 FR 44537, Sept. 25, 2017]

§ 770.15 Composite wood product certification.

(a) Beginning December 12, 2018, only certified composite wood products, whether in the form of panels or incorporated into component parts or finished goods, are permitted to be sold, supplied, offered for sale, or manufactured (including imported) in the United States, unless the product is specifically exempted by this part.

(b) Certified composite wood products are those that are produced or fabricated in accordance with all of the provisions of this part.

(c) To obtain product certification, a panel producer must apply to an EPA TSCA Title VI TPC.

(1) For panel producers that do not have any previous product certifications from a CARB-approved TPC or an EPA TSCA Title VI TPC, the application must contain the following:

(i) The panel producer's name, address, telephone number, and other contact information;

(ii) A copy of the panel producer's quality control manual as required by § 770.21(a);

(iii) Name and contact information for the panel producer's quality control manager;

(iv) An identification of the specific products for which certification is requested, and the resin system used in panel production;

(v) At least five tests conducted under the supervision of an EPA TSCA Title VI TPC pursuant to test method ASTM E1333–14 or ASTM D6007–14 (incorporated by reference, see § 770.99). Test results obtained by ASTM D6007–14 must include a showing of equivalence in accordance with § 770.20(d)(1);

(vi) At least five quality control tests conducted in accordance with § 770.20(b)(1);

(vii) Linear regression equation and correlation data; and

(viii) Results of an initial, on-site inspection by the TPC of the panel producer.

(2) For panel producers applying for certification of a new product type but that have previous product certifications from a CARB-approved TPC or an EPA TSCA Title VI TPC, the application must contain the following:

(i) The panel producer's name, address, and telephone number;

(ii) An identification of the specific products for which certification is requested, and the resin system used in panel production;

(iii) At least five tests conducted under the supervision of an EPA TSCA Title VI TPC pursuant to test method ASTM E1333–14 or ASTM D6007–14 (incorporated by reference, see §770.99). Test results obtained by ASTM D6007–14 must include a showing of equivalence in accordance with §770.20(d)(1);

(iv) At least five quality control tests conducted in accordance with §770.20(b)(1);

(v) Linear regression equation and correlation data; and

(vi) Description of any changes in the panel producer's quality control manual and a copy of those changes.

(d) The EPA TSCA Title VI TPC must act on a panel producer's complete application within 90 calendar days of receipt by reviewing all of the components of the application.

(1) If the application indicates that the candidate product achieves the applicable emission standards described in §770.10, adequate correlation as described in §770.20(d)(2), and that the panel producer is meeting the requirements in §770.21, the EPA TSCA Title VI TPC will approve the application.

(2) If the application is from a panel producer that did not previously have products certified by a CARB-approved TPC or an EPA TSCA Title VI TPC, the EPA TSCA Title VI TPC will review the quality control manual and results of the on-site initial inspection and approve or disapprove the quality control manual.

(3) If the application does not demonstrate that the candidate product achieves the applicable emission standards described in §770.10, the EPA TSCA Title VI TPC will disapprove the application. A new application may be submitted for the candidate product at any time.

(e) If a product is certified by a CARB-approved TPC that is also recognized by EPA, the product will also be considered certified under TSCA Title VI until March 22, 2019 after which the TPC needs to comply with all the requirements of this part as an EPA TSCA Title VI TPC under Section 770.7(d) in order for the product to remain certified.

(f) To maintain certification, the panel producer making the certified product must get inspected by its EPA TSCA Title VI TPC quarterly as well as meet the testing requirements under §770.20.

(g) If the certified product fails a quarterly test, certification for any product types represented by the sample is suspended until a compliant quarterly test result is obtained in accordance with §770.22.

[81 FR 89724, Dec. 12, 2016, as amended at 82 FR 44537, Sept. 25, 2017; 83 FR 5347, Feb. 7, 2018]

§770.17 No-added formaldehyde-based resins.

(a) Producers of composite wood product panels made with no-added formaldehyde-based resins may apply to an EPA TSCA Title VI TPC or to CARB for a two-year exemption from the testing requirements in §770.20 and certification requirements in §§770.15 and 770.40(b). The application must contain the following:

(1) The panel producer's name, address, and telephone number;

(2) An identification of the specific product and the resin system;

(3) At least one test conducted under the supervision of an EPA TSCA Title VI TPC pursuant to test method ASTM E1333–14 or ASTM D6007–14 (incorporated by reference, see §770.99). Test results obtained by ASTM D6007–14 must include a showing of equivalence in accordance with §770.20(d)(1); and

(4) Three months of routine quality control tests under §770.20, including a showing of correlation in accordance with §770.20(d)(2), totaling not less than five quality control tests.

(b) The EPA TSCA Title VI TPC will approve a panel producer's application within 90 calendar days of receipt if the application is complete and demonstrates that the candidate product achieves the emission standards described in paragraph (c) of this section.

(c) As measured according to paragraphs (a)(3) and (4) of this section, the emission standards for composite wood products made with no-added formaldehyde-based resins are as follows:

(1) No test result higher than 0.05 parts per million (ppm) of formaldehyde for hardwood plywood and 0.06 ppm for particleboard, medium-density fiberboard, and thin medium-density fiberboard.

(2) No higher than 0.04 ppm of formaldehyde for 90% of the three months of routine quality control testing data required under paragraph (a)(4) of this section.

(d) Products that meet the requirements specified under § 770.17(c)(1) and (2) and have obtained exemption from the California Air Resources Board will also be exempt from the requirements in §§ 770.15, 770.20, and 770.40(b), as long as the requirements of the California Air Resources Board remain as stringent as EPA's requirements.

(e) After the two-year period of the initial exemption, and every two years thereafter, in order to continue to qualify for the exemption from the testing and certification requirements, the panel producer must reapply to an EPA TSCA Title VI TPC or to CARB and obtain at least one test result in accordance with paragraph (a)(3) of this section that complies with the emission standards in paragraph (c)(1) of this section.

(f) Any time there is an operational or process change that is likely to affect formaldehyde emissions, such as a change in resin formulation, press cycle duration, temperature, or amount of resin used per panel, at least one quality control test under § 770.20 and at least one test result in accordance with paragraph (a)(3) of this section that indicate compliance with the emission standards in paragraph (c)(1) of this section are required.

(g) A change in the resin system invalidates the exemption for any product produced with the different resin after such a change.

[81 FR 89724, Dec. 12, 2016, as amended at 83 FR 5347, Feb. 7, 2018]

§ 770.18 Ultra low-emitting formaldehyde resins.

(a) Producers of composite wood product panels made with ultra low-emitting formaldehyde resins may apply to an EPA TSCA Title VI TPC or CARB for approval either to conduct less frequent testing than is specified in § 770.20 or approval for a two-year exemption from the testing requirements in § 770.20 and certification requirements in §§ 770.15 and 770.40(b). The application must contain the following:

(1) The panel producer's name, address, and telephone number;

(2) An identification of the specific product type, including resin system;

(3) At least two tests conducted under the supervision of an EPA TSCA Title VI TPC pursuant to test method ASTM E1333–14 or ASTM D6007–14 (incorporated by reference, see § 770.99). Test results obtained by ASTM D6007–14 must include a showing of equivalence in accordance with § 770.20(d)(1); and

(4) Six months of routine quality control tests under § 770.20, including a showing of correlation in accordance with § 770.20(d)(2), totaling not less than ten quality control tests.

(b) The EPA TSCA Title VI TPC will approve a panel producer's application within 90 calendar days of receipt if the application is complete and demonstrates that the candidate product achieves the emission standards required for reduced testing as described in paragraph (c) of this section or the emission standards required for a two-year exemption as described in paragraph (d) of this section.

(c) As measured according to paragraphs (a)(3) and (4) of this section, the emission standards for reduced testing for composite wood products made with ultra low-emitting formaldehyde resins are as follows:

(1) No test result higher than 0.05 parts per million (ppm) of formaldehyde for hardwood plywood, 0.08 ppm for particleboard, 0.09 ppm for medium-density fiberboard, and 0.11 ppm for thin medium-density fiberboard.

(2) For 90% of the six months of routine quality control testing data required under paragraph (a)(4) of this section, no higher than 0.05 ppm of formaldehyde for particleboard, no higher than 0.06 ppm of formaldehyde for medium-density fiberboard, and no higher than 0.08 ppm of formaldehyde for thin medium-density fiberboard.

(d) As measured according to paragraphs (a)(3) and (4) of this section, the emission standards for an exemption from the testing and certification requirements of § 770.20 for composite wood products made with ultra low-emitting formaldehyde resins are as follows:

(1) No test result higher than 0.05 ppm of formaldehyde for hardwood plywood or 0.06 ppm of formaldehyde for particleboard, medium-density fiberboard, and thin medium-density fiberboard.

(2) For 90% of the six months of routine quality control testing data required under paragraph (a)(4) of this section, no higher than 0.04 parts per million of formaldehyde.

(e) Products that have obtained an exemption from the California Air Resources Board will also be exempt from the requirements in §§ 770.15, 770.20, and 770.40(b) if they meet the requirements under § 770.18(d) and the requirements of the California Air Resources Board remain as stringent as EPA's requirements. Products that have obtained approval for reduced testing from the California Air Resources Board will be granted approval to conduct less frequent testing than is specified in § 770.20 if they meet the requirements under § 770.18(c) and the requirements of the California Air Resources Board remain as stringent as EPA's requirements.

(f) Products that are represented by a quarterly test result that exceeds the applicable emission standard in this section or a quality control test that indicates that the product exceeds the applicable emission standard in this section lose their reduced testing approval and must reapply as specified under § 770.18(a).

(g) After the two-year period of the initial exemption, and every two years thereafter, in order to continue to qualify for the exemption from the testing and certification requirements, the panel producer must reapply to an EPA TSCA Title VI TPC or CARB and obtain at least two test results in accordance with paragraph (a)(3) of this section that comply with the emission standards in paragraph (d)(1) of this section.

(h) Any time there is an operational or process change such as a change in resin formulation, press cycle duration, temperature, or amount of resin used per panel, at least five quality control tests under § 770.20 and at least one test result in accordance with paragraph (a)(3) of this section that indicate compliance with the emission standards in paragraph (d)(1) of this section are required.

(i) A change in the resin system invalidates the exemption or reduced testing approval for any product type produced after such a change.

[81 FR 89724, Dec. 12, 2016, as amended at 83 FR 5347, Feb. 7, 2018]

§ 770.20 Testing requirements.

(a) *General requirements.* (1) All panels must be tested in an unfinished condition, prior to the application of a finishing or topcoat, as soon as possible after their production but no later than 30 calendar days after production.

(2) Facilities that conduct the formaldehyde testing required by this section must follow the procedures and specifications, such as testing conditions and loading ratios, of the test method being used.

(3) All equipment used in the formaldehyde testing required by this section must be calibrated and otherwise maintained and used in accordance with the equipment manufacturer's instructions.

(b) *Quality control testing*—(1) *Allowable methods.* Quality control testing must be performed using any of the following methods, with a showing of correlation for each method pursuant to paragraph (d) of this section:

(i) ASTM D6007–14 (incorporated by reference, see § 770.99).

(ii) ASTM D5582–14 (incorporated by reference, see § 770.99).

(iii) BS EN ISO 12460–3:2015 E (Gas Analysis Method) (incorporated by reference, see § 770.99).

(iv) DMC 2007 User's Manual (incorporated by reference, see § 770.99).

(v) DMC 2012 GP User's Manual (incorporated by reference, see § 770.99).

(vi) BS EN ISO 12460–5:2015 E (Perforator Method) (incorporated by reference, see § 770.99).

(vii) JIS A 1460:2015(E) (24-hr Desiccator Method) (incorporated by reference, see § 770.99).

(2) *Frequency of testing.* (i) Particleboard and medium-density fiberboard must be tested at least once per shift (eight or twelve hours, plus or minus one hour of production) for each production line for each product type. Quality control tests must also be conducted whenever:

(A) A product type production ends, even if eight hours of production has not been reached;

(B) The resin formulation is changed so that the formaldehyde to urea ratio is increased;

(C) There is an increase by more than ten percent in the amount of formaldehyde resin used, by square foot or by panel;

(D) There is a decrease in the designated press time by more than 20%; or

(E) The quality control manager or quality control employee has reason to believe that the panel being produced may not meet the requirements of the applicable standards.

(ii) Particleboard and medium-density fiberboard panel producers are eligible for reduced quality control testing if they demonstrate consistent operations and low variability of test values.

(A) To qualify, panel producers must:

(*1*) Apply in writing to an EPA TSCA Title VI TPC; and

(*2*) Maintain a 30 panel running average.

(B) With respect to reduced quality control testing, EPA TSCA Title VI TPCs:

(*1*) May approve a reduction to one quality control test per 24-hour production period if the 30 panel running average remains two standard deviations below the designated QCL for the previous 60 consecutive calendar days or more;

(*2*) May approve a reduction to one quality control test per 48-hour production period if the 30 panel running average remains three standard deviations below the designated QCL for the previous 60 consecutive calendar days or more;

(*3*) Will approve a request for reduced quality control testing as long as the data submitted by the panel producer demonstrate compliance with the criteria and the EPA TSCA Title VI TPC does not otherwise have reason to believe that the data are inaccurate or the panel producer's production processes are inadequate to ensure continued compliance with the emission standards; and

(*4*) Will revoke approval for reduced quality control testing if testing or inspections indicate a panel producer no longer demonstrates consistent operations and low variability of test values.

(iii) Hardwood plywood must be tested as follows:

(A) At least one test per week per product type if the weekly hardwood plywood production at the panel producer is more than 100,000 but less than 200,000 square feet.

(B) At least two tests per week per product type if the weekly hardwood plywood production at the panel producer is 200,000 square feet or more, but less than 400,000 square feet.

(C) At least four tests per week per product type if the weekly hardwood plywood production at the panel producer is 400,000 square feet or more.

(D) If weekly production of hardwood plywood at the panel producer is 100,000 square feet or less, at least one test per 100,000 square feet for each product type produced; or, if less than 100,000 square feet of a particular product type is produced, one quality control test of that product type every month that it is produced.

(E) Quality control tests must also be conducted whenever:

(*1*) The resin formulation is changed so that the formaldehyde to urea ratio is increased;

(*2*) There is an increase by more than ten percent in the amount of formaldehyde resin used, by square foot or by panel;

(*3*) There is an increase by more than 20% in the adhesive application rate;

(*4*) There is a decrease in the designated press time by more than 20%; or

(*5*) The quality control manager or quality control employee has reason to believe that the panel being produced may not meet the requirements of the applicable standard.

(iv) Composite wood products that have been approved by an EPA TSCA Title VI TPC or CARB for reduced testing under § 770.18(b) through (c) must be tested at least once per week per product type and, for particle board and medium-density fiberboard, per production line, for products produced that week, except that hardwood plywood panel producers who qualify for less frequent testing under paragraph

(b)(2)(iii)(D) of this section may continue to perform quality control testing under that provision.

(3) *Results.* Any test result that exceeds the QCL established pursuant to §770.7(c)(4)(i)(C) must be reported to the EPA TSCA Title VI TPC in writing within 72 hours. The panel producer must comply with §770.22 with respect to any lot represented by a quality control sample that exceeds the QCL. Where multiple products are grouped in a single product type for testing, this includes all products in the group represented by the sample.

(c) *Quarterly testing.* Quarterly testing must be supervised by EPA TSCA Title VI TPCs and performed by TPC laboratories.

(1) *Allowable methods.* Quarterly testing must be performed using ASTM E1333–14 (incorporated by reference, see §770.99) or, with a showing of equivalence pursuant to paragraph (d) of this section, ASTM D6007–14 (incorporated by reference, see §770.99).

(2) *Sample selection.* (i) Samples must be randomly chosen by an EPA TSCA Title VI TPC.

(ii) Samples must be selected from each certified product type for quarterly testing purposes. For hardwood plywood samples, the samples must be randomly selected from products that represent the range of formaldehyde emissions of products produced by the panel producer.

(iii) Samples must not include the top or the bottom composite wood product of a bundle.

(3) *Sample handling.* Samples must be closely stacked or air-tight wrapped between the time of sample selection and the start of test conditioning. Samples must be labeled as such, signed by the EPA TSCA Title VI TPC, bundled air-tight, wrapped in polyethylene, protected by cover sheets, and promptly shipped to the TPC laboratory. Conditioning must begin as soon as possible, but no later than 30 calendar days after the samples were produced.

(4) *Results.* Any sample that exceeds the applicable formaldehyde emission standard in §770.10 must be reported by the EPA TSCA Title VI TPC to the panel producer in writing and to EPA, in accordance with §770.8, within 72 hours. The panel producer must comply with §770.22 with respect to any lot represented by a sample result that exceeds the applicable formaldehyde emission standard. Where multiple products are grouped in a single product type for testing, this includes all products in the group represented by the sample.

(5) *Reduced testing frequency.* Composite wood products that have been approved by an EPA TSCA Title VI TPC or CARB for reduced testing under §770.18(c) need only undergo quarterly testing every six months.

(d) *Equivalence or correlation.* Equivalence or correlation between ASTM E1333–14 (incorporated by reference, see §770.99) and any other test method used for quarterly or quality control testing must be demonstrated by EPA TSCA Title VI TPCs or panel producers, respectively, at least once each year for each testing apparatus or whenever there is a significant change in equipment, procedure, or the qualifications of testing personnel. Once equivalence or correlation have been established for three consecutive years, equivalence or correlation must be demonstrated every two years or whenever there is a significant change in equipment, procedure, or the qualifications of testing personnel.

(1) *Equivalence between ASTM E1333–14 and ASTM D6007–14 when used by the TPC for quarterly testing.* Equivalence must be demonstrated for at least five comparison sample sets, which compare the results of the two methods. Equivalence must be demonstrated for each small chamber used and for the ranges of emissions of composite wood products tested by the TPC.

(i) *Samples.* (A) For the ASTM E1333–14 method (incorporated by reference, see §770.99), each comparison sample must consist of the result of testing panels, using the applicable loading ratios specified in the ASTM E1333–14 method (incorporated by reference, see §770.99), from similar panels of the same product type tested by the ASTM D6007–14 method (incorporated by reference, see §770.99).

(B) For the ASTM D6007–14 method (incorporated by reference, see §770.99), each comparison sample shall consist

of testing specimens representing portions of panels similar to the panels tested in the ASTM E1333–14 method (incorporated by reference, see § 770.99) and matched to their respective ASTM E1333–14 method (incorporated by reference, see § 770.99) comparison sample result. The ratio of air flow to sample surface area specified in ASTM D6007–14 (incorporated by reference, see § 770.99) must be used.

(C) The five comparison sample must consist of testing a minimum of five sample sets as measured by the ASTM E1333–14 method (incorporated by reference, see § 770.99).

(ii) *Average and standard deviation.* The arithmetic mean, x, and standard deviation, S, of the difference of all comparison sets must be calculated as follows:

$$\overline{X} = \sum_{i=1}^{n} D_i / n \qquad S = \sqrt{\sum_{i=1}^{n} (D_i - \overline{X})^2 / (n-1)}$$

Where x = arithmetic mean; S = standard deviation; n = number of sets; D i = difference between the ASTM E1333–14 and ASTM D6007–14 method (incorporated by reference, see § 770.99) values for the i th set; and i ranges from 1 to n.

(iii) *Equivalence determination.* The ASTM D6007–14 method (incorporated by reference, see § 770.99) is considered equivalent to the ASTM E1333–14 method (incorporated by reference, see § 770.99) if the following condition is met:

$$\left|\overline{X}\right| + 0.88S \leq C$$

Where C is equal to 0.026.

(2) *Correlation between ASTM E1333–14 and any quality control test method.* Correlation must be demonstrated by establishing an acceptable correlation coefficient (''r'' value).

(i) *Correlation.* The correlation must be based on a minimum sample size of five data pairs and a simple linear regression where the dependent variable (Y-axis) is the quality control test value and the independent variable (X-axis) is the ASTM E1333–14 (incorporated by reference, see § 770.99) test value or, upon a showing of equivalence in accordance with paragraph (d) of this section, the equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test value. Either composite wood products or formaldehyde emissions reference materials can be used to establish the correlation.

(ii) *Minimum acceptable correlation coefficients (''r'' values).* The minimum acceptable correlation coefficients are as follows, where ''n'' is equal to the number of data pairs, and ''r'' is the correlation coefficient:

Degrees of freedom (n-2)	''r'' value
3	0.878
4	0.811
5	0.754
6	0.707

Degrees of freedom (n-2)	"r" value
7	0.666
8	0.632
9	0.602
10 or more	0.576

(iii) *Variation from previous results.* If data from an EPA TSCA Title VI TPC's quarterly test results and a panel producer's quality control test results do not fit the previously established correlation, the panel producer must have its TPC establish a new correlation and new QCLs.

(iv) *Failed quarterly tests.* If a panel producer fails two quarterly tests in a row for the same product type, the panel producer must have its TPC establish a new correlation curve.

(e) *Quality assurance and quality control requirements for panel producers.* Panel producers are responsible for product compliance with the applicable emission standards.

[81 FR 89724, Dec. 12, 2016, as amended at 83 FR 5347, Feb. 7, 2018]

§ 770.21 Quality control manual, facilities, and personnel.

(a) *Quality control manual.* (1) Each panel producer must have a written quality control manual. The manual must contain, at a minimum, the following:

(i) A description of the organizational structure of the quality control department, including the names of the quality control manager and quality control employees;

(ii) A description of the sampling procedures to be followed;

(iii) A description of the method of handling samples, including a specific maximum time period for analyzing quality control samples;

(iv) A description of the frequency of quality control testing;

(v) A description of the procedures used to identify changes in formaldehyde emissions resulting from production changes (*e.g.*, increase in the percentage of resin, increase in formaldehyde/urea molar ratio in the resin, or decrease in press time);

(vi) A description of provisions for additional testing;

(vii) A description of recordkeeping procedures;

(viii) A description of labeling procedures;

(ix) The average percentage of resin and press time for each product type;

(x) A description of product types, and if applicable, a description of product variables covered under each product type;

(xi) Procedures for reduced quality control testing, if applicable; and

(xii) Procedures for handling noncomplying lots, including a description of how the panel producer will ensure compliance with the notification requirements of § 770.22(d)(1).

(2) The quality control manual must be approved by an EPA TSCA Title VI TPC.

(b) *Quality control facilities.* Each panel producer must designate a quality control facility for conducting quality control formaldehyde testing.

(1) The quality control facility must be an EPA TSCA Title VI TPC, a contract laboratory, or a laboratory owned and operated by the panel producer.

(2) Each quality control facility must have quality control employees with adequate experience and/or training to conduct accurate chemical quantitative analytical tests. The quality control manager must identify each person conducting formaldehyde quality control testing to the EPA TSCA Title VI TPC.

(c) *Quality control manager.* Each panel producer must designate a person as quality control manager with adequate experience and/or training to be responsible for formaldehyde emissions quality control. The quality control manager must:

(1) Have the authority to take actions necessary to ensure that applicable formaldehyde emission standards are being met on an ongoing basis;

(2) Be identified to the EPA TSCA Title VI TPC that will be overseeing the quality control testing. The panel producer must notify the EPA TSCA Title VI TPC in writing within ten calendar days of any change in the identity of the quality control manager and provide the EPA TSCA Title VI TPC with the new quality control manager's qualifications;

(3) Review and approve all reports of quality control testing conducted on the production of the panel producer;

(4) Ensure that the samples are collected, packaged, and shipped according to the procedures specified in the quality control manual; and

(5) Inform the EPA TSCA Title VI TPC in writing of any significant changes in production that could affect formaldehyde emissions within 72 hours of making those changes.

§ 770.22 Non-complying lots.

(a) Non-complying lots are not certified composite wood products and they may not be sold, supplied or offered for sale in the United States except in accordance with this section.

(b) Non-complying lots must be isolated from certified lots.

(c) Non-complying lots must either be disposed of or retested and certified using the same test method, if each panel is treated with a scavenger or handled by other means of reducing formaldehyde emissions, such as aging. Tests must be performed as follows:

(1) *Quality control tests.* (i) At least one test panel must be selected from each of three separate bundles. The panels must be selected so that they are representative of the entire non-complying lot and they are not the top or bottom panel of a bundle. The panels may be selected from properly stored samples set aside by the panel producer for retest in the event of a failure.

(ii) All samples must test at or below the level that indicates that the product is in compliance with the applicable emission standards in § 770.10.

(2) *Quarterly tests.* (i) At least one test panel must be randomly selected so that it is representative of the entire non-complying lot and is not the top or bottom panel of a bundle. The panel may be selected from properly stored samples set aside by the panel producer for retest in the event of a failure.

(ii) The sample must test at or below the applicable emission standards in § 770.10.

(d) If composite wood products belonging to a non-complying lot have been shipped to a fabricator, importer, distributor, or retailer before the test results are received, the panel producer must:

(1) Ensure that the composite wood products are not distributed further by notifying, within 72 hours of the time that the panel producer is made aware of the failing test result, the fabricators, importers, distributors, and retailers that received the composite wood products. The notification must include the following:

(i) Panel producer name, contact information, and date of notice;

(ii) A description of the composite wood products that belong to the non-complying lot that is sufficient to allow the fabricator, importer, distributor, or retailer to identify the products;

(iii) Whether the failed test result was of a quarterly test, a quality control test, or a retest of composite wood products belonging to a non-complying lot;

(iv) A statement that composite wood products belonging to the non-complying lot must be isolated from other composite wood products and cannot be further distributed in commerce; and

(v) A description of the steps the panel producer intends to take to either recall the composite wood products belonging to the non-complying lot or to treat and retest the products and certify the lot.

(2) Do one of the following:

(i) Recall the composite wood products belonging to the non-complying lot and either treat and retest products belonging to the non-complying lot or dispose of them; or

(ii) Treat and retest composite wood products belonging to the non-complying lot while they remain in possession of a fabricator, importer, distributor, or retailer.

(e) Information on the disposition of non-complying lots, including product type and amount of composite wood products affected, lot numbers, mitigation measures used, results of retesting, and final disposition, must be provided to the EPA TSCA Title VI TPC within seven calendar days of final disposition.

(f) Fabricators, importers, distributors, or retailers who are notified that they have received composite wood products belonging to a non-complying lot and who have further distributed the composite wood products are responsible for notifying the purchasers

of the composite wood products in accordance with paragraph (d)(1) of this section.

§ 770.24 Samples for testing.

(a) Composite wood products may be shipped into and transported across the United States for quality control or quarterly tests. TPCs that ship composite panels into or across the United States solely for quality control or quarterly tests are not considered importers or distributors or importers for the purposes of § 770.7(c)(3)(i).

(1) Such panels must not be sold, offered for sale or supplied to any entity other than a TPC laboratory before testing in accordance with § 770.17, § 770.18, or § 770.20.

(2) If test results for such products demonstrate compliance with the emission standards in this subpart, the panels may be relabeled in accordance with § 770.45 and sold, offered for sale, or supplied.

(b) [Reserved]

§ 770.30 Importers, fabricators, distributors, and retailers.

(a) Importers, fabricators, distributors, and retailers must take reasonable precautions to ensure that the composite wood products they sell, supply, offer for sale, or hold for sale, whether in the form of panels, component parts, or finished goods, comply with the emission standards and other requirements of this subpart.

(b) Importers must demonstrate that they have taken reasonable precautions by maintaining, for three years, bills of lading, invoices, or comparable documents that include a written statement from the supplier that the composite wood products, component parts, or finished goods are TSCA Title VI compliant or were produced before December 12, 2018 and by ensuring the following records are made available to EPA within 30 calendar days of request:

(1) Records identifying the panel producer and the date the composite wood products were produced; and

(2) Records identifying the supplier, if different, and the date the composite wood products, component parts, or finished goods were purchased.

(c) Fabricators, distributors, and retailers must demonstrate that they have taken reasonable precautions by obtaining bills of lading, invoices, or comparable documents that include a written statement from the supplier that the composite wood products, component parts, or finished goods are TSCA Title VI compliant or that the composite wood products were produced before December 12, 2018.

(d) Beginning March 22, 2019, importers of articles that are regulated composite wood products, or articles that contain regulated composite wood products, must comply with the import certification regulations for ''Chemical Substances in Bulk and As Part of Mixtures and Articles,'' as found at 19 CFR 12.118 through 12.127.

(e) Records required by this section must be maintained in accordance with § 770.40(d).

[81 FR 89724, Dec. 12, 2016, as amended at 82 FR 44537, Sept. 25, 2017]

§ 770.40 Reporting and recordkeeping.

(a) Panel producers must maintain the following records for a period of three years, except that records demonstrating initial eligibility for reduced testing or third-party certification exemption under § 770.17 or § 770.18 must be kept for as long as the panel producer is producing composite wood products with reduced testing or under a third-party certification exemption. The following records must also be made available to the panel producers' EPA TSCA Title VI TPCs. Panel producers must make the records described in paragraph (a)(1) of this section available to direct purchasers of their composite wood products. This information may not be withheld from direct purchasers as confidential business information.

(1) Records of all quarterly emissions testing. These records must identify the EPA TSCA Title VI TPC conducting or overseeing the testing. These records must also include the date, the product type tested, the lot number that the tested material represents, the test method used, and the test results.

(2) Records of all ongoing quality control testing. These records must identify the EPA TSCA Title VI TPC

conducting or overseeing the testing and the facility actually performing the testing. These records must also include the date, the product type tested, the lot number that the tested material represents, the test method used, and the test results.

(3) Production records, including a description of the composite wood product(s), the date of manufacture, lot numbers, and tracking information allowing each product to be traced to a specific lot produced.

(4) Records of changes in production, including changes of more than ten percent in the resin use percentage, changes in resin composition that result in a higher ratio of formaldehyde to other resin components, and changes in the process, such as changes in press time by more than 20%.

(5) Records demonstrating initial and continued eligibility for the reduced testing provisions in §§ 770.17 and 770.18, if applicable. These records must include:

(i) Approval for reduced testing from an EPA TSCA Title VI TPC or CARB;

(ii) Amount of resin use reported by volume and weight;

(iii) Production volume reported as square feet per product type;

(iv) Resin trade name, resin manufacturer contact information (name, address, phone number, and email), and resin supplier contact information (name, address, phone number, and email); and

(v) Any changes in the formulation of the resin.

(6) Purchaser information for each composite wood product, if applicable, including the name, contact person if available, address, telephone number, email address if available, purchase order or invoice number, and amount purchased.

(7) Transporter information for each composite wood product, if applicable, including name, contact person, address, telephone number, email address if available, and shipping invoice number.

(8) Information on the disposition of non-complying lots, including product type and amount of composite wood products affected, lot numbers, purchasers who received product belonging to non-complying lots (if any), copies of purchaser notifications used (if any), mitigation measures used, results of retesting, and final disposition.

(9) Representative copies of labels used.

(b) Panel producers must provide their EPA TSCA Title VI TPC with monthly product data reports for each production facility, production line, and product type, maintain copies of the reports for a minimum of three years from the date that they are produced. Monthly product data reports must contain a data sheet for each specific product type with test and production information, and a quality control graph containing the following:

(1) QCL;

(2) Shipping QCL (if applicable);

(3) Results of quality control tests; and

(4) Retest values.

(c) Laminated product producers whose products are exempt from the definition of hardwood plywood must keep records demonstrating eligibility for the exemption. These records must be kept for a minimum of three years from the date they are produced and must include:

(1) Resin trade name, resin manufacturer contact information (name, address, phone number, and email), resin supplier contact information (name, address, phone number, and email), and resin purchase records;

(2) Panel producer contact information and panel purchase records;

(3) For panels produced in-house, records demonstrating that the panels have been certified by an EPA TSCA Title VI TPC; and

(4) For resins produced in-house, records demonstrating the production of phenol-formaldehyde resins or resins formulated with no added formaldehyde as part of the resin cross-linking structure.

(d) Importers, fabricators, distributors, and retailers must maintain the records described in § 770.30 for a minimum of three years from the import date or the date of the purchases or shipments described therein.

§ 770.45 Labeling.

(a) Panels or bundles of panels that are sold, supplied, or offered for sale in the United States must be labeled with

the panel producer's name, the lot number, the number of the EPA TSCA Title VI TPC, and a statement that the products are TSCA Title VI certified. If a composite wood panel is not individually labeled, the panel producer, importer, distributor, fabricator, or retailer must have a method (*e.g.*, color-coded edge marking) sufficient to identify the supplier of the panel and linking the information on the label to the products. This information must be made available to potential customers upon request. The label may be applied as a stamp, tag, or sticker.

(1) A panel producer number may be used instead of a name to protect identity, so long as the identity of the panel producer can be determined at the request of EPA.

(2) Only panels or bundles of panels manufactured in accordance with §770.17 may also be labeled that they were made with no-added formaldehyde-based resins in addition to the other information required by this section.

(3) Only panels or bundles of panels manufactured in accordance with §770.18 may also be labeled that they were made with ultra low-emitting formaldehyde resins in addition to the other information required by this section.

(b) Panels imported into or transported across the United States for quarterly or quality control testing purposes in accordance with §770.20 must be labeled ''For TSCA Title VI testing only, not for sale in the United States.'' The panels may be re-labeled if test results are below the applicable emission standards in this subpart.

(c) Fabricators of finished goods containing composite wood products must label every finished good they produce or every box or bundle containing finished goods. If a finished good (including component parts sold separately to end users) is not individually labeled, the importer, distributor, or retailer must retain a copy of the label, be able to identify the products associated with that label, and make the label information available to potential customers upon request.

(1) The label may be applied as a stamp, tag, or sticker.

(2) The label must include, at a minimum, in legible English text, the fabricator's name, the date the finished good was produced (in month/year format), and a statement that the finished goods are TSCA Title VI compliant.

(3) Finished goods made from panels manufactured in accordance with §770.17 and/or §770.18 may also be labeled that they were made with no-added formaldehyde-based resins, or ultra low-emitting formaldehyde resins in addition to the other information required by this section. They may be labeled as being made with a combination of compliant composite wood, no-added formaldehyde-based resins, and ultra low-emitting formaldehyde resins, if this is accurate.

(4) Fabricators may substitute the name of a responsible downstream fabricator, importer, distributor, or retailer for their name on the label if they obtain and maintain written consent from the downstream entity.

(d) Importers, distributors, and retailers must leave intact labels on finished goods, including component parts sold separately to end users.

(e) Finished goods, including component parts sold separately to end users, containing only a *de minimis* amount of regulated composite wood product are excepted from the labeling requirements. A finished good, including component parts sold directly to consumers, contains a *de minimis* amount of regulated composite wood product if its regulated composite wood product content does not exceed 144 square inches, based on the surface area of its largest face. The exception does not apply to finished goods or component parts that are designed to be used in combination or in multiples to create larger surfaces, finished goods, or component parts.

[81 FR 89724, Dec. 12, 2016, as amended at 82 FR 31924, July 11, 2017]

Subpart D—Incorporation by Reference

§ 770.99 Incorporation by reference.

The materials listed in this section are incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C.

552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, a document must be published in the FEDERAL REGISTER and the material must be available to the public. All approved materials are available for inspection at the OPPT Docket in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. In addition, these materials are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. These materials may also be obtained from the sources listed in this section.

(a) *CPA, APA, and HPVA Materials.* Copies of these materials may be obtained from the specific publisher, as noted in this paragraph (a), or from the American National Standards Institute, 1899 L Street NW, 11th Floor, Washington, DC 20036, or by calling (202) 293–8020, or at *http://ansi.org/*. Note that ANSI A190.1–2017 is published by APA—the Engineered Wood Association. ANSI A135.4–2012, ANSI A135.5–2012, ANSI A135.6–2012, ANSI A135.7–2012, ANSI A208.1–2016 and ANSI A208.2–2016 are published by the Composite Panel Association; and ANSI/HPVA–HP–1–2016 is published by the Hardwood Plywood Veneer Association.

(1) ANSI A135.4–2012, Basic Hardboard, Approved June 8, 2012, IBR approved for § 770.3.

(2) ANSI A135.5–2012, Prefinished Hardboard Paneling, Approved March 29, 2012, IBR approved for § 770.3.

(3) ANSI A135.6–2012, Engineered Wood Siding, Approved June 5, 2012, IBR approved for § 770.3.

(4) ANSI A135.7–2012, Engineered Wood Trim, Approved July 17, 2012, IBR approved for § 770.3.

(5) ANSI A190.1–2017, Standard for Wood Products—Structural Glued Laminated Timber, Approved January 24, 2017, IBR approved for § 770.1(c).

(6) ANSI A208.1–2016, Particleboard, Approved May 12, 2016, IBR approved for § 770.3.

(7) ANSI A208.2–2016, Medium Density Fiberboard (MDF) for Interior Applications, Approved May 12, 2016, IBR approved for § 770.3.

(8) ANSI/HPVA HP–1–2016, American National Standard for Hardwood and Decorative Plywood, Approved January 12, 2016, IBR approved for § 770.3.

(b) *ASTM material.* Copies of these materials may be obtained from ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959, or by calling (877) 909–ASTM, or at *http://www.astm.org*.

(1) ASTM D5055–16, Standard Specification for Establishing and Monitoring Structural Capacities of Prefabricated Wood I-Joists, Approved June 1, 2016, IBR approved for § 770.1(c).

(2) ASTM D5456–14b, Standard Specification for Evaluation of Structural Composite Lumber Products, Approved October 1, 2014, IBR approved for § 770.1(c).

(3) ASTM D5582–14, Standard Test Method for Determining Formaldehyde Levels from Wood Products Using a Desiccator, Approved-August 1, 2014, IBR approved for § 770.20(b).

(4) ASTM D6007–14, Standard Test Method for Determining Formaldehyde Concentrations in Air from Wood Products Using a Small-Scale Chamber, Approved October 1, 2014, IBR approved for §§ 770.3, 770.7(a) through (c), 770.15(c), 770.17(a), 770.18(a), and 770.20(b) through (d).

(5) ASTM E1333–14, Standard Test Method for Determining Formaldehyde Concentrations in Air and Emission Rates from Wood Products Using a Large Chamber, Approved October 1, 2014, IBR approved for §§ 770.3, 770.7(a) through (c), 770.10(b), 770.15(c), 770.17(a), 770.18(a), and 770.20(c) and (d).

(c) *CEN materials.* Copies of these materials are not directly available from the European Committee for Standardization, but from one of CEN's National Members, Affiliates, or Partner Standardization Bodies. To purchase a standard, go to CEN's Web site, *http://*

www.cen.eu, and select ''Products'' for more detailed information.

(1) BS EN ISO 12460–3:2015 E, Wood-based panels.—Determination of formaldehyde release—Part 3: Gas analysis method, November 2015, IBR approved for § 770.20(b).

(2) BS EN ISO 12460–5:2015 E, Wood based panels.—Determination of formaldehyde release—Part 5: Extraction method (called the perforator method), December 2015, IBR approved for § 770.20(b).

(d) *Georgia Pacific material*. Copies of this material may be obtained from Georgia-Pacific Chemicals LLC, 133 Peachtree Street, Atlanta, GA 30303, or by calling (877) 377–2737, or at *http://www.gp-dmc.com/default.aspx*.

(1) The Dynamic Microchamber computer integrated formaldehyde test system, User Manual, revised March 2007 (DMC 2007 User's Manual) IBR approved for § 770.20(b).

(2) The GP Dynamic Microchamber Computer-integrated formaldehyde test system, User Manual, copyright 2012 (DMC 2012 GP User's Manual), IBR approved for § 770.20(b).

(e) *ISO material*. Copies of these materials may be obtained from the International Organization for Standardization, 1, ch. de la Voie- Creuse, CP 56, CH–1211, Geneve 20, Switzerland, or by calling +41–22–749–01–11, or at *http://www.iso.org*.

(1) ISO/IEC 17011:2004(E), Conformity assessments—General requirements for accreditation bodies accrediting conformity assessments bodies, First edition, Corrected version, 2005–02–15, IBR approved for §§ 770.3 and 770.7(a) through (b).

(2) ISO/IEC 17020:2012(E), Conformity assessment–Requirements for the operation of various bodies performing inspection, Second edition, 2012–03–01 IBR approved for §§ 770.3 and 770.7(a) through (c).

(3) ISO/IEC 17025:2005(E), General requirements for the competence of testing and calibration laboratories, Second edition, 2005–05–15, IBR approved for §§ 770.3 and 770.7(a) through (c).

(4) ISO/IEC 17065:2012(E), Conformity assessment—Requirements for bodies certifying products, processes and services, First edition, 2012–09–15, IBR approved for §§ 770.3 and 770.7(a) and (c).

(f) *Japanese Standards Association*. Copies of this material may be obtained from Japanese Industrial Standards, 1–24, Akasaka 4, Minatoku, Tokyo 107– 8440, Japan, or by calling +81–3–3583–8000, or at *http://www.jsa.or.jp/*.

(1) JIS A 1460:2015(E), Determination of the emission of formaldehyde from building boards—Desiccator method, First English edition, published 2015–10, IBR approved for § 770.20(b).

(2) [Reserved]

(g) *NIST material*. Copies of these materials may be obtained from the National Institute of Standards and Technology (NIST) by calling (800) 553–6847 or from the U.S. Government Printing Office (GPO). To purchase a NIST publication you must have the order number. Order numbers may be obtained from the Public Inquiries Unit at (301) 975–NIST. Mailing address: Public Inquiries Unit, NIST, 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899–1070. If you have a GPO stock number, you can purchase printed copies of NIST publications from GPO. GPO orders may be mailed to: U.S. Government Printing Office, P.O. Box 979050, St. Louis, MO 63197–9000, placed by telephone at (866) 512–1800 (DC Area only: (202) 512–1800), or faxed to (202) 512–2104. Additional information is available online at: *http://www.nist.gov*.

(1) PS 1–09, Structural Plywood, May 2010, IBR approved for §§ 770.1(c) and 770.3.

(2) PS 2–10, Performance Standard for Wood-Based Structural-Use Panels, June 2011, IBR approved for §§ 770.1(c) and 770.3.

[81 FR 89724, Dec. 12, 2016, as amended at 83 FR 5348, Feb. 7, 2018]

PARTS 771–789 [RESERVED]

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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