

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 63**

[OAR-2005-0155; FRL-8008-4]

RIN 2060-AK18

National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: The EPA is proposing revised standards to limit emissions of perchloroethylene (PCE) from existing and new dry cleaning facilities. In 1993, EPA promulgated technology-based emission standards to control emissions of PCE from dry cleaning facilities. As required by section 112(d)(6) of the Clean Air Act (CAA), EPA has reviewed the standards and is proposing revisions to take into account new developments in production practices, processes, and control technologies. In addition, pursuant to CAA section 112(f), EPA has evaluated the remaining risk to public health and the environment following implementation of the technology-based rule and is proposing more stringent standards in order to protect public health with an ample margin of safety. The proposed standards are expected to provide further reductions of PCE beyond the 1993 national emission standards for hazardous air pollutants (NESHAP), based on application of equipment and work practice standards.

DATES: *Comments.* Comments must be received on or before February 6, 2006.

Public Hearing. A public hearing is currently scheduled for January 5, 2006. If this date falls on a weekend, the hearing will be held the next business day. Under the Paperwork Reduction Act, comments on the information collection provisions must be received by OMB on or before January 20, 2006.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. OAR-2005-0155, by one of the following methods:

- <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Agency Web site:* <http://www.epa.gov/edocket>. EDOCKET, EPA's electronic public docket and comment system, will be replaced by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov>. When that occurs, you will be redirected to that site to access the docket and submit comments. Follow

the on-line instructions for submitting comments.

- *E-mail:* a-and-r-Docket@epa.gov, Attention Docket ID No. OAR-2005-0155.
- *Fax:* (202) 566-1741, Attention Docket ID No. OAR-2005-0155.
- *Mail:* U.S. Postal Service, send comments to: EPA Docket Center (6102T), Attention Docket ID No. OAR 2005-0155, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.
- *Hand Delivery:* In person or by courier, deliver your comments to: EPA Docket Center (6102T), Attention Docket ID No. OAR-2005-0155, 1301 Constitution Avenue, NW., EPA West Building, Room B-108, Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. Please include a total of two copies.

Instructions: Direct your comments to Docket ID No. OAR-2005-0155. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. Send or deliver information identified as CBI to only the following address: Mr. Roberto Morales, OAQPS Document Control Officer, EPA (C404-02), Attention Docket ID No. OAR 2005-0155, Research Triangle Park, NC 27711. Clearly mark the part or all of the information that you claim to be CBI. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic

comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm> or see the **Federal Register** of May 31, 2002 (67 FR 38102).

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the EPA Docket Center, Docket ID No. OAR 2005-0155, EPA West Building, Room B-102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-1742. A reasonable fee may be charged for copying docket materials.

Public Hearing: If a public hearing is held, it will begin at 10 a.m. and will be held at EPA's campus at 109 T.W. Alexander Drive, Research Triangle Park, NC, or at an alternate facility nearby. Persons interested in presenting oral testimony or inquiring as to whether a public hearing is to be held should contact Ms. Janet Eck, Coatings and Consumer Products Group, Emission Standards Division, EPA (C539-03), Research Triangle Park, NC 27711, telephone (919) 541-7946, at least 2 days in advance of the hearing. If no one contacts Ms. Eck in advance of the hearing with a request to present oral testimony at the hearing, we will cancel the hearing.

FOR FURTHER INFORMATION CONTACT: For questions about the proposed rule, contact Ms. Rhea Jones, EPA, Office of Air Quality Planning and Standards, Emission Standards Division, Coatings and Consumer Products Group (C539-03), Research Triangle Park, NC 27711;

telephone number (919) 541-2940; fax number (919) 541-5689; e-mail address: jones.rhea@epa.gov. For questions on the residual risk analysis, contact Mr. Neal Fann, EPA, Office of Air Quality Planning and Standards, Emission Standards Division, Risk and Exposure

Assessment Group (C404-01), Research Triangle Park, NC 27711; telephone number (919) 541-0209; fax number (919) 541-0840; e-mail address: fann.neal@epa.gov.

SUPPLEMENTARY INFORMATION:

Regulated Entities. Categories and entities potentially regulated by the proposed rule are industrial and commercial PCE dry cleaners. The proposed rule affects the following categories of sources:

Category	NAICS ¹ code	Examples of potentially regulated entities
Coin-operated Laundries and Dry Cleaners	812310	Dry-to-dry machines, Transfer machines.
Dry Cleaning and Laundry Services (except coin-operated)	812320	Dry-to-dry machines, Transfer machines.
Industrial Launderers	812332	Dry-to-dry machines, Transfer machines.

¹ North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the proposed rule. To determine whether your facility is regulated by the proposed rule, you should examine the applicability criteria in 40 CFR 63.320 of subpart M (1993 Dry Cleaning NESHAP). If you have any questions regarding the applicability of the proposed rule to a particular entity, contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Submitting CBI. Do not submit information which you claim to be CBI to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

If you have any questions about CBI or the procedures for claiming CBI, please consult either of the persons identified in the **FOR FURTHER INFORMATION CONTACT** section. **Worldwide Web (WWW).** In addition to being available in the docket, an electronic copy of the proposed rule is also available on the WWW. Following the Administrator's signature, a copy of the proposed rule will be posted on EPA's Technology Transfer Network (TTN) policy and guidance page for newly proposed or promulgated rules at <http://www.epa.gov/ttn/oarpg>. The TTN provides information and technology exchange in various areas of air pollution control.

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

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 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132: Federalism
 - F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
 - G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks
 - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
 - I. National Technology Transfer Advancement Act

I. Background

A. What is the statutory authority for regulating hazardous air pollutants (HAP)?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, after EPA has identified categories of sources emitting one or more of the HAP listed in the CAA, section 112(d) calls for us to promulgate national technology-based emission standards for sources within those categories that emit or have the potential to emit any single HAP at a rate of 10 tons or more per year or any combination of HAP at a rate of 25 tons or more per year (known as major sources), as well as for certain area sources emitting less than those amounts. These technology-based standards must reflect the maximum reductions of HAP achievable (after considering cost, energy requirements, and non-air health and environmental impacts) and are commonly referred to as maximum achievable control technology (MACT) standards.

For area sources, CAA section 112(d)(5) provides that the standards may reflect generally available control technology or management practices in lieu of MACT, and are commonly

referred to as generally available control technology (GACT) standards. We published MACT and GACT standards for PCE dry cleaning facilities on September 22, 1993 at 58 FR 49376. The EPA is then required, pursuant to section 112(d)(6), to review these technology-based standards and to revise them "as necessary, taking into account developments in practices, processes and control technologies," no less frequently than every 8 years.

The second stage in standard-setting is described in section 112(f) of the CAA. This provision requires, first, that EPA prepare a Report to Congress discussing (among other things) methods of calculating risk posed (or potentially posed) by sources after implementation of the MACT standards, the public health significance of those risks, the means and costs of controlling them, actual health effects to persons in proximity to emitting sources, and recommendations as to legislation regarding such remaining risk. The EPA prepared and submitted this report (Residual Risk Report to Congress, EPA-453/R-99-001) in March 1999. The Congress did not act on any of the recommendations in the report, thereby triggering the second stage of the standard-setting process, the residual risk phase.

Section 112(f)(2) of the CAA requires us to determine for each section 112(d) source category whether the MACT standards protect public health with an ample margin of safety. If the MACT standards for HAP "classified as a known, probable, or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than 1-in-1-million," EPA must promulgate residual risk standards for the source category (or subcategory) as necessary to protect public health with an ample margin of safety. The EPA must also adopt more stringent standards if required to prevent an adverse environmental effect (defined in section 112(a)(7) as "any significant and widespread adverse effect * * * to wildlife, aquatic life, or natural resources * * *"), but must consider cost, energy, safety, and other relevant factors in doing so.

B. What are PCE dry cleaning facilities?

Dry cleaners use PCE in a dry cleaning machine to clean all types of garments, including clothes, gloves, leather garments, blankets, and absorbent materials. There are approximately 28,000 PCE dry cleaning facilities in the United States. Of the 28,000 dry cleaners, 15 of the facilities

are major sources and the remaining are area sources. Major source PCE dry cleaners are those that emit 10 tons or more of PCE per year upon the compliance date of the 1993 Dry Cleaning NESHAP. The 1993 Dry Cleaning NESHAP defines this as facilities that purchase more than 2,100 gallons (gal) of PCE per year (1,800 gal per year if the facility uses transfer machines). Area sources are typically the common neighborhood dry cleaner. Area sources were divided into large or small in the 1993 Dry Cleaning NESHAP, with large area sources defined as those facilities that use between 140 to 2,100 gal of PCE per year (or 140 to 1,800 gal per year if the facility uses transfer machines). Small area sources use less than 140 gal per year. Some area sources are collocated in the same building with residences. In the 1993 Dry Cleaning NESHAP we did not specifically discuss these sources, but in this notice we refer to them as co-residential dry cleaners. A co-residential dry cleaning facility is located in a building in which people reside. Co-residential facilities are located primarily in urban areas.

In general, PCE dry cleaning facilities can be classified into three types: commercial, industrial, and leather. Commercial facilities typically clean household items such as suits, dresses, coats, pants, comforters, curtains, and formalwear. Industrial dry cleaners clean heavily-stained articles such as work gloves, uniforms, mechanics' overalls, mops, and shop rags. Leather cleaners mostly clean household leather products like jackets and other leather clothing. The 15 major sources include eight industrial facilities, five commercial facilities, and two leather facilities. The five commercial facilities are each the central plant for a chain of retail storefronts. We do not expect any new source facilities constructed in the future to be major sources. Based on the low emission rates of current PCE dry cleaning machines and the typical business models used in the industrial and commercial dry cleaning sectors, it is unlikely that any new sources that are constructed will emit PCE at major levels, or that any existing area sources will become major sources due to business growth.

Dry cleaning machines can be classified into two types: Transfer and dry-to-dry. Similar to residential washing machines and dryers, transfer machines have a unit for washing/extracting and another unit for drying. Following the wash cycle, PCE-laden articles are manually transferred from the washer/extractor to the dryer. The transfer of wet fabrics is the

predominant source of PCE emissions in these systems. Dry-to-dry machines wash, extract, and dry the articles in the same drum in a single machine, so the articles enter and exit the machine dry. Because the transfer step is eliminated, dry-to-dry machines have much lower emissions than transfer machines.

New transfer machines are effectively prohibited at major and area sources due to the 1993 Dry Cleaning NESHAP requirement that new dry cleaning systems eliminate any emissions of PCE while transferring articles from the washer to the dryer. Therefore, transfer machines are no longer sold. Existing transfer machines are becoming an increasingly smaller segment of the dry cleaning population as these machines reach the end of their useful lives and are replaced by dry-to-dry machines. There are approximately 200 transfer machines currently being used, all at area sources.

The primary sources of PCE emissions from dry-to-dry machines are the drying cycle and fugitive emissions from the dry cleaning equipment (including equipment used to recycle PCE and dispose of PCE-laden waste). Machines are designed to be either vented or non-vented during the drying cycle. Approximately 200 dry cleaners (1 percent) use vented machines, and the remaining facilities use the lower-polluting, non-vented machines. (The 1993 Dry Cleaning NESHAP prohibits new dry cleaning machines at major and area sources that vent to the atmosphere while the dry cleaning drum is rotating.) In vented machines, the majority of emissions from the drying cycle are vented outside the building. In non-vented machines, dryer emissions are released when the door is opened to remove garments. Currently, the largest sources of emissions from dry cleaning are from equipment leaks, which come from leaking valves and seals, and the loading and unloading of garments.

C. What are the health effects of PCE?

The main health effects of PCE are neurological, liver, and kidney damage following acute (short-term) and chronic (long-term) inhalation exposure. Animal studies have reported an increased incidence of liver cancer in mice via inhalation, kidney cancer and mononuclear cell leukemia in rats. PCE was considered to be a "probable carcinogen" (Group B) when assessed under the previous 1986 Guidelines by the EPA Science Advisory Board. See the risk characterization memorandum in the public docket for additional information regarding the health effects of PCE.

D. What does the 1993 NESHAP require?

The 1993 NESHAP prescribes a combination of equipment, work practices, and operational requirements. The requirements for process controls

are summarized in table 1 of this preamble. The 1993 Dry Cleaning NESHAP defines major and area sources based on the annual PCE purchases for all machines at a facility. The consumption criterion (which affects

the amount of PCE purchased) varies depending on whether the facility has dry-to-dry machines only, transfer machines only, or a combination of both. The affected source is each individual dry cleaning system.

TABLE 1.—SUMMARY OF THE 1993 DRY CLEANING NESHAP PROCESS CONTROLS

Sources	Annual PCE purchased	New ¹ (after 12/9/91)	Existing ²
Major Sources	Dry-to-dry ONLY > 2,100 gal/yr ... Transfer ONLY > 1,800 gal/yr Dry-to-dry AND Transfer > 1,800 gal/yr.	Dry-to-dry machines with a refrigerated condenser, AND carbon adsorber operated immediately before or as the door is opened.	Dry-to-dry machines: must have refrigerated AND condenser. ³ Transfer machines: must be enclosed in a room exhausting to a dedicated carbon adsorber.
Large Area Sources	Dry-to-dry ONLY 140 to 2,100 gal/yr. Transfer ONLY 200 to 1,800 gal/yr. Dry-to-dry AND Transfer 140 to 1,800 gal/yr.	Dry-to-dry machines with a refrigerated condenser.	Dry-to-dry with machines: must have a refrigerated condenser. ³ Transfer machines: No controls required.
Small Area Sources	Dry-to-dry ONLY < 140 gal/yr Transfer ONLY < 200 gal/yr Dry-to-dry AND Transfer < 140 gal/yr.	Same as large area sources	No controls required.

¹ No new transfer machines are allowed after 9/23/93.

² Compliance date = 9/23/96.

³ Alternatively, carbon adsorber is allowed only if installed before 9/22/93.

In addition, all sources must comply with certain operating requirements, including recording PCE purchases, storing PCE and PCE-containing waste in non-leaking containers, and inspecting for perceptible leaks. Owners or operators are required to operate and maintain the control equipment according to procedures specified in the 1993 Dry Cleaning NESHAP and to use pollution prevention procedures, such as good operation and maintenance, for both dry cleaning machines and auxiliary equipment (such as filter, muck cookers, stills, and solvent tanks) to prevent liquid and vapor leaks of PCE from these sources.

II. Summary of Proposed Rule

A. What are the proposed requirements for major sources?

Under the proposed revisions, the requirements for all new and existing major sources would be the same. The proposed revisions would require the implementation of an enhanced leak detection and repair (LDAR) program and the use of dry-to-dry machines that do not vent to the atmosphere (closed-loop) during any phase of the dry cleaning cycle. A refrigerated condenser and a secondary carbon adsorber would be required control equipment for all machines. The secondary carbon adsorber would control the PCE emissions during the final stage of the dry cleaning cycle immediately before and as the drum door is opened. Under the enhanced LDAR program, the

facility owner or operator would have to use a PCE gas analyzer (photoionization detector, flameionization detector, or infrared analyzer) and perform leak checks according to EPA Method 21 on a monthly basis. The facility owner or operator would also be required to continue the weekly perceptible leak check according to the requirements of the 1993 Dry Cleaning NESHAP.

B. What are the proposed requirements for area sources?

For existing area sources (large and small), the proposed revisions would require implementation of an enhanced LDAR program and a prohibition on the use of existing transfer machines.

For new area sources (large and small), the proposed rule would require implementation of an enhanced LDAR program and use of a non-vented dry-to-dry machine with a refrigerated condenser and secondary carbon adsorber. The enhanced LDAR program for area sources would require facilities to use a halogenated leak detector (instead of a more costly gas analyzer proposed for major sources) to perform leak checks on a monthly basis. The facility would also be required to continue to inspect for perceptible leaks biweekly for small area sources and weekly for large area sources according to the requirements of the 1993 Dry Cleaning NESHAP.

For co-residential area sources, we are proposing two options. The first proposed option would effectively

prohibit new PCE sources from locating in residential buildings by requiring that owners or operators eliminate PCE emissions from the dry cleaning process. Existing co-residential sources, under this option, would only be subject to the same requirements proposed for all other existing area sources (*i.e.*, enhanced LDAR and elimination of transfer machines). The second proposed option would, instead of a prohibition on new co-residential sources, require that existing and new co-residential sources comply with standards based on those required by New York State Department of Environmental Conservation (NYSDEC) in their Title 6 NYCRR Part 232 rules, which include using machines equipped with refrigerated condensers and carbon adsorbers, enclosed in a vapor barrier to help prevent exposures to PCE emissions. We expect to select one of these options, with possible modifications in response to public comments, in the final rule.

C. What are the proposed requirements for transfer machines at major and area sources?

The proposed rule would effectively prohibit the use of all existing transfer machines 90 days from the effective date of the final rule by requiring owners or operators to eliminate any PCE emissions from clothing transfer between the washer and dryer. Similarly, the installation of new transfer machines was prohibited by the

1993 Dry Cleaning NESHAP. We estimate that about 200 transfer machines remain in use within the population of 28,000 dry cleaning machines located at area sources (estimated one PCE dry cleaning machine per facility with approximately 28,000 facilities). Most of these machines will be at or near the end of their useful economic life by the time final rule requirements are promulgated. The typical life of a dry cleaning machine is 10 to 15 years. By the end of 2006, the newest transfer machines in the industry will be 13 years old.

III. Rationale for the Proposed Rule

A. What is our approach for developing residual risk standards?

Following our initial determination that the individual most exposed to emissions from the category considered exceeds a 1-in-1 million individual cancer risk, our approach to developing residual risk standards is based on a two-step determination of acceptable risk and ample margin of safety. The first step, consideration of acceptable risk, is only a starting point for the analysis that determines the final standards. The second step determines an ample margin of safety, which is the level at which the standards are set.

The terms "individual most exposed," "acceptable level," and "ample margin of safety" are not specifically defined in the CAA. However, CAA section 112(f)(2)(B) refers positively to the interpretation of these terms in our 1989 rulemaking (54 FR 38044, September 14, 1989), "National Emission Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP)," essentially directing us to use the interpretation set out in that notice¹ or to utilize approaches affording at least the same level of protection.² We likewise notified Congress in the Residual Risk Report that we intended to utilize the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations.³

¹ This reading is confirmed by the Legislative History to CAA section 112(f); see, e.g., "A Legislative History of the Clean Air Act Amendments of 1990," vol. 1, page 877 (Senate Debate on Conference Report).

² Legislative History, vol. 1, p. 877, stating that: "* * * the managers intend that the Administrator shall interpret this requirement [to establish standards reflecting an ample margin of safety] in a manner no less protective of the most exposed individual than the policy set forth in the Administrator's benzene regulations * * *."

³ Residual Risk Report to Congress. March 1999. EPA-453/R-99-001, page ES-11.

In the Benzene NESHAP (54 FR 38044, September 14, 1989), we stated as an overall objective:

* * * in protecting public health with an ample margin of safety, we strive to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million; and (2) limiting to no higher than approximately 1 in 10 thousand [i.e., 100 in 1 million] the estimated risk that a person living near a facility would have if he or she were exposed to the maximum pollutant concentrations for 70 years.

As explained more fully in our Residual Risk Report, these goals are not "rigid line[s] of acceptability, but rather broad objectives to be weighed "with a series of other health measures and factors."⁴

B. How did we estimate residual risk?

The "Residual Risk Report to Congress" (EPA-453/R-99-001) provides the general framework for conducting risk assessments to support decisions made under the residual risk program. The report acknowledged that each risk assessment design would have some common elements, including a problem formulation phase, an analysis phase, and the risk characterization phase. The risk assessment for PCE dry cleaners used both site-specific data for many modeling parameters and population characteristics derived from census data, as well as default assumptions for exposure parameters—some of which were assumed to be health protective (e.g., exposure frequency and exposure duration, 70-year constant emission rates).^{5,6} To estimate the cancer risk and non-cancer hazard for major source facilities, we performed refined modeling for a subset of major source facilities we determined were representative of all major sources, including industrial cleaners, commercial cleaners, and leather cleaners. Facilities within each of these three specializations tend to be homogenous with respect to factors that affect the emissions, pollutant dispersion, and population size in the modeling radius, allowing us to extrapolate risks from facilities modeled to those that were not modeled. We used a combination of modeling and monitoring approaches to analyze risks

⁴ *Id.*

⁵ Additional details are provided in the risk characterization memorandum in the rulemaking docket.

⁶ Residual Risk Report to Congress, pp. B-18 and B-22. The approach used to assess the risks associated with standards for the dry cleaning industry are consistent with the technical approach and policies described in the Report to Congress.

for area sources. See the risk characterization memorandum in the public docket for a complete discussion of the major and area source risk assessment.

1. How did we estimate the atmospheric dispersion of PCE emitted from major and area sources?

We used the Industrial Source Complex Short-term model, version 3 (ISCST-3) to estimate the dispersion of PCE from facilities to receptor locations. For a complete description of the dispersion modeling, please see the risk characterization memorandum.

2. How did we assess public health risk associated with PCE emitted from PCE dry cleaners?

PCE has been associated with a variety of health effects, including cancer. Although PCE has not yet been reassessed under the Agency's recently revised Guidelines for Cancer Risk Assessment,⁷ it was considered to be a "probable carcinogen" (Group B)⁸ when assessed under the previous 1986 Guidelines by the EPA Science Advisory Board. Since that time, the United States Department of Health and Human Services has concluded that PCE is "reasonably anticipated to be a human carcinogen,"⁹ and the International Agency for Research on Cancer has concluded that PCE is "probably carcinogenic to humans."¹⁰

In our assessment of public health risk associated with PCE emitted from PCE dry cleaners, we considered risks of cancer and other health effects. Cancer risks associated with inhalation exposure were assessed using lifetime cancer risk estimates. The noncancer risks were characterized through the use of hazard quotient (HQ) and hazard index (HI) estimates. An HQ is calculated as the ratio of the exposure concentration of a pollutant to its health-based non-cancer threshold.

In this assessment, values that are below 1.0 are not likely to be associated with adverse health effects. An HI is the sum of HQ for pollutants that target the same organ or system. For dry cleaners, PCE is the only HAP emitted, therefore, HI and HQ are the same.

⁷ USEPA. 2005. Guidelines for Carcinogen Risk Assessment. EPA/650/P-03/001B. Risk Assessment Forum, Washington, DC.

⁸ March 9, 1988 letter to Lee Thomas, Administrator, U.S. Environmental Protection Agency, from Norton Nelson, Chair, Executive Committee of EPA Science Advisory Board.

⁹ USDHHS. 1989. Report on Carcinogens, Fifth Edition; U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program.

¹⁰ IARC. 1995. Monographs on the evaluation of carcinogenic risks to humans. Volume 63. Dry Cleaning, Some Chlorinated Solvents and Other Industrial Chemicals. ISBN 9283212630. Geneva, Switzerland.

Several sources were considered for cancer and noncancer dose-response assessment information. In a 1998 assessment of PCE cancer risks associated with dry cleaners, EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) derived and used a lifetime inhalation unit risk estimate (URE) of 7.1×10^{-7} per microgram per cubic meter ($\mu\text{g}/\text{m}^3$).¹¹ This reflected an update of the URE of 5.8×10^{-7} per $\mu\text{g}/\text{m}^3$ that was derived by EPA in the 1980s.¹² The PCE cancer dose-response assessments developed by others include a lifetime URE of 5.9×10^{-6} per $\mu\text{g}/\text{m}^3$ developed by the California Environmental Protection Agency (CalEPA),¹³ and a lifetime URE of 3.8×10^{-7} per $\mu\text{g}/\text{m}^3$ developed by Clewell and others.¹⁴

We are currently reevaluating the available information on health effects of PCE, including cancer, as part of a hazard and dose-response assessment for the Agency's Integrated Risk Information System (IRIS). The cancer component of this evaluation is being conducted in accordance with the 2005 Guidelines for Carcinogen Risk Assessment. Data have become available from the Japanese Industrial Safety Association (1993) that includes rodent inhalation studies with a cancer bioassay which was not considered by the sources above.¹⁵ The document describing the evaluation is expected to be released for external scientific peer review and public comment. The projected schedule for completion of the IRIS assessment is available at <http://cfpub.epa.gov/iristrac/index.cfm>.

While all of the available lifetime URE are based on the same animal bioassay¹⁶

(1986), there are several factors contributing to the differences in magnitude among them. One significant contributing factor is characterization of human metabolism of PCE. This is an area in which widely diverging quantitative estimates have been published, and their use leads to notable differences in human cancer dose-response value derived from animal data, illustrated to some extent by the range of values presented above.

As an interim approach in lieu of the completed IRIS assessment, we used two dose-response values to characterize cancer risk. These two values were chosen to represent the best available peer-reviewed science. As we have stated previously, we will not be relying exclusively on IRIS values, but will be considering all credible and readily available assessments.¹⁷ We used the CalEPA URE (5.9×10^{-6} per $\mu\text{g}/\text{m}^3$) and the estimate developed by OPPTS (7.1×10^{-7} per $\mu\text{g}/\text{m}^3$). Both are derived with consideration of findings of liver tumors in mouse laboratory bioassays, with the OPPTS value additionally considering laboratory findings of mononuclear cell leukemia in rats, and both have received public comment and scientific peer review by external panels. Dose-response modeling performed in both assessments involved use of metabolized doses with different estimates of human PCE metabolism contributing to differences in the resulting URE.

Effects other than cancer associated with long-term inhalation of PCE in worker or animal studies include neurotoxicity, liver and kidney damage, and, at higher levels, developmental effects. To characterize noncancer hazard in lieu of the completed IRIS assessment, we used the Agency for Toxic Substances and Disease Registry's (ATSDR) Minimum Risk Level (MRL) ($270 \mu\text{g}/\text{m}^3$).¹⁸ This value is based on a study of neurological effects in workers in dry cleaning shops, and is derived in a manner similar to EPA's method for derivation of reference concentrations (RfC), and with scientific and public review. The ATSDR MRL is quite similar to the provisional RfC ($170 \mu\text{g}/\text{m}^3$) derived by OPPTS in 1997 based on

a study of kidney effects in workers in dry cleaning shops¹⁹ that reported effects at similar exposure concentrations than those elsewhere reported associated with neurological effects. The OPPTS value was termed a provisional RfC because it was derived by a single EPA program office with limited cross-office review. This value is based on a study of neurological effects in workers in dry cleaning shops. Since that time, more recent studies have been published, particularly with regard to more sensitive neurological effects at lower exposures.²⁰ We are reviewing these and all of the available information on the noncancer health effects of PCE as part of the IRIS assessment.

The proposed rule is based on both the risk estimates derived using both the CalEPA cancer dose-response values and the ATSDR noncancer MRL. The CalEPA cancer dose-response value is higher than the value derived by OPPTS, leading to higher cancer risk estimates. Given our uncertainty regarding the pending IRIS dose-response values, we have considered the range of available potencies with which to calculate inhalation cancer risk. We calculate cancer risk using both values, but propose to use the CalEPA value. We request comment on both this approach of using the more health protective end of the dose-response range and our selection of dose-response values. Based on the findings and status of the IRIS assessment at the time of promulgation, we may reassess our estimates of cancer risk and noncancer hazard. The Agency is aware that some stakeholders have suggested that we defer certain action pending completion of the IRIS assessment for PCE. In today's notice, we request comment on our proposal to use the available CalEPA and OPPTS potency values, and we request comments on whether we should defer further development of the risk assessment and any rulemakings under section 112(f)(2) for area sources pending completion of the IRIS assessment for PCE.

¹⁹ V. Vu. 1997. Memorandum titled "Provisional RfC for perchloroethylene" From Vanessa Vu, Acting Director, Health and Environmental Review Division, to William Waugh, Acting Director, Chemical Screening and Risk Assessment Division, OPPT, USEPA. As cited in OPPTS 1998. Cleaner Technologies Substitutes Assessment: Professional Fabricare Processes. EPA-744-B-98-001. USEPA, Office of Pollution Prevention and Toxics, Washington, DC.

²⁰ USEPA. 2004. Summary report of the peer review workshop on the neurotoxicity of tetrachloroethylene (perchloroethylene) discussion paper. National Center for Environmental Assessment, Washington, DC; EPA-600-R-04-041. Available online at <http://www.epa.gov/ncea>.

¹¹ USEPA. 1998. Cleaner Technologies Substitutes Assessment: Professional Fabricare Processes. EPA 744-B-98-001. U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Washington, DC.

¹² USEPA. 1996. Addendum to the Health Assessment Document for Tetrachloroethylene (Perchloroethylene). Updated Carcinogenicity Assessment for Tetrachloroethylene (Perchloroethylene, PERC, PCE). EPA/600/8-82/005FA. External Review Draft. U.S. Environmental Protection Agency, Office of Health and Environmental Assessment, Washington, DC.

¹³ CDHS. 1991. Health Effects of Tetrachloroethylene (PCE). California Department of Health Services (subsequently CalEPA, Office of Environmental Health Hazard Assessment), Berkeley, CA.

¹⁴ H.J. Clewell, P.R. Gentry, J.E. Kester, and M.E. Andersen. 2005. Evaluation of physiologically based pharmacokinetic perchloroethylene.

¹⁵ JISA (Japan Industrial Safety Association). 1993. Carcinogenicity Study of Tetrachloroethylene by Inhalation in Rats and Mice. Data No. 3-1. Available from: EPA-IRIS Information Desk.

¹⁶ NTP. 1986. NTP technical report on the toxicology and carcinogenesis of tetrachloroethylene (perchloroethylene) (CAS No. 127-18-4) in F344/N rats and B6C3F1 mice (inhalation studies). National Toxicology Program,

Research Triangle Park, NC. NTP TR 311, NIH Publication No. 86-2567. August 1986.

¹⁷ USEPA. March 1999. Residual Risk Report to Congress. Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711. EPA-453/R-99-001; available at <http://www.epa.gov/ttn/oarpg/t3/meta/m8690.html>.

¹⁸ ATSDR. 1997. Toxicological Profile for Tetrachloroethylene. Department of Health and Human Services, Public Health Services, Agency for Toxic Substances and Disease Registry, Atlanta, Georgia.

3. How did we assess environmental impacts of major sources and typical area sources?

The chemical properties of PCE suggest that once it is emitted into the atmosphere as a vapor, it is not likely to partition significantly into soil, water, or sediment. Based on fugacity modeling, we estimate that 99.8 percent of ambient PCE remains in the atmosphere, with the remainder partitioning into water (0.17 percent), and soil (0.05 percent). Thus, PCE emitted from major stationary sources is not likely to pose a significant ecological risk due to any exposure pathway other than inhalation.

Further, to assess the potential inhalation risk to mammals from PCE inhalation, we compared the minimum lowest observable adverse effect level (LOAEL) for rats with the highest level of modeled ambient concentration from PCE cleaners; the rat LOAEL for PCE can be found in the ATSDR toxicological profile that documents the development of the MRL (<http://www.atsdr.cdc.gov/toxprofiles/tp18.html>). The lowest rat LOAEL (9 parts per million (ppm), or 60 mg/m³) is about 2,000 times higher than the highest modeled post-control ambient concentrations from major stationary sources.

This large margin of exposure leads us to conclude that risks to mammals from PCE inhalation are likely insignificant, obviating the need to further quantify ecological risks to any degree.

In the atmosphere, PCE is known to degrade into many compounds, including trichloroacetic acid (TCAA). TCAA is a persistent, known phytotoxin, which has been discontinued as a herbicide. Atmospheric transformation of PCE to

TCAA is the subject of great debate, with potential conversion efficiencies estimated to be on the order of 5 to 15 percent. However, there are very few data quantifying TCAA concentrations in the air, precipitation, water, soil, or sediment in the United States. This scarcity of data makes it difficult to determine whether there is any potential for adverse ecological impacts on plant life from PCE emissions from dry cleaners due to conversion to TCAA. While we have no direct evidence that this will present a significant ecological risk, we nonetheless invite public comment and solicit additional scientific information on this issue. Since our results showed no screening level ecological effects, we do not believe that there is any potential for an effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). Because of these results, we concluded a consultation with the Fish and Wildlife Service is not necessary.

C. What are the residual risks from major sources?

Table 2 of this preamble summarizes the estimated risks remaining for the seven modeled major source facilities after compliance with MACT. In performing residual risk assessments under the CAA section 112(f)(2), EPA believes it may evaluate potential risk based on consideration of both emission levels allowed under the MACT standard and actual emissions levels achieved in compliance with MACT. See, e.g., 70 FR 19992, 19998 (April 15, 2005). Generally, allowable emissions are the maximum levels sources could emit and still comply with existing standards. It is also reasonable that we

consider actual emissions when available, as a factor in both steps of the residual risk determination, to avoid unrealistic inflation of risk levels or where other factors suggest basing the evaluation solely on allowables is not appropriate. Essentially, the existing dry cleaning MACT standard is comprised of equipment standards and various work practices. Compliance with the existing MACT standard is demonstrated by use of the required equipment and implementation of the required work practices, and there are no numeric emissions levels to model. Therefore, the seven facilities were modeled using actual 2000–2002 emissions and are representative of the emissions from major sources. We conclude that the sampled facilities represent characteristics of the major source facility population, including commercial, industrial, and leather facilities. The risk analysis shows that each of the seven modeled facilities poses a cancer risk of 1-in-1 million or greater. The highest maximum individual cancer risk (MIR) is between 300-in-1 million and 2,400-in-1 million. The MIR is the lifetime risk of developing cancer for the individual facing the highest estimated exposure over a 70-year lifetime. Five of the modeled facilities pose a risk greater than 100-in-1 million (the presumptive unacceptable risk level), and about 550 people are exposed at this level. One facility has a HQ of greater than 1.0. As described below in section III.E, we expect a continuing decline in PCE emissions even in the absence of additional Federal regulation. These baseline risk estimates do not reflect such a trend, therefore; baseline risks are likely to be overestimated.

TABLE 2.—MAJOR SOURCE BASELINE RISK ESTIMATES FOR MODELED FACILITIES AFTER APPLICATION OF 1993 DRY CLEANING NESHAP, BASED ON 70-YEAR EXPOSURE DURATION ¹

Parameter	MACT level (OPPTS URE)	MACT level (CalEPA URE)
MIR from facility with highest risk	300-in-1 million	2,400-in-1 million.
Maximum HQ from facility with highest risk based on ATSDR MRL	2	2.
Population at risk across all modeled facilities [modeled to 10 kilometers (km)]:		
> 1-in-1 million	16,000	175,000.
> 10-in-1 million	800	12,500.
> 100-in-1 million	10	550.
Total population exposed	3,300,000	3,300,000.

¹ In this table, all risk and population estimates are rounded.

To account for the fact that individuals may move through areas (microenvironments) of differing concentrations during their daily activities, EPA conducted an exposure variability analysis in which it used the Total Risk Integration Methodology

Exposure model (TRIM.Expo, also known as the Air Pollutant Exposure Model 3, or APEX3). The TRIM.Expo model uses a personal profile approach in which it stochastically simulates exposures for individuals of differing demographic characteristics and

associated daily activity patterns. The model output provides a distribution of exposure estimates which are intended to be representative of the study population with respect to their demographically based behavior, in terms of the microenvironments through

which they move during a day and throughout a year (see <http://www.epa.gov/ttn/fera> for more information regarding the model). To

estimate cancer risk, EPA assumes that this 1-year exposure scenario continues for 70 years. Table 3 contrasts ISCST-3 and TRIM.Expo estimates of

population risk for the worst-case facility, using the CalEPA URE; this example is illustrative only.²¹

TABLE 3.—COMPARISON OF ISCST-3 EXPOSURE ESTIMATES WITH ACTIVITY-PATTERNED/DAY, LIFETIME EXPOSURE [ISCST-3+Trim.Expo]

Model	Total population at cancer risk		
	>100-in-1 million	>10-in-1 million	>1-in-1 million
ISCST-3	900	14,000	75,000
TRIM.Expo	400	9,000	80,000

TRIM.Expo provides a more central tendency estimate of risk by accounting for variability in personal exposure. The table above shows a smaller number of individuals exposed at the higher levels of cancer risk and a slightly larger number of individuals exposed at a cancer risk of at least 1-in-1 million. While we performed this analysis for the worst-case facility, it is reasonable to infer that the risk distribution above would be similar to the remainder of the

major source facilities. One limitation of this analysis is that we assume continuous 70-year exposure when calculating cancer risk, and some individuals are likely to move away from the facility. However, given the large number of area source dry cleaners nation wide, and the consequent ubiquity of PCE exposure, it is unlikely that the PCE exposure of individuals moving out of the TRIM.Expo study area would fall to zero.

For illustrative purposes, below we provide estimates of individual inhalation cancer risk based on different assumptions regarding exposure duration. In contrast to the TRIM.Expo estimates above, the risk estimates below do not account for personal activity patterns and assume that individuals receive continuous exposure for the duration noted.

TABLE 4.—ESTIMATES OF INDIVIDUAL INHALATION CANCER RISK BASED ON DIFFERENT EXPOSURE DURATIONS

Estimated lifetime cancer risk	Assumed exposure duration ¹				
	70	50	30	20	10
Risk per Million (CalEPA)	2,400	1,700	1,030	700	340
Risk per Million (OPPTS)	300	210	130	90	40

¹ Risk estimates derived using maximum exposure concentration.

D. What are the options for reducing risk, their costs, and risk reduction impacts for major sources?

We evaluated several methods for reducing risks. These methods include enhanced LDAR and three emission control technologies.

Enhanced LDAR. Enhanced LDAR would require the facility owner or operator to use a portable PCE gas analyzer to perform leak checks on a monthly basis. Two major sources and several State and local agencies currently use a photoionization detector, one type of gas analyzer, for leak inspections. The detection probe is moved slowly along the equipment part, and if PCE is detected, the device gives a concentration reading of the leak. The proposed leak definition is a concentration of 25 ppm. Portable gas analyzers cost about \$3,300 and have a 10-year life expectancy. The facility would be required to continue to perform the weekly perceptible leak checks as required by the 1993 Dry

Cleaning NESHAP. A nominal amount of additional labor would be required as a result of the proposed requirement to use a gas analyzer. We estimated 1 hour of labor per machine per month to perform the leak inspection. The estimated total capital cost to the industry to establish an enhanced LDAR program is \$40,000, with a annual cost savings of \$390,000. The cost savings is due to reduced PCE consumption.

Control Technologies. Three types of emission control technologies can be used to reduce emissions from dry cleaning machines. The first two are a refrigerated condenser and a secondary carbon adsorber. The third technology is a PCE sensor and lockout. By using the first two control technologies together, and by operating them properly, a significant amount of PCE can be recovered.

Refrigerated condensers are the most effective method for reducing PCE from the drying cycle. They are used to condense PCE vapor for reuse. By

operating at lower temperatures than water-cooled condensers, refrigerated condensers recover more PCE from the drying air and reduce emissions. By the end of the cool-down cycle, refrigerated condensers can reduce PCE concentrations in the drum to between 2,000 and 8,600 ppm. Refrigerated condensers require relatively little maintenance, needing only to have their refrigerant recharged and to have lint removed from the coils (yearly or even less frequently).

A secondary carbon adsorber controls the PCE emissions during the final stage of the dry cleaning cycle just prior to the drum door opening. A carbon adsorber removes organic compounds from air by adsorption onto a bed of activated carbon as the air passes over the bed. Carbon adsorbers have a PCE removal efficiency of 95 percent or greater. Properly designed and operated secondary adsorbers have been shown to reduce the PCE concentration in the drum from several thousand ppm to less

²¹ Note that the ISCST-3 modeling results do not match earlier risk estimates due to the fact that EPA

used an earlier set of ISCST-3 modeling results for the TRIM.Expo analysis. The original ISCST-3

results are retained here so that the comparison with TRIM.Expo will be consistent.

than 100 ppm, and in some cases, to less than 10 ppm. Most new dry cleaning machines sold today are equipped with secondary carbon adsorbers. Carbon adsorbers require periodic desorption to recover PCE and maintain their peak PCE collection efficiency.

The technologies currently in use by major and area source dry cleaners include vented dry-to-dry machines with water-cooled condensers and carbon adsorbers, non-vented (closed-loop) dry-to-dry machines with refrigerated condensers, non-vented dry-to-dry machines with refrigerated condensers and secondary carbon adsorbers and transfer machines. To meet a standard requiring a refrigerated condenser and secondary carbon adsorber, existing dry cleaning machines without this control could be retrofitted, or new replacement machines could be purchased

depending on the remaining useful life of each existing machine. The costs to add control technologies range from \$13,000 to \$40,000 per machine, depending on the size of the existing machine and the level of control of the machine. Machine replacement costs are approximately \$900 to \$1,000 per pound of capacity. Additional analysis of costs can be found in the Background Information Document in the public docket.

A PCE sensor is the third control technology used in machines with a secondary carbon adsorber. The sensor controls the carbon adsorption cycle to achieve a set PCE concentration in the drum. This device uses a single-beam infrared photometer to measure the concentration of PCE in the drum, and prolongs the carbon adsorption cycle until the concentration set point is achieved. An interlock (lock-out)

ensures that the PCE set-point has been attained before the machine door can be opened.

Regulatory Options. We considered three options for reducing risk from major source dry cleaners. Option I would require all major sources to use an enhanced LDAR program and have dry-to-dry machines with a refrigerated condenser and a secondary carbon adsorber. Option II would require a PCE sensor and lock-out in addition to the Option I controls. Option III would require no PCE emissions from major sources (a ban on the use of PCE).

Table 5 of this preamble shows the costs and risk estimates for each regulatory option. The population risk estimates were extrapolated from the seven modeled facilities to all 15 major source facilities. The cost estimates are also for all 15 major source facilities.

TABLE 5.—RISK ESTIMATES AND COSTS OF CONTROL OPTIONS FOR MAJOR SOURCES BASED ON 70-YEAR EXPOSURE DURATION ¹

Parameter	MACT level	Option I	Option II	Option III
MIR from facility with highest risk (CalEPA URE).	2,400-in-1 million	270-in-1 million	150-in-1 million	NA. ²
MIR from facility with highest risk (OPPTS URE).	300-in-1 million	30-in-1 million	20-in-1 million	NA.
Maximum HQ from facility with highest risk ..	2	0.2	0.1	NA.
Population at Risk Across All Facilities ³ (Population Risk Range Represents Difference Between OPPTS and CalEPA URE)				
> 1-in-1 million	35,000 to 375,000	2,000 to 55,000	1,000 to 26,000	NA.
> 10-in-1 million	2,000 to 27,000	20 to 1,800	10 to 900	NA.
> 100-in-1 million	10 to 1,200	0 to 13	0 to 6	NA.
Total population exposed (within 10 km)	9,300,000			NA.
Capital Cost (\$1000)		830	5,700	8,200.
Annualized Cost (\$1000)		(220)	420	Not Estimated.
Emission Reduction (tons per year (tpy))		209	249 (40 incremental) ..	293 (44 incremental).

¹ In this table, risk estimates are based on both OPPTS and the CalEPA URE. All risk and population estimates are rounded.

² NA = not applicable. Under Option III, risk from PCE would be eliminated, however, potential risks from alternative solvents were not analyzed.

³ Modeled to 10 km.

E. What is our proposed decision on acceptable risk and ample margin of safety for major sources?

Section 112(f)(2)(A) of the CAA states that if the MACT standards for a source emitting a:

* * * known, probable, or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category * * * to less than one in one million, the Administrator shall promulgate [residual risk] standards * * * for such source category.

The residual risk to the individual most exposed to emissions from PCE dry cleaners is estimated at 1-in-1 million or greater at each major source dry cleaner modeled. Major source dry cleaners subject to the proposed rule

emit a possible to probable human carcinogen, and, as shown in table 3 of this preamble, we estimate that the MIR associated with the 1993 Dry Cleaning NESHAP limits is between 300-in-1 million and 2,400-in-1 million. Therefore, we believe a residual risk standard is necessary.

In the 1989 Benzene NESHAP, the first step of the residual risk decision framework is the determination of acceptable risk (*i.e.*, are the estimated risks due to emissions from these facilities “acceptable”). This determination is based on health considerations only, without consideration of costs. The determination of what represents an “acceptable” risk level is based on a judgment of “what risks are acceptable in the world in which we live” (54 FR

38045, 1987, quoting the Vinyl Chloride decision at DC Circuit Courts Decision in *NRDC vs. EPA*, 824 F.2d at 1165) recognizing that our world is not risk-free.

In the 1989 Benzene NESHAP, we stated that a MIR of approximately 100-in-1 million should ordinarily be the upper end of the range of acceptable risks associated with an individual source of pollution. We characterized the MIR as “the estimated risk that a person living near a facility would have if he or she were exposed to the maximum pollutant concentrations for 70 years.” We explained that this measure of risk “is an estimate of the upper bound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years.” We acknowledge that

the MIR “does not necessarily reflect the true risk, but displays a conservative risk level which is an upper bound that is unlikely to be exceeded.”

Understanding that there are both benefits and limitations to using MIR as a metric for determining acceptability, we acknowledged in the 1989 Benzene NESHAP that “consideration of maximum individual risk * * * must take into account the strengths and weaknesses of this measure of risk.” Consequently, the presumptive risk level of 100-in-1 million provides a benchmark for judging the acceptability of MIR, but does not constitute a rigid line for making that determination. In establishing a presumption for the acceptability of maximum risk, rather than a rigid line for acceptability, we explained in the 1989 Benzene NESHAP that risk levels should also be weighed with a series of other health measures and factors, including the following:

- The numbers of persons exposed within each individual lifetime risk range and associated incidence within, typically, a 50 km (about 30 miles) exposure radius around facilities.
- The science policy assumptions and estimation uncertainties associated with the risk measures.
- Weight of the scientific evidence for human health effects.
- Other quantified or unquantified health effects.
- The overall incidence of cancer or other serious health effects within the exposed population.

In some cases, these health measures and factors taken together may provide a more realistic description of the magnitude of risk in the exposed population than that provided by MIR alone.

Based on use of the criteria identified above, we judge the level of risk resulting from regulatory option I to be acceptable for this source category (table 3 of this preamble). This option requires dry cleaning machines at all major sources to have an enhanced LDAR program and closed-loop, dry-to-dry machines with refrigerated condensers and secondary carbon adsorbers. The calculated MIR is between 30-in-1 million and 270-in-1 million. While the upper-end of this risk range is greater than the presumptively acceptable level of MIR under the 1989 Benzene NESHAP formulation (100-in-1 million), we also considered other factors in making our determination of acceptability, as directed by the 1989 Benzene NESHAP. The principal factors that influenced our decision were that nearly all of the population living within 10 km of each facility receive cancer risk at less than 1-in-1 million.

Considering the very small number of individuals that are estimated to receive greater than 100-in-1 million cancer risk coupled with the exposure and dose-response assessment methodology that was conservatively health protective, it is likely that no actual persons are exposed at risk levels above 100-in-1 million. Among the exposed population of 9.3 million individuals, a maximum of between 0 and 13 people are estimated to receive risks of more than 100-in-1 million. Under option I, the exposure to maximum exposed individuals would be reduced from between 300-in-1 million to 2,400-in-1 million to between 30-in-1 million and 270-in-1 million. Total combined cancer incidence would be between 0.002 and 0.003 cases per year for all seven major source facilities that were modeled. In addition, no significant non-cancer health effects are predicted. The maximum HQ would be reduced from 2 to 0.2, and no adverse ecological impacts are predicted under option I. In addition, we expect that PCE usage will continue to drop as has been the trend over the past 10 years. This trend has been caused by the greater use of alternative solvents, older machines at the end of their useful lives being replaced with newer, lower emitting dry-to-dry machines with refrigerated condensers and secondary carbon adsorbers, and State and industry programs that improve machine efficiency and reduce PCE consumption. All of these factors will cause risks to continue to decrease in the future in the absence of further Federal regulatory requirements. Therefore, we have determined that the risks associated with regulatory option I are acceptable after considering MIR, the population exposed at different risk levels, the projected absence of noncancer effects and adverse ecological effects, and the projected decline in PCE usage.

While not relevant for determining the acceptable risk level, the national capital costs of regulatory option I are \$830,000 and annualized cost savings of \$220,000. Most facilities would recognize a cost savings primarily from implementing the enhanced LDAR program. Leak detection and repair is a pollution prevention approach where reduced emissions translate into less PCE consumption and reduced operating costs because facilities would need to purchase less PCE. The capital costs for individual facilities would range from \$0 to \$313,000, with a median cost of \$51,000. Annualized costs would range from a cost savings of \$106,000 per year to a cost of \$22,000 per year.

The second step in the residual risk decision framework is the determination of standards that are equal to or lower than the acceptable risk level and that protect public health with an ample margin of safety. In making this determination, we considered the estimate of health risk and other health information along with additional factors relating to the appropriate level of control, including costs and economic impacts of controls, technological feasibility, uncertainties, and other relevant factors, consistent with the approach of the 1989 Benzene NESHAP.

We evaluated regulatory option II as the first level of control more stringent than the acceptable risk level for this source category. Our analysis showed a relatively small incremental risk reduction beyond that achieved by option I. Under option I, one of the seven modeled facilities would pose risks greater than 100-in-1 million using the CalEPA URE and no facility would pose risks greater than 100-in-1 million using the OPPTS URE. Under option II, this facility would still have risks above 100-in-1 million using the CalEPA URE only. For the other six modeled facilities, the risks would remain in the range of 10-in-1 million under option II using the CalEPA URE and risks would drop below the range of 10-in-1 million for three of seven facilities using the OPPTS URE.

The national capital cost for option II (all 15 major sources) is \$5.7 million with an annualized cost of \$420,000. These costs include retrofitting PCE sensors and lockout systems on machines that were manufactured in 1998 or later, and the costs of replacing machines installed before 1998, which cannot reliably meet the same level of emission reduction with a PCE sensor.

Overall, option II has high costs considering the relatively low risk reduction for most of the major sources. These costs do not achieve a significant risk reduction for most sources. Consequently, we determined that requiring the addition of a PCE sensor and lock-out was not a reasonable or economically feasible option for all major sources.

We also evaluated regulatory option III, a ban on PCE use, as a level of control more stringent than the acceptable risk level for this source category. This would completely eliminate risk from PCE for the population around the 15 major source facilities by essentially eliminating the sources of PCE. The costs to eliminate PCE usage at major sources would require a capital cost to the industry of approximately \$8.2 million. This

estimate was based on the total cost of replacing all PCE machines with machines using an alternative solvent (not an incremental cost of a new PCE machine versus a new alternative solvent machine). Alternative solvents currently being used in the industry include cyclic siloxanes, liquid carbon dioxide, wetcleaning, and synthetic hydrocarbon. There are some uncertainties that these solvents do not have the cleaning power (kB value) of PCE for the heavy soiled or greasy garments like leather work gloves and aprons which are the typical garments cleaned by industrial major sources. There are some fabrics that cannot be cleaned in the alternative solvents. There are also some uncertainties about whether the waste from alternative solvent systems would be classified as hazardous. Alternative solvents have a role in the industry, and are being used

for certain cleaning applications. However, there is not enough experience to determine that these technologies are sufficiently demonstrated for all applications such that PCE should be eliminated from the marketplace. Therefore, we have determined that regulatory option III is not a viable option at this time considering cost, economic impacts, technical feasibility, and uncertainties.

Based on the information analyzed for the three options, we are proposing that option I provides an ample margin of safety to protect public health for major sources in the dry cleaning industry.

F. What are the risks from typical area sources?

We are not mandated to develop residual risk standards for area sources regulated by GACT. Under our discretion, we have developed estimates

of the remaining risk for these sources. In estimating the inhalation cancer risk that area sources pose, we considered the risks from facilities co-located with residences (co-residential area sources) separately from those located in all other settings (typical area sources).

To assess risks from area sources, we first analyzed readily available data. The 1999 National Air Toxics Assessment (NATA) provides census tract level estimates of cancer risk and noncancer hazard across the United States for a subset of the 188 HAP. Using this assessment, we were able to generate a course-scale estimate of population risk for PCE area source dry cleaners by scaling the NATA cancer for PCE by the relative contribution of area source cleaners to PCE emissions. See table 6 below for a summary of the NATA-derived estimated risks for area source cleaners.

TABLE 6.—ESTIMATED NATA-DERIVED POPULATION CANCER RISK FOR PCE AREA SOURCE DRY CLEANERS

Dose-response value	Estimated cancer risk at least:		
	100-in-1 million	10-in-1 million	1-in-1 million
OPPTS	0	0	960,000
CalEPA	0	400,000	56,000,000

This assessment provides a screening-level estimate of PCE risk to the general population.

Next, we performed a “model facility” assessment. In this modeling scenario, we used information regarding typical

facility size and dispersion parameters and average and upper-end emissions of a facility meeting the 1993 Dry Cleaning NESHAP to create a set of “model facilities.” See the risk characterization memorandum in the public docket for a

complete description of the two modeling methodologies. Table 7 of this preamble summarizes the cancer and noncancer risk for typical area sources (excluding transfer machines).

TABLE 7.—ESTIMATED INCREMENTAL LIFETIME INDIVIDUAL CANCER RISK AND NON-CANCER HAZARD FOR TYPICAL AREA SOURCES USING A RANGE OF EMISSIONS AND WORST-CASE DISPERSION MODELING

Risk estimate	Model facility emissions		Maximum (8 tons)
	Average (.05 tons)	99th percentile (4 tons)	
MIR (OPPTS URE)	2-in-1 million	20-in-1 million	30-in-1 million.
MIR (CalEPA URE)	15-in-1 million	120-in-1 million	220-in-1 million.
Noncancer HQ ¹	0.001	0.07	0.1.

¹ HQ estimates have been rounded.

G. What are the options for reducing risk, their costs, and risk reduction impacts for typical area sources?

We evaluated three control measures to reduce risks from typical area sources. These measures are an enhanced LDAR program for area sources, elimination of emissions from existing transfer machines, and the use of a refrigerated condenser and secondary carbon adsorber (same control technologies described above for major sources). These control measures have been commercially demonstrated

at area source dry cleaners in the United States. The three control measures were used to develop two regulatory options to reduce risk.

The enhanced LDAR program for area sources would require the use of a halogenated leak detector instead of a gas analyzer, which is being proposed for major sources. The cost of a halogenated leak detector (\$250) is significantly less than a gas analyzer (\$3,300). A gas analyzer is a more accurate device that provides a quantitative reading of PCE

concentration. This device can be particularly useful in pinpointing leaks at major sources that have high background concentrations of PCE. The halogenated leak detector is a non-quantitative device that provides an audible or visual display when it detects a leak above 25 ppm. We have concluded that a halogenated leak detector is sufficient for detecting leaks at area source dry cleaners and will provide a significant improvement in reducing emissions compared to the

current requirement to inspect for perceptible leaks only.

Transfer machines have substantially higher emissions than dry-to-dry machines. The 1993 Dry Cleaning NESHAP effectively bans new transfer machines, but existing machines were grandfathered. In 1993, we determined that the capital costs required to replace all transfer machines would have created an adverse economic impact on a substantial portion of the industry, especially small businesses that had recently purchased new transfer machines. We estimate that about 200 transfer machines remain in use within

the population of 28,000 dry cleaning machines located at area sources (estimated one PCE dry cleaning machine per facility with approximately 28,000 facilities). Most of these machines will be at or near the end of their useful economic life by the time final rule requirements are promulgated. The typical life of a dry cleaning machine is 10 to 15 years. By the end of 2006, the newest transfer machines in the industry will be 13 years old. Replacing these machines with new machines meeting the requirements for new sources under the proposed

amendments would reduce PCE emissions substantially.

We developed two regulatory options to evaluate area source risk reductions. Option I would require enhanced LDAR and eliminate emissions from existing transfer machines by requiring that they be replaced with new machines. This option would apply to both large and small area sources. Option II would require all area sources to use a refrigerated condenser and secondary carbon adsorber in addition to option I. Table 8 of this preamble summarizes the cancer and noncancer risks from these control options.

TABLE 8.—ESTIMATED MAXIMUM¹ CANCER RISK AND NONCANCER HAZARD FOR TYPICAL AREA SOURCES

Risk metric	Control option		
	1993 NESHAP	Option I—LDAR	Option II—LDAR + secondary controls
Estimated Lifetime Cancer Risk (OPPTS URE)	30-in-1 million	20-in-1 million	15-in-1 million.
Estimated Lifetime Cancer Risk (CalEPA URE)	220-in-1 million	175-in-1 million	110-in-1 million
Noncancer HQ	0.1	0.1	0.1
Capital Cost—(\$1,000,000)	\$12.4	\$85.7
Annualized Cost—(\$1,000,000)	(\$2.7)	\$7.9
Emission Reduction (tpy)	3,236	5,749

¹Assumes a facility using a dry-to-dry machine with a refrigerated condenser emitting 8 tons of PCE a year (highest known emitting dry-to-dry machine). Risks from transfer machines are not included in the tables. The costs and risk estimates in this table do not consider the impacts of future trends of declining PCE usage.

H. What is our proposal for addressing the remaining emissions for typical area sources?

We are considering adopting a residual risk decision process for area sources which is based on that used for major sources. This involves first determining an acceptable level of risk to the public and then determining an ample margin of safety to protect public health, considering costs and economic impacts of controls, technological feasibility, uncertainties, and other relevant factors. We request comments on this approach for area sources.

As part of this rulemaking, we have determined that exposure to emissions under the 1993 Dry Cleaning NESHAP constitutes an acceptable level of risk for typical area sources. Currently, we estimate that more than 98 percent of 28,000 existing dry cleaners use a dry-to-dry machine with a refrigerated condenser to comply with the 1993 Dry Cleaning NESHAP or State emission standards. Using the most health protective modeling assumptions for meteorology and location, the model facility analysis indicated that the highest known emitting area source would pose cancer risks of between 30-in-1 million and 220-in-1 million. The risk from the vast majority of area sources would be substantially less. For example, cancer risk for the typical area

source, which emits approximately 0.5 ton of PCE per year, is estimated at between 4-in-1 million and 15-in-1 million. In addition, the assessment showed no significant acute health effects (HQ of 1.0 for the highest emitting area source facility). Considering the relatively low level of risk posed by the great majority of area sources, the projected absence of significant noncancer and ecological effects, and the projected decline in PCE usage, we believe that the 1993 Dry Cleaning NESHAP level of control results in an acceptable level of risk to the public.

Replacing transfer machines with new dry-to-dry equipment would reduce risks from the potentially highest-emitting sources. Under either option I or II, transfer machines would be replaced with dry-to-dry machines with a refrigerated condenser and a secondary carbon adsorber (*i.e.*, the proposed new source requirements for area sources, which are discussed below).

For dry-to-dry machines, equipment leaks are the largest source of emissions, particularly from older dry cleaning machines. While the perceptible leaks program under the 1993 Dry Cleaning NESHAP may prevent major leaks, a substantial emission reduction can be achieved by earlier leak detection using

an instrument like a halogenated hydrocarbon leak detector.

Therefore, to protect public health with an ample margin of safety, we are proposing to eliminate the use of transfer machines and require an enhanced LDAR program for dry-to-dry machines (option I). This option would reduce PCE emissions by 3,200 tpy and reduce risks to the public from between 30-in-1 million and 220-in-1 million to between 20-in-1 million and 175-in-1 million.

Option I would require total capital costs of \$12 million. The enhanced LDAR program would cost about \$5 million. About 20,000 facilities would be required to purchase a halogenated hydrocarbon detector at a cost of \$250 each. About 200 facilities would be required to replace their existing transfer machines with dry-to-dry machines with refrigerated condensers and carbon adsorber at a cost of about \$36,000 each for a total industry cost of \$7.3 million. Annually, option I is expected to result in a cost savings to industry of about \$2.7 million per year. Cost saving would be realized because both replacement of transfer machines and enhanced LDAR will reduce annual PCE consumption. The reduction in annual PCE consumption at the 200 businesses that would replace transfer machines is more than sufficient to

offset the annualized cost of the new equipment. In particular, we believe most of the transfer machines are at the end of their useful life and it would be economically beneficial for the facilities to replace the transfer machines with dry-to-dry machines. Thus, we believe the economic impacts to the affected businesses and facilities are negligible. Finally, these costs and risk estimates do not consider the impacts of future trends of declining PCE usage.

We are not proposing the option of requiring existing area sources to install secondary carbon adsorbers (option II). Secondary carbon adsorbers would reduce maximum risks at the highest risk area sources from between 20-in-1 million and 175-in-1 million under option I to between 15-in-1 million and 110-in-1 million under option II. Under option II, about 7,500 facilities would be required to raise capital to install carbon adsorbers (27 percent of the industry). For these sources, the capital costs for compliance would be about \$85 million with an annualized cost of about \$8 million. The capital cost for individual facilities would range from \$4,000 to \$45,000. A majority of sources that would be affected by option II are small businesses. For these small businesses, the annualized costs would average from 10 to 20 percent of sales, and this amount is much higher than the average profit per unit of sales that small dry cleaners normally experience (1 to 3 percent). This cost would lead to a high number of small businesses owning affected facilities that will likely close due to the lack of available capital for the needed investment in carbon adsorbers. Therefore, we are not proposing to require a secondary carbon adsorber on existing area sources, because the risk reduction would be relatively minor and the costs would impose adverse economic impacts on a number of small businesses.

We do not believe that the proposed requirements for area sources pose more

than a minimal burden; however, we specifically ask for comment on methods by which EPA could focus the additional regulatory requirements being proposed by this rule to only those area sources (typical and co-residential) which pose significant risks to human health. For example, we seek comments on whether there could be a methodology by which facilities could conduct site specific risk assessments to demonstrate that their PCE emissions pose cancer risk levels that are less than 1-in-1 million, with a HI of less than 1, and with no acute human health risks or adverse environmental effects, and thereby avoid the additional requirements that would otherwise apply under the proposed rule revisions. Comments should address whether such an approach is feasible (for example, if facilities would be able to conduct these risk assessments), the legal authority for such an approach, the methodology sources would use for conducting risk assessments, the specific criteria by which potential "low-risk" sources would be evaluated, the mechanism for evaluating and determining whether source risk assessments meet those criteria, how the process would be implemented by Federal and/or State and local agencies, how it would be enforced (for example, through a permitting program or other regulatory structure to ensure that any sources found to be "low-risk" remain so), and what would be the consequences if and when a source, for whatever reason, is found to no longer qualify as a "low-risk" source.

I. What are the risks from co-residential area sources?

Residents living in the same building with a dry cleaner may receive significantly higher exposures to PCE than people not living above or in the same building as a dry cleaner. We estimate there are approximately 1,300 co-residential dry cleaning facilities in

the United States. Residents in these buildings can receive elevated PCE concentrations because PCE vapor travels through the building walls and up elevator and pipe shafts into residences. Emissions of PCE also can enter from the ambient air into residences via open windows. Even after the dry cleaner closes, PCE absorbed onto surfaces can continue to be emitted throughout the day and night. To assess potential risks, we used indoor air monitoring data collected by the New York Department of Health and the New York State Department of Environmental Conservation (NYSDEC) between 2001–2003 as part of an epidemiological study examining neurological endpoints. In considering the New York data, it should be recognized that the data resulted from an epidemiological study, and dry cleaner building and apartment inclusion and exclusion criteria influenced buildings that were ultimately sampled. Also, certain buildings were identified in order to potentially increase the likelihood of finding apartments with elevated PCE levels. Data collected during this period indicate that resident exposures ranged from a geometric mean of 33 ug/m³ to a maximum of 5,000 ug/m³. The New York Department of Health collected these data during the final implementation of title 6 NYCRR Part 232 rules, which require the use of a refrigerated condenser and secondary carbon adsorber, and a vapor barrier or room enclosure around co-residential dry cleaning machines. We extrapolated these 24-hour samples to lifetime exposure to estimate inhalation cancer risk and noncancer hazard. For a full description of the methodology that we used, see the risk characterization memorandum in the public docket. Table 9 of this preamble summarizes the inhalation cancer risk and noncancer hazard of co-residential area sources.

TABLE 9.—ESTIMATED INCREMENTAL LIFETIME INDIVIDUAL CANCER RISK AND NONCANCER HAZARD FOR CO-RESIDENTIAL AREA SOURCES USING A RANGE OF MONITORED EXPOSURES

Risk metric ³	Distribution of Monitored Exposure				
	Lower 5th percentile ²	Median	Geometric mean	Upper 95th percentile	Maximum
Estimated Lifetime Cancer Risk (OPPTSURE).	4-in-1 million	10-in-1 million	20-in-1 million	500-in-1 million	4,000-in-1 million.
Estimated Lifetime Cancer Risk (CalEPAURE).	30-in-1 million	50-in-1 million	200-in-1 million	4,000-in-1 million ..	30,000-in-1 million.
Noncancer HQ ¹	0.02	0.06	0.1	3	20

¹ HQ estimates have been rounded.

² The lowest 5th percentile of exposure is equal to the non-detect limit of the monitors, which is 5 ug/m³.

³ These estimates reflect only facilities in full compliance with Title 6 NYCRR Part 232.

To better characterize inhalation cancer risk among residents of apartments co-located with area source

cleaners, we performed a sensitivity analysis in which we varied the

assumed exposure duration. Table 10 illustrates the results from this analysis.

TABLE 10.—ESTIMATED HIGH-END CANCER RISKS FOR RESIDENTS OF CO-LOCATED APARTMENTS: EXPOSURE DURATION SENSITIVITY ANALYSIS ¹

Estimated Lifetime Cancer Risk	Assumed Exposure Duration				
	70 years	50 years	30 years	20 years	10 years
Risk per million (CalEPAURE)	4,000	3,000	2,000	1,000	600
Risk per million (OPPTSURE)	500	400	200	100	80
HQ	7	5	3	2	1

Inhalation cancer risk estimates using the 95th percentile exposure level range from a maximum of between 4,000 and 500-in-1 million, assuming 70-year exposure to between 600 and 80-in-1 million assuming 10-year experience.

¹Cancer risk estimates derived using 95th percentile PCE exposures for monitoring data from facilities in full compliance with NYSDEC requirements.

The PCE exposure concentrations presented in table 11 of this preamble show the potential risk levels that co-residential sources may pose. The MIR was predicted at between 4,000-in-1

million and 30,000-in-1 million, which is higher than the maximum risk at both major sources and typical area sources. This table suggests that maximum co-residential area source risks are about 13

times higher than the maximum major source risks and about 140 times higher than the maximum typical area source risk.

TABLE 11.—COMPARISON OF PCE EXPOSURE CONCENTRATIONS BY TYPE OF FACILITY ³

Facility	Co-residential area source	Typical area source	Major source
Maximum Exposure Concentration (ug/m ³)	5,000 ¹	37	405
Geometric Mean Exposure Concentration (ug/m ³)	33	1	1.3
Maximum Inhalation Risk (per million)	3,000 to 30,000 ²	30 to 220	300 to 2,400
Maximum Noncancer HQ	20	0.1	2
Geometric Mean Noncancer HQ	0.1	0.004	0.004

¹ New York Department of Health monitoring data.

²Inhalation cancer risks were extrapolated from 24-hour monitoring data, assuming continuous exposure for 70 years at the maximum monitored concentration.

³Estimate range represents difference between estimated risk using OPPTS and CalEPA URE.

J. What is our proposed decision on co-residential area sources?

We are proposing two options for co-residential area sources in today's proposal. We expect to select one of these options, with possible modifications in response to comments, in the final rule. The first option addresses both risks and technological developments for new co-residential area sources as a combined CAA Section 112(f) residual risk and Section 112(d)(6) rulemaking, and is described further in this section. This is consistent with the approach we are taking for typical area sources and for major sources. However, for existing co-residential area sources under this option, we are not exercising our discretion to impose a section 112(f) residual risk standard, but only a section 112(d)(6) standard. We recognize that developing residual risk standards for area sources is discretionary under the CAA, and that emissions reductions can also be achieved under CAA section 112(d)(6) that do not rely upon our section 112(f) authority. Therefore, we are also

proposing a second option to achieve emissions reductions through a technology based standard for both existing and new co-residential sources relying only on our Section 112(d)(6) authority, as discussed below and in section III.K. We request comment on alternative approaches that might protect public health with an ample margin of safety.

As our first option, we are proposing different requirements for new and existing co-residential sources. For new sources, we propose not to allow any new co-residential machines that emit PCE. Our proposal is based on the high-end estimated MIR of between 4,000-in-1 million and 30,000-in-1 million, and on our conclusion that risks from new co-residential sources should be substantially reduced. These risk estimates are based on monitored concentrations taken from apartments above co-residential dry cleaners with the level of equipment control required by NYSDEC in their title 6 NYCRR Part 232 rules (e.g., a refrigerated condenser and secondary carbon adsorber, and a vapor barrier or room enclosure).

For new co-residential sources, the most stringent possible control option with the greatest risk reduction is a prohibition of PCE use at such sources. This option would eliminate PCE risks for new sources and require that any new dry cleaning machines located in a residential building would have to use an alternative cleaning solvent. We believe the owner/operator can choose from other alternative solvent dry cleaning systems to use in a residential building.

The national capital costs of this regulatory option for new co-residential sources are \$8.6 million, and the annualized costs are approximately \$950,000. These cost estimates are based on the assumption that existing facilities will replace PCE machines that have reached the end of their useful lives (15 years) and are estimated for facilities affected within the first 5 years after the final rule takes effect. These costs reflect the incremental cost between replacing existing machines with PCE machines with refrigerated condensers and carbon adsorbers, and replacing them with machines using hydrocarbon solvents.

This analysis includes costs for all affected facilities, such as the cost incurred to install fire protection sprinklers required by most applicable fire codes to operate a hydrocarbon technology, that would not be necessary with other options. Cost estimates would be much lower if facilities using this option have sprinkler systems in place, or if they choose a less costly alternative garment cleaning option utilizing non-flammable solvents, or conducting dry cleaning operations off-site from the co-residential facility. We estimate that this control option for new co-residential sources may, after about 15 years, result in the elimination of cancer risks from all co-residential sources, as existing sources would be replaced by new non-PCE sources. This means that maximum individual risk levels due to these sources would decline from between 30,000- and 4,000-in-1 million to 0; average individual risk would decline from between 1,000- and 200-in-1 million to 0; and annual incidence would decline from between 2.2 and 0.3 cases per year to 0. These risk reduction estimates for all co-residential dry cleaners are subject to a number of limitations, the greatest of which are likely: (1) The degree to which the small sampled subset of co-residential dry cleaners (16) is representative of the full set (about 1,300) of all co-residential dry cleaners; (2) our uncertainty of the size of the affected population; and (3) the possible range of cancer potency factors used in our analysis, which is reflected in the ranges of the risk metrics reported above.

We also recognize that a proposal to prohibit new co-residential sources could encourage continued operation of existing co-residential PCE machines beyond their useful lives rather than replacement with new machines. We request comment on a sunset provision, where, after some period of time that reflects the typical lifetime of a dry cleaning machine, existing co-residential sources would have to be replaced with new machines that do not emit PCE.

As part of this first option, we are proposing no additional control requirements for existing co-residential dry cleaners beyond the proposed requirements for existing area sources. However, we also request comment on the appropriateness of adopting other alternatives. In particular, we are continuing to analyze the potential health risks at co-residential sources and the range of options to reduce these risks. Options under consideration range from voluntary initiatives to regulatory action. About 1,100 of the

estimated 1,300 co-residential sources are located in New York and California. These sources are controlled with the technology equivalent to the requirements of the 1993 Dry Cleaning NESHAP for new major sources; plus, the facilities in New York have installed room enclosures to reduce exposure from residual emissions.

At this time we have limited data on co-residential sources outside of New York and California. We do not know how representative the dataset is of all facilities in New York City. We do not know how many people are exposed at other sources and if the exposure and risk levels in other parts of the United States are similar to those in New York City buildings. We have little information on the distribution of PCE concentrations, the number of persons living in co-residential buildings, or the number of persons exposed to various PCE concentration levels. Based on the New York monitoring data, we know the level of PCE concentrations can vary substantially within co-residential buildings. While we believe that the dataset used for this risk assessment represents a high-quality set of measurements which is appropriate for estimating risks, we are also aware that the dataset may contain a selection bias due to the fact that the study from which the data were taken was an epidemiological study aimed at identifying high exposures within minority and economically-disadvantaged populations. Moreover, we are also aware that variable attention to work practices, difficulties in achieving compliance with newly-installed equipment, and poor ventilation in sampled apartments may also have increased the measured concentration values relative to the remaining population of apartments co-located with area source dry cleaners. Thus, we specifically request comment on the appropriateness of using this dataset to develop a risk assessment which represents the population of co-residential facilities. We also request any additional data that might be used to characterize these risks.

If a long-term time series dataset of concentration measurements were available, we would estimate chronic exposure based on it to take into account the true temporal variability of exposures. However, we do not have such a dataset. Instead, we base our exposure and risk estimates on snapshot data available, recognizing that an extrapolation from short-term monitoring values can lead to an upward bias of the high-end chronic exposures and risks and a downward bias of the low-end chronic exposures

and risks. We request comment on ways to minimize these biases. In evaluating the potential impact of NYSDEC requirements, our analysis focused on those facilities which were deemed to be in compliance with the NYSDEC part 232 regulations. However, it is not always clear from the available data what the exact compliance status of the facilities was at the time that measurements were taken. For example, we note that the highest measured exposure level (5,000 ug/m³), which is associated with a facility that was reported to be in full compliance with the NYSDEC regulations at the time of the measurements, has been called into question by industry stakeholders based on evidence that the facility was inspected and found to be out of compliance (due to equipment operation problems) approximately 2 months after the measurements were taken. These problems were remedied and compliance was certified a week later. This uncertainty in exact compliance status leads to an uncertainty in whether the measured concentration values actually reflect a level of control consistent with implementation of the NYSDEC requirements. Thus, we request comment on whether and to what extent temporal variability or compliance problems among the facilities located in buildings with the sampled apartments may have biased the sampled measurements high or low and influenced the results of the risk assessment.

We believe that the risk assessment underlying the proposal of our first option is appropriate for rulemaking purposes, however, given the uncertainties discussed above, we are proposing a second option solely under the authority of section 112(d)(6) of the CAA. We propose the NYSDEC title 6 NYCRR Part 232 rules (or similar standards) as the basis for control standards for both new and existing sources, instead of prohibiting any new co-residential machines that emit PCE and the standards proposed for typical area sources and existing co-residential sources. The NYSDEC requires that co-residential dry cleaning machines have refrigerated condensers and secondary carbon adsorbers, and that equipment be housed inside a vapor barrier with general ventilation to the outside air for both new and existing facilities. Facilities must conduct weekly leak inspections using a leak detection device such as a halogenated hydrocarbon detector. Facilities are required to obtain annual third party inspections by a professional engineer,

and must make available the most recent inspection report to interested individuals for their review. The NYSDEC also requires that the facility owner and/or manager and the dry cleaning machine operator be certified by an organization that offers a training program approved by the State agency. Most co-residential facilities meet the New York standards (of the 1,300 co-residential facilities nationwide, approximately 900 are in New York), but approximately 240 facilities across the country would need to upgrade their equipment to comply with this second proposal option. The capital cost of this option is approximately \$3 million, and the annual cost is \$0.5 million. These estimates include the cost for approximately 240 existing facilities to either upgrade or replace their existing equipment to include a refrigerated condenser and carbon adsorber, install a vapor barrier and conduct the leak detection and repair described above. These estimates do not include the cost of third party inspections and operator training, so cost impacts may be understated. Emissions reduction is estimated to be about 48 tons per year from the use of refrigerated condensers and carbon adsorbers. Vapor barriers do not remove emissions, but contain them to help prevent exposures to emissions.

For this second option, we request data on the emission levels, exposure, and risks associated with meeting the level of control required by the NYSDEC standards and for any other control options for co-residential sources that may substantially reduce emissions from co-residential sources (*e.g.*, periodic gasket replacement in lieu of inspections).

K. What determination is EPA proposing pursuant to review of the 1993 Dry Cleaning NESHAP under CAA section 112(d)(6)?

Section 112(d)(6) of the CAA requires us to review and revise MACT standards, as necessary, every 8 years, taking into account developments in practices, processes, and control technologies that have occurred during that time. If we find relevant changes, we may revise the MACT standards and develop additional standards. We do not interpret CAA section 112(d)(6) as requiring another analysis of MACT floors for existing and new sources.

For major sources, we considered as a MACT alternative the same options considered above for residual risk (table 5 of this preamble). The use of a PCE sensor/lock system (option II on table 5 of this preamble) is an option more stringent than the level of control that we are proposing to protect the public

from residual risks with an ample margin of safety. The system would reduce emissions by 40 tpy. Total capital costs are estimated to be \$5.7 million for the 15 major sources with an annualized cost of \$420,000. Additional analysis of costs can be found in the Background Information Document in the public docket. The incremental cost-effectiveness of the option is \$17,000 per ton of PCE removed (overall, considering all 15 facilities). Consequently, we propose that requiring enhanced LDAR and a refrigerated condenser/secondary carbon adsorber would meet the requirements for CAA section 112(d)(6).

Section 112(d)(6) of the CAA also requires that we review and, if necessary, revise the technology-based standards for area sources. The 1993 Dry Cleaning NESHAP for area sources was based on the use of GACT. The options selected for evaluating GACT for existing area sources are the same two options that we discussed above; enhanced LDAR and eliminating transfer machines (option I on table 8 of this preamble), and the use of secondary carbon adsorbers (option II on table 8 of this preamble). Option I would reduce emissions by an estimated 3,200 tpy and would result in a net cost savings to area sources. Option II would reduce emissions by an additional 3,000 tpy. However, as explained above, retrofitting a secondary carbon adsorber would not be cost-effective for many existing area source dry cleaners. Consequently, we propose that requiring enhanced LDAR and eliminating transfer machines at existing area sources would meet the requirements of CAA section 112(d)(6).

For new machines located at area source dry cleaners, we are proposing the use of refrigerated condensers, secondary carbon adsorbers, and enhanced LDAR. Requiring the use of secondary carbon adsorbers on new machines will not impose any significant new costs to the industry, because the majority of new machines today are sold with secondary carbon adsorbers. Vented machines, water-cooled condensers, and transfer machines are no longer sold. Many area source dry cleaners are buying this latest technology (dry-to-dry machine with refrigerated condenser and secondary carbon adsorber) because they are easier to operate, use less PCE, and produce less hazardous waste. In addition, several States require the use of this technology. A machine manufacturer stated that 70 percent of the new PCE machines sold in the year 2000 were dry-to-dry machines with refrigerated condensers and secondary

carbon adsorbers, and by 2003 nearly all of the PCE machines sold would have this technology. New York and, beginning in 2007, California, will require this technology for all existing major and area sources. Due to the vast number of area sources compared to major sources, the majority of the new PCE machines are purchased by area sources to replace older technology machines. Therefore, we are proposing the use of dry-to-dry machines with refrigerated condensers and secondary carbon adsorbers for new machines at area sources to meet the requirements of CAA section 112(d)(6).

For co-residential area sources, the most stringent standards currently in place are those enforced by NYSDEC (described in section III.J). In some cases, these and related requirements have been effective in reducing exposure levels; the mean exposure has dropped by tenfold since 1997 (McDermott, et al., 2005). However, as described earlier, a monitoring study in New York City suggests that risk levels after implementation of these standards may remain relatively high. Under our first option for addressing co-residential area sources discussed above in section III.J of this preamble, we are not proposing the NYSDEC levels of control under Section 112(d)(6). However, under the second option for co-residential sources, we are proposing under CAA section 112(d)(6) standards based on those required by NYSDEC Part 232 for new and existing co-residential sources, which would be modified, as appropriate, to function as nationally applicable Federal standards rather than State standards. While the first proposed option would eventually eliminate PCE exposures from co-residential sources, this second option would initially reduce exposures from existing co-residential sources more than the first option to require enhanced LDAR for all area sources. This second option for co-residential sources eliminates the continued use of equipment without secondary carbon adsorbers at new and existing co-residential sources; this contrasts with the first option discussed in section J above, which prohibits the use of new PCE machines and may give facilities the incentive to prolong the use of existing machines rather than purchase newer, lower emitting PCE machines at existing sources. With respect to new facilities, this option would allow new co-residential facilities to use PCE only if they also use equipment with refrigerated condensers and secondary carbon adsorbers housed in a vapor barrier. EPA is seeking comment and

additional information in section III.J to help assess risk reductions that could be achieved through application of standards similar to NYSDEC part 232.

L. What additional changes are we making to the 1993 Dry Cleaning NESHAP?

In 40 CFR 63.322(e), we are deleting the term “diverter valve,” but retaining the requirement to prevent air drawn into the door of the dry cleaning machine from passing through the refrigerated condenser. We are proposing this change because some newer machines accomplish this objective without a diverter valve. This change does not subject sources to any new requirements and does not change the requirement for machines with diverter valves.

In 40 CFR 63.322(m) and 40 CFR 63.324(d), we are changing “perceptible leaks” to “leaks” because the requirements now apply to both the monthly inspection for vapor leaks, which would require the use of a leak detection instrument, as well as the weekly or biweekly inspections for perceptible leaks. This harmonizing change would not change the nature of existing inspection requirements. To support the proposed requirements for monthly vapor leak inspection, we have proposed to add definitions of “vapor leak,” “PCE gas analyzer,” and “halogenated hydrocarbon detector.”

The 40 CFR 63.323(b) would be revised to add PCE gas analyzers as an acceptable monitoring instrument in addition to colorimetric tubes. Major sources would need a PCE gas analyzer for enhanced leak detection and repair. This analyzer could also be used for monitoring a carbon adsorber. Also, the phrase “or removal of the activated carbon” would be added to clarify that any major source required to use a carbon adsorber is required to monitor the adsorber exhaust weekly for PCE. Previously, this requirement was unclear for sources that disposed of the carbon instead of desorbing it.

IV. Solicitation of Public Comments

We request comments on all aspects of the proposed amendments. We are also considering additional rule amendments and specifically solicit comments on these potential amendments. The additional amendments are described in the following sections. All significant comments received will be considered in the development and selection of the final amendments.

A. Additional Requirements for Highest Risk Facilities

For one of the modeled major source facilities, the estimated emissions after installing controls required by the proposed rule would pose a MIR greater than 100-in-1 million using the CalEPA URE. An alternative approach we are considering is establishing more stringent requirements for this source. We would like information about whether such an approach would be appropriate and what would be a suitable regulatory basis for creating a separate class for this major source. We are considering requiring this facility to install a PCE sensor and lockout on each dry cleaning machine.

Under the proposed rule, this facility would be required to install a refrigerated condenser and secondary carbon adsorber. Most dry cleaning machines with secondary carbon adsorbers sold in this country since 1998 are equipped with a lockout that prevents the drum from being opened until the completion of the timed adsorption cycle. These machines have been demonstrated to achieve a concentration inside the drum of less than 300 ppm without a PCE sensor. The addition of a sensor ensures that this target concentration will be met for every load, thereby preventing episodes of high emissions caused by operator error or machine malfunction.

The PCE sensor and lockout system originally was developed to meet the 2. BImSchV German Emission Control Law, which requires a PCE concentration in the dry cleaning machine drum of less than 2 grams per cubic meter (~300 ppm) at the end of the drying cycle. Dry cleaning machines equipped with PCE sensors are widely used in Germany and are available in the United States. However, there is limited experience with this technology in the United States. We are aware of only two commercial dry cleaners in the United States and one industrial dry cleaner in Canada that use a PCE sensor. Because of the limited United States experience, we do not have emission test data to evaluate the performance of this system relative to machines with a timed lockout system, particularly with industrial articles such as work gloves. The emissions reductions that we used to evaluate the PCE sensor and lockout system were based on estimates of solvent mileage (pounds garments cleaned per gal of PCE used) compared to machines with a refrigerated condenser and secondary carbon adsorber. The estimated mileage of the various dry cleaning systems was obtained from engineering judgment by

several industry experts. Facilities using a PCE sensor and lockout system could possibly observe a wide range of emission reduction potential. For example, facilities that use good maintenance procedures and follow manufacturers specifications would achieve lower emission reductions than facilities with poor maintenance procedures. This control technology ensures optimal operation of the carbon adsorber by preventing the door from being opened until the PCE concentration in the drum is less than 300 ppm at the end of the drying cycle. Facilities with good maintenance procedures will have fewer high emission episodes caused by premature termination of the drying cycle.

We solicit comments on the appropriateness of requiring greater emission reduction at the highest risk source, the performance of the PCE sensor and lockout system and its effectiveness in reducing risks from this source, and the basis for creating a separate class for this major source dry cleaner. We also request information on the feasibility, cost, and amount of emission reduction that could be achieved at this source through other techniques, such as the use of alternative solvents or other approaches.

B. Requirement for PCE Sensor and Lockout as New Source MACT for Major Sources

We are considering making PCE sensor and lockout controls a requirement for new machines installed at major sources. The decision to select option I instead of this control option for major sources was based on the relatively small emission reduction estimated to result from the installation of PCE sensor and lockout controls. We would like additional data on the amount of PCE reduction achieved by these controls in both industrial and commercial applications, and about how site-specific factors influence the reduction achieved.

C. Alternative Performance-Based Standard for Existing Major Sources

We are considering establishing an alternative performance-based standard for existing major sources. The alternative standard would be a facility-wide PCE use limitation (e.g., gal PCE per year, solvent mileage or other metrics), which would be determined as a percent reduction of actual PCE use from a baseline year. If adopted, a source could elect to comply with either the proposed process vent controls (i.e., closed loop machine with refrigerated condenser and secondary carbon adsorber) or the performance-based

alternative. Facilities that use the performance-based alternative still would be required to comply with the operating controls (*i.e.*, enhanced leak detection and repair, etc.) in the proposed rule.

The alternative standard would provide more flexibility in choosing the method of reducing emissions. This flexibility provides the opportunity to decrease compliance costs, reduce recordkeeping, and simplify compliance and enforcement. We anticipate that any facility selecting this alternative would reduce emissions by replacing some machines with alternative solvent machines and continuing to operate some PCE machines without secondary controls. Additional emission reductions could also be achieved by more aggressive maintenance and leak detection programs.

The performance-based alternative we are considering would limit annual PCE consumption on a facility-wide basis. Usage of PCE correlates directly with PCE emissions. The limit would be based on the average fraction of emissions reduced by the control technology requirement for the different types of affected sources. For the three major source industrial facilities that would be required to make equipment changes to comply with the proposed rule, the average estimated facility-wide emission reduction, including enhanced leak detection and repair, would be 76 percent. For the four affected major source commercial facilities, the average estimated total emission facility-wide reduction would be 67 percent. These reductions are relative to estimated emissions from these facilities in 2002. Therefore, we envision that facilities that clean industrial articles such as work gloves would be required to reduce PCE usage by at least 76 percent. For facilities that do not clean work gloves or shop rags, we envision a PCE reduction of 67 percent. For a description of how the emission reduction percentages were estimated, refer to the Background Information Document in the public docket. The baseline year for determining the PCE usage limit would be 2002. Annual PCE usage would be calculated based on the amount of PCE purchased during the calendar year, adjusted for the PCE in use and storage at the beginning and end of the calendar year.

If the performance alternative is selected, the required PCE usage percent reduction levels will be prescribed in the final rule. The percent reductions would be selected to be equivalent to the emission reductions achieved by the technology based MACT requirements

and the residual risk requirements adopted in the final rule.

The performance-based alternative would apply only to existing major sources. New major sources are not eligible for these performance-based alternative standards because no baseline PCE data exists for determining a required emission reduction level. This alternative also would not be practicable for area sources because the proposed rule has no process vent requirements for existing area sources. The only requirements for existing area sources are the ban on transfer machines, enhanced LDAR, and the operating requirements. Moreover, most area sources operate only one dry cleaning machine.

We solicit comments on whether such an approach would be appropriate for major sources. We would also like comments from affected sources regarding the likelihood that they would select this alternative standard. In addition, we welcome comments on other options for a performance-based alternative. Please include in your comments how the option ensures equivalent emission reductions to the proposed equipment standards and how the option could be enforced, including any recordkeeping needed.

D. Environmental Impacts of PCE Emissions

As discussed above, due to the large margin of exposures relative to known thresholds, risks to mammals from PCE inhalation are likely insignificant. Also, the scarcity of data makes it difficult to identify any potential for adverse ecological impacts to plant life from PCE emissions from dry cleaners due to conversion to TCAA. While we have no direct evidence that this will present a significant ecological risk, we nonetheless, invite public comment and solicit additional scientific information on this issue.

E. Additional Time for Complying With Provisions for Transfer Machines

As discussed in section III.H of this preamble, we are proposing to eliminate the use of transfer machines. Per section 112(f) of the CAA, sources have 90 days to comply with health based standards. However, we are soliciting comment on what additional time beyond the 90-day compliance period, if any, might be necessary for area sources to replace existing transfer machines with dry-to-dry machines, and on whether, if EPA were to grant area sources replacing transfer machines additional compliance time in the final rule, any further steps should be taken by these area sources before achieving

compliance to assure that the health of persons will be protected from imminent endangerment, consistent with section 112(f)(4)(B) of the CAA.

V. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

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

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

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

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

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

Pursuant to the terms of Executive Order 12866, OMB has determined that it considers this proposed rule a “significant regulatory action” within the meaning of the Executive Order. The EPA has submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 1415.06 and OMB Control Number 2060–0234.

The 2005 proposed revisions to the Dry Cleaning NESHAP contain recordkeeping and reporting requirements beyond the recordkeeping and reporting requirements that were promulgated on September 22, 1993. Owners or operators will continue to keep records and submit required reports to us or the delegated State regulatory authority. Notifications,

reports, and records are essential in determining compliance and are required, in general, of all sources subject to the 1993 Dry Cleaning NESHAP. Owners or operators subject to the 1993 Dry Cleaning NESHAP continue to maintain records and retain them for at least 5 years following the date of such measurements, reports, and records. Information collection requirements that were promulgated on September 22, 1993 in the Dry Cleaning NESHAP prior to the 2005 proposed amendments, as well the NESHAP General Provisions (40 CFR part 63, subpart A), which are mandatory for all owners or operators subject to national emission standards, are documented in EPA ICR No. 1415.05.

The information collection requirements described here are only those notification, recordkeeping, and reporting requirements that are contained in the 2005 proposed revisions to the Dry Cleaning NESHAP. To comply with the 2005 proposed revisions to the 1993 Dry Cleaning NESHAP, owners or operators of dry cleaning facilities would read instructions to determine how they would be affected. All sources would begin an enhanced leak detection and repair program that requires a handheld portable monitor. Major source facilities would purchase a PCE gas analyzer and area sources would purchase a halogenated hydrocarbon leak detector. Owners and operators would incur the capital/startup cost of purchasing the monitors, plus ongoing annual operation and maintenance costs. The total capital/startup cost for this ICR is \$5,049,000. Annual operation and maintenance cost would be \$552,825.

Owners and operators of major and area sources would conduct enhanced leak detection and repair and keep monthly records of enhanced leak detection and repair events.

Approximately 28,000 existing area sources and 15 existing major sources are subject to the proposed rule and are subject to the 1993 Dry Cleaning NESHAP. We estimate that an average of 2,330 new area sources per year will become subject to the regulation in the next 3 years, but that the overall number of facilities will remain constant as the new owners will take over old existing facilities. No new major sources are expected. The estimated annual labor cost for major and area sources to comply with the 2005 proposed rule is approximately \$3.9 million.

The recordkeeping and reporting requirements are specifically authorized by CAA section 114 (42 U.S.C. 7414). All information submitted to us pursuant to the recordkeeping and

reporting requirements for which a claim of confidentiality is made is safeguarded according to our policies set forth in 40 CFR part 2, subpart B.

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

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

To comment on EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for the proposed rule, which includes this ICR, under Docket ID No. OAR-2005-0155. Submit any comments related to the ICR for the proposed rule to EPA and OMB. See the **ADDRESSES** section at the beginning of today's notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, OMB, 725 17th Street, NW., Washington, DC 20503. Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after December 21, 2005, a comment to OMB is best assured of having its full effect if OMB receives it by January 20, 2006. The final rule will respond to any OMB or public comments on the information collection requirements contained in the proposed rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant

economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For the purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business based on the following Small Business Administration (SBA) size standards, which are based on annual sales receipts: NAICS 812310—Coin-Operated Laundries and Dry Cleaners—\$6.0 million; NAICS 812320—Dry Cleaning and Laundry Services (Except Coin-Operated)—\$4.0 million; NAICS 812332—Industrial Launderers—\$12.0 million; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. Under these definitions, over 99 percent of commercial dry cleaning firms are small. For more information, refer to <http://www.sba.gov/size/sizetable2002.html>. The economic impacts of the regulatory alternatives were analyzed based on consumption of PCE, but are described in terms of comparing the compliance costs to dry cleaning revenues at affected firms. For more detail, see the current Economic Impact Analysis in the public docket.

After considering the economic impacts of today's proposed rule on small entities, I certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This certification is based on the economic impact of the proposed rule to affected small entities in the entire PCE dry cleaning source category and considers the economic impact associated with both proposed options for co-residential facilities. Over 98 percent of the approximately 20,000 small entities directly regulated by the proposed rule, including both major and area sources, are expected to have costs of less than 1 percent of sales. The cost impacts for all regulated small entities range from cost savings to less than 1.9 percent of sales. The small entities directly regulated by the proposed rule are dry cleaning businesses within the NAICS codes 812310, 812320, and 812332. We have determined that all of the major sources affected by the proposed rule are owned by businesses within NAICS 812332. The proposed rule is expected to affect 14 ultimate parent businesses that would be regulated as major

sources. Eight of the parent businesses are small according to the SBA small business size standard. None of the eight firms would have an annualized cost of more than 1 percent of sales associated with meeting the requirements for major sources (option I noted earlier in this preamble).

We have determined that virtually all of the affected small businesses that own area source dry cleaners are in NAICS 812320. Small businesses complying with the proposed area source requirements (area source option I described earlier in this preamble) are expected to have the following impacts. Over 98 percent of the approximately 20,000 small entities owning area sources directly regulated by the proposed rule, are expected to have costs of less than 1 percent of sales. The one-time cost of \$250 for purchasing a halogenated hydrocarbon detector is less than 0.10 percent of the average annual revenues for dry cleaning businesses in NAICS 812320, and there are minimal annualized costs associated with a detector's use. Of the nearly 200 small businesses that would have to replace their transfer machines (or 1 percent of the total number of affected small entities), most of these businesses would experience an annual cost savings and the others would have compliance costs of less than 1.2 percent of sales. Of the remaining 200 affected small businesses (or 1 percent of the total number of affected small entities), all of which are owners of co-residential facilities, the compliance costs based on the first proposed option for co-residential area sources range from 0.9 to 1.9 percent of sales. For the second proposed option for co-residential area sources, there are 240 small firms that will be affected, and these firms will have compliance costs ranging from 0.4 to 1.9 percent of sales.

Cost impacts associated with the proposed decision for major sources are presented in Section III.E of this preamble. These impacts are also presented for area sources in Section III.H, and for co-residential sources in Section III.J. These impacts are detailed in the BID in the public docket as memos 5 through 7. For more information on the small entity economic impacts associated with the proposed decisions for dry cleaners affected by today's action, please refer to the Economic Impact and Small Business Analyses in the public docket.

Although the proposed rule would not have a significant economic impact on a substantial number of small entities, we nonetheless tried to reduce the impact of the proposed rule on small entities. When developing the revised

standards, we took special steps to ensure that the burdens imposed on small entities were minimal. We conducted several meetings with industry trade associations to discuss regulatory options and the corresponding burden on industry, such as recordkeeping and reporting.

Following publication of the proposed rule, copies of the **Federal Register** notice and, in some cases, background documents, will be publically available to all industries, organizations, and trade associations that have had input during the regulation development, as well as State and local agencies. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

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

informing, educating, and advising small governments on compliance with the regulatory requirements.

We have determined that the proposed rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or to the private sector in any 1 year. Thus, the proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that today's proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments because it contains no requirements that apply to such governments or impose obligations upon them. Therefore, the proposed rule is not subject to section 203 of the UMRA.

E. Executive Order 13132, Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999) requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

The proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. None of the affected dry cleaning facilities are owned or operated by State or local governments. Thus, Executive Order 13132 does not apply to the proposed rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on the proposed rule from State and local officials.

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

Executive Order 13175 (65 FR 67249, November 9, 2000) requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal

implications." The proposed rule does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. No tribal governments own dry cleaning facilities subject to the proposed standards for dry cleaning facilities. Thus, Executive Order 13175 does not apply to the proposed rule. EPA specifically solicits additional comment on this proposed rule from tribal officials.

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

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

The proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This conclusion is based on our assessment of the information on PCE effects on human health and exposures associated with dry cleaner operations.

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

The proposed rule is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

The proposed rule would have a negligible impact on energy consumption because less than 1 percent of the industry would have to install additional emission control equipment to comply. The cost of energy distribution should not be affected by the proposed rule at all since the standards do not affect energy

distribution facilities. We also expect that there would be no impact on the import of foreign energy supplies, and no other adverse outcomes are expected to occur with regards to energy supplies. Further, we have concluded that the proposed rule is not likely to have any significant adverse energy effects.

I. National Technology Transfer Advancement Act

Section 112(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Public Law No. 104-113, 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS.

The proposed revisions to the 1993 NESHAP for PCE dry cleaners do not include requirements for technical standards beyond what the NESHAP requires. Therefore, the requirements of the NTTAA do not apply to this action.

List of Subjects in 40 CFR Part 63

Environmental Protection, Air pollution control, Hazardous substances, Reporting and Recordkeeping requirements.

Dated: December 9, 2005.

Stephen L. Johnson,
Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 63—[AMENDED]

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

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

Subpart M—[Amended]

2. Section 63.320 is amended by revising paragraphs (b), (c), (d), and (e) to read as follows:

§ 63.320 Applicability.

* * * * *

(b) The compliance date for a new dry cleaning system depends on the date that construction or reconstruction commences.

(1) Each dry cleaning system that commences construction or reconstruction on or after December 9,

1991 and before December 21, 2005, shall be in compliance with the provisions of this subpart except § 63.322(o) beginning on September 22, 1993 or immediately upon startup, whichever is later, except for dry cleaning systems complying with section 112(i)(2) of the Clean Air Act; and shall be in compliance with the provisions of § 63.322(o) beginning on [90 DAYS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**] or immediately upon startup, whichever is later, except as provided by § 63.6(b)(4).

(2) Each dry cleaning system that commences construction or reconstruction on or after December 21, 2005 and before [DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**], shall be in compliance with the provisions of this subpart except § 63.322(o) immediately upon startup, and shall be in compliance with the provisions of § 63.322(o) beginning on [DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**] or immediately upon startup, whichever is later.

(3) Each dry cleaning system that commences construction or reconstruction on or after [DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**], shall be in compliance with provisions of this subpart, including § 63.322(o) immediately upon startup.

(c) Each dry cleaning system that commenced construction or reconstruction before December 9, 1991, and each new transfer machine system and its ancillary equipment that commenced construction or reconstruction on or after December 9, 1991 and before September 22, 1993, shall comply with §§ 63.322(c), (d), (i), (j), (k), (l), and (m); 63.323(d); and 63.324(a), (b), (d)(1), (d)(2), (d)(3), (d)(4), and (e) beginning on December 20, 1993, and shall comply with other provisions of this subpart except § 63.322(o) by September 23, 1996; and shall comply with § 63.322(o) by [DATE 90 DAYS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(d) Each existing dry-to-dry machine and its ancillary equipment located in a dry cleaning facility that includes only dry-to-dry machines, and each existing transfer machine system and its ancillary equipment, and each new transfer machine system and its ancillary equipment installed between December 9, 1991 and September 22, 1993, as well as each existing dry-to-dry machine and its ancillary equipment, located in a dry cleaning facility that includes both transfer machine system(s) and dry-to-dry machine(s) is exempt from §§ 63.322, 63.323, and 63.324, except paragraphs 63.322(c), (d),

(i), (j), (k), (l), (m), (o)(1), and (o)(4); 63.323(d); and 63.324 (a), (b), (d)(1), (d)(2), (d)(3), (d)(4), and (e) if the total perchloroethylene consumption of the dry cleaning facility is less than 530 liters (140 gallons) per year. Consumption is determined according to § 63.323(d).

(e) Each existing transfer machine system and its ancillary equipment, and each new transfer machine system and its ancillary equipment installed between December 9, 1991 and September 22, 1993, located in a dry cleaning facility that includes only transfer machine system(s), is exempt from §§ 63.322, 63.323, and 63.324, except paragraphs 63.322(c), (d), (i), (j), (k), (l), (m), (o)(1), and (o)(4), 63.323(d), and 63.324 (a), (b), (d)(1), (d)(2), (d)(3), (d)(4), and (e) if the perchloroethylene consumption of the dry cleaning facility is less than 760 liters (200 gallons) per year. Consumption is determined according to § 63.323(d).

3. Section 63.321 is amended by revising the definition of *Filter*, and adding in alphabetical order definitions for *Halogenated hydrocarbon detector*, *Perchloroethylene gas analyzer*, *Residence*, and *Vapor leak* to read as follows:

§ 63.321 Definitions.

Filter means a porous device through which perchloroethylene is passed to remove contaminants in suspension. Examples include, but are not limited to, lint filter, button trap, cartridge filter, tubular filter, regenerative filter, prefilter, polishing filter, and spin disc filter.

Halogenated hydrocarbon detector means a portable device capable of detecting vapor concentrations of perchloroethylene of 25 parts per million by volume and indicating a concentration of 25 parts per million by volume or greater by emitting an audible or visual signal that varies as the concentration changes.

Perchloroethylene gas analyzer means a flame ionization detector, photoionization detector, or infrared analyzer capable of detecting vapor concentrations of perchloroethylene of 25 parts per million by volume.

Residence means any dwelling or housing in which people reside excluding short-term housing that is occupied by the same person for a period of less than 180 days (such as a hotel room).

Vapor leak means a perchloroethylene vapor concentration exceeding 25 parts per million by volume (50 parts per million by volume as methane) as indicated by a halogenated hydrocarbon detector or perchloroethylene gas analyzer.

4. Section 63.322 is amended by revising paragraphs (e)(3), (k) introductory text, and (m), and adding paragraph (o) to read as follows:

§ 63.322 Standards.

(e) * * * (3) Shall prevent air drawn into the dry cleaning machine when the door of the machine is open from passing through the refrigerated condenser.

(k) The owner or operator of a dry cleaning system shall inspect the system weekly for perceptible leaks while the dry cleaning system is operating. Inspection with a halogenated hydrocarbon detector or perchloroethylene gas analyzer also fulfills the requirement for inspection for perceptible leaks. The following components shall be inspected:

(m) The owner or operator of a dry cleaning system shall repair all leaks detected under paragraph (k) or (o)(1) of this section within 24 hours. If repair parts must be ordered, either a written or verbal order for those parts shall be initiated within 2 working days of detecting such a leak. Such repair parts shall be installed within 5 working days after receipt.

(o) Additional requirements: (1) The owner or operator of a dry cleaning system shall inspect the components listed in paragraph (k) of this section for vapor leaks monthly while the component is in operation.

(i) Area sources shall conduct the inspections using a halogenated hydrocarbon detector or perchloroethylene gas analyzer that is operated according to the manufacturer's instructions. The operator shall place the probe inlet at the surface of each component interface where leakage could occur and move it slowly along the interface periphery.

(ii) Major sources shall conduct the inspections using a perchloroethylene gas analyzer operated according to EPA Method 21.

(2) The owner or operator of a dry cleaning system at any major source shall route the air-perchloroethylene gas-vapor stream contained within each dry cleaning machine through a

refrigerated condenser and shall pass the air-perchloroethylene gas-vapor stream from inside the dry cleaning machine drum through a carbon adsorber or equivalent control device immediately before or as the door of the dry cleaning machine is opened. The carbon adsorber must be desorbed in accordance with manufacturer's instructions.

(3) The owner or operator of each dry cleaning system installed after December 21, 2005 at an area source shall route the air-perchloroethylene gas-vapor stream contained within each dry cleaning machine through a refrigerated condenser and pass the air-perchloroethylene gas-vapor stream from inside the dry cleaning machine drum through a carbon adsorber or equivalent control device immediately before the door of the dry cleaning machine is opened. The carbon adsorber must be desorbed in accordance with manufacturer's instructions.

(4) The owner or operator of any dry cleaning system shall eliminate any emission of perchloroethylene during the transfer of articles between the washer and the dryer(s) or reclaimer(s).

(5) The owner or operator shall eliminate any emission of perchloroethylene from any dry cleaning system that is installed after December 21, 2005 and that is located in a building with a residence.

5. Section 63.323 is amended by revising paragraphs (b) introductory text, (b)(1), (b)(2), and (c) to read as follows:

§ 63.323 Test methods and monitoring.

(b) When a carbon adsorber is used to comply with § 63.322(a)(2) or exhaust is passed through a carbon adsorber immediately upon machine door opening to comply with § 63.322(b)(3) or § 63.323(o)(2), the owner or operator shall measure the concentration of perchloroethylene in the exhaust of the carbon adsorber weekly with a colorimetric detector tube or perchloroethylene gas analyzer. The measurement shall be taken while the dry cleaning machine is venting to that carbon adsorber at the end of the last dry cleaning cycle prior to desorption of that carbon adsorber or removal of the activated carbon to determine that the perchloroethylene concentration in the exhaust is equal to or less than 100 parts per million by volume. The owner or operator shall:

(1) Use a colorimetric detector tube or perchloroethylene gas analyzer designed to measure a concentration of 100 parts per million by volume of

perchloroethylene in air to an accuracy of ±25 parts per million by volume; and

(2) Use the colorimetric detector tube or perchloroethylene gas analyzer according to the manufacturer's instructions; and

* * * * *

(c) If the air-perchloroethylene gas vapor stream is passed through a carbon adsorber prior to machine door opening to comply with § 63.322(b)(3) or § 63.323(o)(2), the owner or operator of an affected facility shall measure the concentration of perchloroethylene in the dry cleaning machine drum at the end of the dry cleaning cycle weekly with a colorimetric detector tube or perchloroethylene gas analyzer to determine that the perchloroethylene concentration is equal to or less than 300 parts per million by volume. The owner or operator shall:

(1) Use a colorimetric detector tube or perchloroethylene gas analyzer designed to measure a concentration of 300 parts per million by volume of perchloroethylene in air to an accuracy of ±75 parts per million by volume; and

(2) Use the colorimetric detector tube or perchloroethylene gas analyzer according to the manufacturer's instructions; and

(3) Conduct the weekly monitoring by inserting the colorimetric detector or perchloroethylene gas analyzer tube into the open space above the articles at the rear of the dry cleaning machine drum immediately upon opening the dry cleaning machine door.

* * * * *

6. Section 63.324 is amended by revising paragraphs (d)(3), (d)(5), and (d)(6) to read as follows:

§ 63.324 Reporting and recordkeeping requirements.

* * * * *

(d) * * *

(3) The dates when the dry cleaning system components are inspected for leaks, as specified in § 63.322(k), (l), or (o)(1), and the name or location of dry cleaning system components where leaks are detected;

* * * * *

(5) The date and temperature sensor monitoring results, as specified in § 63.323 if a refrigerated condenser is used to comply with § 63.322(a) or (b); and

(6) The date and monitoring results, as specified in § 63.323, if a carbon adsorber is used to comply with § 63.322(a)(2), (b)(3), or (o)(2).

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