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**40 CFR Parts 50, 51, 53, and 58
National Ambient Air Quality Standards
for Lead; Final Rule**

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 50, 51, 53 and 58**

[EPA-HQ-OAR-2006-0735; FRL-8732-9]

RIN 2060-AN83

National Ambient Air Quality Standards for Lead**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for lead (Pb), EPA is making revisions to the primary and secondary NAAQS for Pb to provide requisite protection of public health and welfare, respectively. With regard to the primary standard, EPA is revising the level to 0.15 $\mu\text{g}/\text{m}^3$. EPA is retaining the current indicator of Pb in total suspended particles (Pb-TSP). EPA is revising the averaging time to a rolling 3-month period with a maximum (not-to-be-exceeded) form, evaluated over a 3-year period. EPA is revising the secondary standard to be identical in all respects to the revised primary standard.

EPA is also revising data handling procedures, including allowance for the use of Pb-PM₁₀ data in certain circumstances, and the treatment of exceptional events, and ambient air monitoring and reporting requirements for Pb, including those related to sampling and analysis methods, network design, sampling schedule, and data reporting. Finally, EPA is revising emissions inventory reporting requirements and providing guidance on its approach for implementing the revised primary and secondary standards for Pb.

DATES: This final rule is effective on January 12, 2009.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2006-0735. All documents in the docket are listed on the www.regulations.gov Web site. Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave.,

NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566-1742.

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I. Summary and Background

A. Summary of Revisions to the Lead NAAQS

Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for lead (Pb), EPA is making revisions to the primary and secondary NAAQS for Pb to provide requisite protection of public health and welfare, respectively. With regard to the primary standard, EPA is revising various elements of the standard to provide increased protection for children and other at-risk populations against an array of adverse health

effects, most notably including neurological effects in children, including neurocognitive and neurobehavioral effects. EPA is revising the level to 0.15 µg/m³. EPA is retaining the current indicator of Pb in total suspended particles (Pb-TSP). EPA is revising the averaging time to a rolling 3-month period with a maximum (not-to-be-exceeded) form, evaluated over a 3-year period.

EPA is revising the secondary standard to be identical in all respects to the revised primary standard.

EPA is also revising data handling procedures, including allowance for the use of Pb-PM₁₀ data in certain circumstances, and the treatment of exceptional events, and ambient air monitoring and reporting requirements for Pb, including those related to sampling and analysis methods, network design, sampling schedule, and data reporting.

B. Legislative Requirements

Two sections of the Clean Air Act (Act) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list each air pollutant, emissions of which “in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health and welfare” and whose “presence * * * in the ambient air results from numerous or diverse mobile or stationary sources” and to issue air quality criteria for those that are listed. Air quality criteria are to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [the] pollutant in ambient air * * *”. Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants listed under section 108. Section 109(b)(1) defines a primary standard as one “the attainment and maintenance of which in the judgment of the Administrator, based on [air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health.”¹ A secondary standard, as defined in section 109(b)(2), must “specify a level of air quality the attainment and

¹ The legislative history of section 109 indicates that a primary standard is to be set at “the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.” S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970).

maintenance of which, in the judgment of the Administrator, based on criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.”²

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied*, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollutant levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries Association v. EPA*, 647 F.2d at 1156 n. 51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association v. EPA*, 647 F.2d at 1161–62. In addressing the requirement for an adequate margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the population(s) at risk, and the kind and degree of the uncertainties that must be addressed. In setting standards that are “requisite” to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more

nor less stringent than necessary for these purposes. *Whitman v. American Trucking Associations*, 531 U.S. 457, 473. Further the Supreme Court ruled that “[t]he text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations from the NAAQS-setting process * * *” *Id.* at 472.³

Section 109(d)(1) of the Act requires that “[n]ot later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 108 and subsection (b) of this section.” Section 109(d)(2)(A) requires that “The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.” Section 109(d)(2)(B) requires that, “[n]ot later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 108 and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.” Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

C. Review of Air Quality Criteria and Standards for Lead

On October 5, 1978, EPA promulgated primary and secondary NAAQS for Pb under section 109 of the Act (43 FR 46246). Both primary and secondary standards were set at a level of 1.5

micrograms per cubic meter ($\mu\text{g}/\text{m}^3$), measured as Pb in total suspended particulate matter (Pb-TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. This standard was based on the 1977 *Air Quality Criteria for Lead* (USEPA, 1977).

A review of the Pb standards was initiated in the mid-1980s. The scientific assessment for that review is described in the 1986 *Air Quality Criteria for Lead* (USEPA, 1986a), the associated Addendum (USEPA, 1986b) and the 1990 Supplement (USEPA, 1990a). As part of the review, the Agency designed and performed human exposure and health risk analyses (USEPA, 1989), the results of which were presented in a 1990 Staff Paper (USEPA, 1990b). Based on the scientific assessment and the human exposure and health risk analyses, the 1990 Staff Paper presented options for the Pb NAAQS level in the range of 0.5 to 1.5 $\mu\text{g}/\text{m}^3$, and suggested the second highest monthly average in three years for the form and averaging time of the standard (USEPA, 1990b). After consideration of the documents developed during the review and the significantly changed circumstances since Pb was listed in 1976, the Agency did not propose any revisions to the 1978 Pb NAAQS. In a parallel effort, the Agency developed the broad, multi-program, multimedia, integrated *U.S. Strategy for Reducing Lead Exposure* (USEPA, 1991). As part of implementing this strategy, the Agency focused efforts primarily on regulatory and remedial clean-up actions aimed at reducing Pb exposures from a variety of nonair sources judged to pose more extensive public health risks to U.S. populations, as well as on actions to reduce Pb emissions to air, such as bringing more areas into compliance with the existing Pb NAAQS (USEPA, 1991).

EPA initiated the current review of the air quality criteria for Pb on November 9, 2004 with a general call for information (69 FR 64926). A project work plan (USEPA, 2005a) for the preparation of the Criteria Document was released in January 2005 for CASAC and public review. EPA held a series of workshops in August 2005, inviting recognized scientific experts to discuss initial draft materials that dealt with various lead-related issues being addressed in the Pb air quality criteria document. In February 2006, EPA released the *Plan for Review of the National Ambient Air Quality Standards for Lead* (USEPA 2006c) that described Agency plans and a timeline for reviewing the air quality criteria, developing human exposure and risk

² Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, “effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.”

³ In considering whether the CAA allowed for economic considerations to play a role in the promulgation of the NAAQS, the Supreme Court rejected arguments that because many more factors than air pollution might affect public health, EPA should consider compliance costs that produce health losses in setting the NAAQS. *Whitman v. American Trucking Associations*, 531 U.S. at 466. Thus, EPA may not take into account possible public health impacts from the economic cost of implementation. *Id.*

assessments and an ecological risk assessment, preparing a policy assessment, and developing the proposed and final rulemakings.

The first draft of the Criteria Document (USEPA, 2005b) was released for CASAC and public review in December 2005 and discussed at a CASAC meeting held on February 28–March 1, 2006. A second draft Criteria Document (USEPA, 2006b) was released for CASAC and public review in May 2006, and discussed at the CASAC meeting on June 28, 2006. A subsequent draft of *Chapter 7—Integrative Synthesis* (chapter 8 in the final Criteria Document), released on July 31, 2006, was discussed at an August 15, 2006 CASAC teleconference. The final Criteria Document was released on September 30, 2006 (USEPA, 2006a; cited throughout this preamble as CD). While the Criteria Document focuses on new scientific information available since the last review, it integrates that information with scientific information from previous reviews.

In May 2006, EPA released for CASAC and public review a draft *Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards* (USEPA, 2006d), which was discussed at a June 29, 2006 CASAC meeting (Henderson, 2006). The May 2006 assessment plan discussed two assessment phases: A pilot phase and a full-scale phase. The pilot phase of both the human health and ecological risk assessments was presented in the draft *Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas* (ICF, 2006; henceforth referred to as the first draft Risk Assessment Report) which was released for CASAC and public review in December 2006. The first draft Staff Paper, also released in December 2006, discussed the pilot assessments and the most policy-relevant science from the Criteria Document. These documents were reviewed by CASAC and the public at a public meeting on February 6–7, 2007 (Henderson, 2007a).

Subsequent to that meeting, EPA conducted full-scale human exposure and health risk assessments, although no further work was done on the ecological assessment due to resource limitations. A second draft Risk Assessment Report (USEPA, 2007a), containing the full-scale human exposure and health risk assessments, was released in July 2007 for review by CASAC at a meeting held on August 28–29, 2007. Taking into consideration CASAC comments (Henderson, 2007b) and public comments on that document, we conducted additional human

exposure and health risk assessments. A final Risk Assessment Report (USEPA, 2007b) and final Staff Paper (USEPA, 2007c) were released on November 1, 2007.

The final Staff Paper presents OAQPS staff's evaluation of the public health and welfare policy implications of the key studies and scientific information contained in the Criteria Document and presents and interprets results from the quantitative risk/exposure analyses conducted for this review. Further, the Staff Paper presents OAQPS staff recommendations on a range of policy options for the Administrator to consider concerning whether, and if so how, to revise the primary and secondary Pb NAAQS. Such an evaluation of policy implications is intended to help "bridge the gap" between the scientific assessment contained in the Criteria Document and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS for Pb. In evaluating the adequacy of the current standard and a range of alternatives, the Staff Paper considered the available scientific evidence and quantitative risk-based analyses, together with related limitations and uncertainties, and focused on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: Indicator,⁴ averaging time, form,⁵ and level. These elements, which together serve to define each standard, must be considered collectively in evaluating the public health and welfare protection afforded by the Pb standards. The information, conclusions, and OAQPS staff recommendations presented in the Staff Paper were informed by comments and advice received from CASAC in its reviews of the earlier draft Staff Paper and drafts of related risk/exposure assessment reports, as well as comments on these earlier draft documents submitted by public commenters.

Subsequent to completion of the Staff Paper, EPA issued an advance notice of proposed rulemaking (ANPR) that was signed by the Administrator on December 5, 2007 (72 FR 71488). The ANPR is one of the key features of the new NAAQS review process that EPA has instituted over the past two years to help to improve the efficiency of the

process the Agency uses in reviewing the NAAQS while ensuring that the Agency's decisions are informed by the best available science and broad participation among experts in the scientific community and the public. The ANPR provided the public an opportunity to comment on a wide range of policy options that could be considered by the Administrator.

A public meeting of CASAC was held on December 12–13, 2007 to provide advice and recommendations to the Administrator based on its review of the ANPR and the previously released final Staff Paper and Risk Assessment Report. Transcripts of the meeting and CASAC's letter to the Administrator (Henderson, 2008a) are in the docket for this review and CASAC's letter is also available on the EPA Web site (<http://www.epa.gov/sab>).

A public comment period for the ANPR extended through January 16, 2008 and comments received are in the docket for this review. Comments were received from nearly 9000 private citizens (roughly 200 of them were not part of one of several mass comment campaigns), 13 State and local agencies, one federal agency, three regional or national associations of government agencies or officials, 15 nongovernmental environmental or public health organizations (including one submission on behalf of a coalition of 23 organizations) and five businesses or industry organizations.

The proposed decision (henceforth "proposal") on revisions to the Pb NAAQS was signed on May 1, 2008 and published in the **Federal Register** on May 20, 2008. Public teleconferences of the CASAC Pb Panel were held on June 9 and July 8, 2008 to provide advice and recommendations to the Administrator based on its review of the proposal notice. CASAC's letter to the Administrator (Henderson, 2008b) is in the docket for this review and also available on the EPA Web site (<http://www.epa.gov/sab>).

The EPA held two public hearings to provide direct opportunities for oral testimony by the public on the proposal. The hearings were held concurrently on June 12, 2008 in Baltimore, Maryland and St. Louis, Missouri. At these public hearings, EPA heard testimony from 33 individuals representing themselves or specific interested organizations. Transcripts from these hearings and written testimony provided at the hearings are in the docket for this review. Additionally, a large number of written comments were received from various commenters during the public comment period on the proposal. Comments were received from EPA's

⁴The "indicator" of a standard defines the chemical species or mixture that is to be measured in determining whether an area attains the standard.

⁵The "form" of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

Children's Health Protection Advisory Committee, the American Academy of Pediatrics, the American Medical Association, the American Thoracic Society, two organizations of state and local air agencies (National Association of Clean Air Agencies and Northeast States for Coordinated Air Use Management), approximately 40 State, Tribal and local government agencies, approximately 20 environmental or public health organizations or coalitions, approximately 20 industry organizations or companies, and approximately 6200 private citizens (roughly 150 of whom were not part of one of several mass comment campaigns). Significant issues raised in the public comments are discussed throughout the preamble of this final action. A summary of all other significant comments, along with EPA's responses (henceforth "Response to Comments"), can be found in the docket for this review.

The schedule for completion of this review has been governed by a judicial order in *Missouri Coalition for the Environment v. EPA* (No. 4:04CV00660 ERW, Sept. 14, 2005). The court-ordered schedule governing this review, entered by the court on September 14, 2005 and amended on April 29, 2008 and July 1, 2008, requires EPA to sign, for publication, a notice of final rulemaking concerning its review of the Pb NAAQS no later than October 15, 2008.

Some commenters have referred to and discussed individual scientific studies on the health effects of Pb that were not included in the Criteria Document (EPA, 2006a) ("new studies"). In considering and responding to comments for which such "new" studies were cited in support, EPA has provisionally considered the cited studies in conjunction with other relevant "new" studies published since the completion of the Criteria Document in the context of the findings of the Criteria Document.

As in prior NAAQS reviews, EPA is basing its decision in this review on studies and related information included in the Criteria Document and Staff Paper, which have undergone CASAC and public review. In this Pb NAAQS review, EPA also prepared an ANPR, consistent with the Agency's new NAAQS process. The ANPR discussed studies that were included in the Criteria Document and Staff Paper. The studies assessed in the Criteria Document and Staff Paper, and the integration of the scientific evidence presented in them, have undergone extensive critical review by EPA, CASAC, and the public. The rigor of that review makes these studies, and

their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process. EPA's provisional consideration of these studies did not and could not provide that kind of in-depth critical review.

This decision is consistent with EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. See 71 FR 61144, 61148 (October 17, 2006) (final decision on review of PM NAAQS) for a detailed discussion of this issue and EPA's past practice.

As discussed in EPA's 1993 decision not to revise the NAAQS for ozone, "new" studies may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013-13014, March 9, 1993). In the present case, EPA's provisional consideration of "new" studies concludes that, taken in context, the "new" information and findings do not materially change any of the broad scientific conclusions regarding the health effects and exposure pathways of ambient air Pb made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking.

Accordingly, EPA is basing the final decisions in this review on the studies and related information included in the Pb air quality criteria that have undergone CASAC and public review. EPA will consider the "new" studies for purposes of decision-making in the next periodic review of the Pb NAAQS, which EPA expects to begin soon after the conclusion of this review and which

will provide the opportunity to fully assess these studies through a more rigorous review process involving EPA, CASAC, and the public. Further discussion of these "new" studies can be found in the Response to Comments document.

D. Current Related Lead Control Programs

States are primarily responsible for ensuring attainment and maintenance of national ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program (42 U.S.C. 7470-7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Motor Vehicle Control Program under Title II of the Act (42 U.S.C. 7521-7574), which involves controls for automobile, truck, bus, motorcycle, nonroad engine, and aircraft emissions; the new source performance standards under section 111 of the Act (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 of the Act (42 U.S.C. 7412).

As Pb is a multimedia pollutant, a broad range of Federal programs beyond those that focus on air pollution control provide for nationwide reductions in environmental releases and human exposures. In addition, the Centers for Disease Control and Prevention (CDC) programs provide for the tracking of children's blood Pb levels nationally and provide guidance on levels at which medical and environmental case management activities should be implemented (CDC, 2005a; ACCLPP, 2007).⁶ In 1991, the Secretary of the Health and Human Services (HHS) characterized Pb poisoning as the "number one environmental threat to the health of children in the United States" (Alliance to End Childhood Lead Poisoning, 1991). In 1997, President Clinton created, by Executive Order 13045, the President's Task Force on Environmental Health Risks and Safety Risks to Children in response to

⁶ As described in section II.A.2.a below the CDC stated in 2005 that no "safe" threshold for blood Pb levels in young children has been identified (CDC, 2005a).

increased awareness that children face disproportionate risks from environmental health and safety hazards (62 FR 19885).⁷ By Executive Orders issued in October 2001 and April 2003, President Bush extended the work for the Task Force for an additional three and a half years beyond its original charter (66 FR 52013 and 68 FR 19931). The Task Force set a Federal goal of eliminating childhood Pb poisoning by the year 2010 and reducing Pb poisoning in children was identified as the Task Force's top priority.

Federal abatement programs provide for the reduction in human exposures and environmental releases from in-place materials containing Pb (e.g., Pb-based paint, urban soil and dust, and contaminated waste sites). Federal regulations on disposal of Pb-based paint waste help facilitate the removal of Pb-based paint from residences (68 FR 36487). Further, in 1991, EPA lowered the maximum levels of Pb permitted in public water systems from 50 parts per billion (ppb) to 15 ppb measured at the consumer's tap (56 FR 26460).

Federal programs to reduce exposure to Pb in paint, dust, and soil are specified under the comprehensive federal regulatory framework developed under the Residential Lead-Based Paint Hazard Reduction Act (Title X). Under Title X and Title IV of the Toxic Substances Control Act (TSCA), EPA has established regulations and associated programs in the following five categories: (1) Training and certification requirements for persons engaged in lead-based paint activities; accreditation of training providers; authorization of State and Tribal lead-based paint programs; and work practice standards for the safe, reliable, and effective identification and elimination of lead-based paint hazards; (2) ensuring that, for most housing constructed before 1978, lead-based paint information flows from sellers to purchasers, from landlords to tenants, and from renovators to owners and occupants; (3) establishing standards for identifying dangerous levels of Pb in paint, dust and soil; (4) providing grant funding to establish and maintain State and Tribal lead-based paint programs, and to address childhood lead poisoning in the highest-risk communities; and (5) providing information on Pb hazards to the public, including steps that people can take to

protect themselves and their families from lead-based paint hazards.

Under Title IV of TSCA, EPA established standards identifying hazardous levels of lead in residential paint, dust, and soil in 2001. This regulation supports the implementation of other regulations which deal with worker training and certification, Pb hazard disclosure in real estate transactions, Pb hazard evaluation and control in Federally-owned housing prior to sale and housing receiving Federal assistance, and U.S. Department of Housing and Urban Development grants to local jurisdictions to perform Pb hazard control. The TSCA Title IV term "lead-based paint hazard" implemented through this regulation identifies lead-based paint and all residential lead-containing dust and soil regardless of the source of Pb, which, due to their condition and location, would result in adverse human health effects. One of the underlying principles of Title X is to move the focus of public and private decision makers away from the mere presence of lead-based paint, to the presence of lead-based paint hazards, for which more substantive action should be undertaken to control exposures, especially to young children. In addition the success of the program will rely on the voluntary participation of States and Tribes as well as counties and cities to implement the programs and on property owners to follow the standards and EPA's recommendations. If EPA were to set unreasonable standards (e.g., standards that would recommend removal of all Pb from paint, dust, and soil), States and Tribes may choose to opt out of the Title X Pb program and property owners may choose to ignore EPA's advice believing it lacks credibility and practical value. Consequently, EPA needed to develop standards that would not waste resources by chasing risks of negligible importance and that would be accepted by States, Tribes, local governments and property owners. In addition, a separate regulation establishes, among other things, under authority of TSCA section 402, residential Pb dust cleanup levels and amendments to dust and soil sampling requirements (66 FR 1206).

On March 31, 2008, the Agency issued a new rule (Lead: Renovation, Repair and Painting [RRP] Program, 73 FR 21692) to protect children from lead-based paint hazards. This rule applies to renovators and maintenance professionals who perform renovation, repair, or painting in housing, child-care facilities, and schools built prior to 1978. It requires that contractors and maintenance professionals be certified; that their employees be trained; and that

they follow protective work practice standards. These standards prohibit certain dangerous practices, such as open flame burning or torching of lead-based paint. The required work practices also include posting warning signs, restricting occupants from work areas, containing work areas to prevent dust and debris from spreading, conducting a thorough cleanup, and verifying that cleanup was effective. The rule will be fully effective by April 2010. The rule contains procedures for the authorization of States, territories, and Tribes to administer and enforce these standards and regulations in lieu of a federal program. In announcing this rule, EPA noted that almost 38 million homes in the United States contain some lead-based paint, and that this rule's requirements were key components of a comprehensive effort to eliminate childhood Pb poisoning. To foster adoption of the rule's measures, EPA also intends to conduct an extensive education and outreach campaign to promote awareness of these new requirements.

Programs associated with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) and Resource Conservation Recovery Act (RCRA) also implement abatement programs, reducing exposures to Pb and other pollutants. For example, EPA determines and implements protective levels for Pb in soil at Superfund sites and RCRA corrective action facilities. Federal programs, including those implementing RCRA, provide for management of hazardous substances in hazardous and municipal solid waste (see, e.g., 66 FR 58258). Federal regulations concerning batteries in municipal solid waste facilitate the collection and recycling or proper disposal of batteries containing Pb.⁸ Similarly, Federal programs provide for the reduction in environmental releases of hazardous substances such as Pb in the management of wastewater (<http://www.epa.gov/owm/>).

A variety of federal nonregulatory programs also provide for reduced environmental release of Pb-containing materials through more general encouragement of pollution prevention, promotion of reuse and recycling, reduction of priority and toxic chemicals in products and waste, and

⁸ See, e.g., "Implementation of the Mercury-Containing and Rechargeable Battery Management Act" <http://www.epa.gov/epaoswer/hazwaste/recycle/battery.pdf> and "Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2005" <http://www.epa.gov/epaoswer/osw/conservation/resources/msw-2005.pdf>.

⁷ Co-chaired by the Secretary of the HHS and the Administrator of the EPA, the Task Force consisted of representatives from 16 Federal departments and agencies.

conservation of energy and materials. These include the Resource Conservation Challenge (<http://www.epa.gov/epaoswer/osw/conservation/index.htm>), the National Waste Minimization Program (<http://www.epa.gov/epaoswer/hazwaste/minimize/leadtire.htm>), "Plug in to eCycling" (a partnership between EPA and consumer electronics manufacturers and retailers; <http://www.epa.gov/epaoswer/hazwaste/recycle/electron/crt.htm#crt>), and activities to reduce the practice of backyard trash burning (<http://www.epa.gov/msw/backyard/pubs.htm>).

As a result of coordinated, intensive efforts at the national, state and local levels, including those programs described above, blood Pb levels in all segments of the population have dropped significantly from levels observed around 1990. In particular, blood Pb levels for the general population of children 1 to 5 years of age have dropped to a median level of 1.6 µg/dL and a level of 3.9 µg/dL for the 90th percentile child in the 2003–2004 National Health and Nutrition Examination Survey (NHANES) as compared to median and 90th percentile levels in 1988–1991 of 3.5 µg/dL and 9.4 µg/dL, respectively (http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm). These levels (median and 90th percentile) for the general population of young children⁹ are at the low end of the historic range of blood Pb levels for general population of children aged 1–5 years. However, as recognized in section II.A.2.b, levels have been found to vary among children of different socioeconomic status and other demographic characteristics (CD, p. 4–21) and racial/ethnic and income disparities in blood Pb levels in children persist. The Agency has continued to grapple with soil and dust Pb levels from the historical use of Pb in paint and gasoline and from other sources.

In addition to the Pb control programs summarized above, EPA's research program, with other Federal agencies, identifies, encourages and conducts research needed to locate and assess serious risks and to develop methods and tools to characterize and help reduce risks. For example, EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) for Pb in children and the Adult Lead Methodology are widely used and

accepted as tools that provide guidance in evaluating site specific data. More recently, in recognition of the need for a single model that predicts Pb concentrations in tissues for children and adults, EPA is developing the All Ages Lead Model (AALM) to provide researchers and risk assessors with a pharmacokinetic model capable of estimating blood, tissue, and bone concentrations of Pb based on estimates of exposure over the lifetime of the individual. EPA research activities on substances including Pb focus on better characterizing aspects of health and environmental effects, exposure, and control or management of environmental releases (see <http://www.epa.gov/ord/researchaccomplishments/index.html>).

E. Summary of Proposed Revisions to the Lead NAAQS

For reasons discussed in the proposal, the Administrator proposed to revise the current primary and secondary Pb standards. With regard to the primary Pb standard, the Administrator proposed to revise the level of the Pb standard to a level within the range of 0.10 µg/m³ to 0.30 µg/m³, in conjunction with retaining the current indicator of Pb in total suspended particles (Pb-TSP) but with allowance for the use of Pb-PM₁₀ data. With regard to the averaging time and form, the Administrator proposed two options: to retain the current averaging time of a calendar quarter and the current not-to-be-exceeded form, revised to apply across a 3-year span; and to revise the averaging time to a calendar month and the form to the second-highest monthly average across a 3-year span. With regard to the secondary standard for Pb, the Administrator proposed to revise the standard to make it identical to the proposed primary standard.

F. Organization and Approach to Final Lead NAAQS Decisions

This action presents the Administrator's final decisions regarding the need to revise the current primary and secondary Pb standards. Revisions to the primary standard for Pb are addressed below in section II. The secondary Pb standard is addressed below in section III. Related data completeness, data handling, data reporting and rounding conventions are addressed in section IV, and related ambient monitoring methods and network design are addressed below in section V. Implementation of the revised NAAQS is discussed in section VI, and the exceptional events information submission schedule is described in section VII. A discussion of statutory

and executive order reviews is provided in section VIII.

Today's final decisions are based on a thorough review in the Criteria Document of scientific information on known and potential human health and welfare effects associated with exposure to Pb in the environment. These final decisions also take into account: (1) Assessments in the Staff Paper and ANPR of the most policy-relevant information in the Criteria Document as well as quantitative exposure and risk assessments based on that information; (2) CASAC Panel advice and recommendations, as reflected in its letters to the Administrator, its discussions of drafts of the Criteria Document and Staff Paper, and of the ANPR and the notice of proposed rulemaking at public meetings; (3) public comments received during the development of these documents, either in connection with CASAC Panel meetings or separately; and (4) public comments received on the proposed rulemaking.

II. Rationale for Final Decision on the Primary Standard

A. Introduction

This section presents the rationale for the Administrator's final decision that the current primary standard is not requisite to protect public health with an adequate margin of safety, and that the existing Pb primary standard should be revised. In developing this rationale, EPA has drawn upon an integrative synthesis in the Criteria Document of the entire body of evidence published through late 2006 on human health effects associated with Pb exposure. Some 6000 studies were considered in this review. This body of evidence addresses a broad range of health endpoints associated with exposure to Pb (EPA, 2006a, chapter 8), and includes hundreds of epidemiologic studies conducted in the U.S., Canada, and many countries around the world since the time of the last review (EPA, 2006a, chapter 6).

As discussed below, a significant amount of new research has been conducted since the last review, with important new information coming from epidemiological, toxicological, controlled human exposure, and dosimetric studies. Moreover, the newly available research studies evaluated in the Criteria Document have undergone intensive scrutiny through multiple layers of peer review, with extended opportunities for review and comment by the CASAC Panel and the public. As with virtually any policy-relevant scientific research, there is uncertainty

⁹The 5th percentile, geometric mean, and 95th percentile values for the 2003–2004 NHANES are 0.7, 1.8 and 5.1 µg/dL, respectively (Axelrad, 2008a,b).

in the characterization of health effects attributable to exposure to ambient Pb. While important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence provides an adequate basis for regulatory decision making at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient Pb and health effects.

The health effects information and quantitative exposure and health risk assessment were summarized in sections II.B and II.C of the proposal (73 FR at 29193–29220) and are only briefly outlined below in sections II.A.2 and II.A.3. Responses to public comments specific to the material presented in sections II.A.1 through II.A.3 below are provided in the Response to Comments document.

Subsequent sections of this preamble provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that the current standard is not requisite to protect public health with an adequate margin of safety and that it is appropriate to revise the current primary Pb standard to provide additional public health protection (section II.B), as well as a more complete discussion of the Administrator's rationale for retaining or revising the specific elements of the primary Pb standards (section II.C), namely the indicator (section II.C.1), averaging time and form (section II.C.2), and level (section II.C.3). A summary of the final decisions on revisions to the primary Pb standards is presented in section II.D.

1. Overview of Multimedia, Multipathway Considerations and Background

This section briefly summarizes the information presented in section II.A of the proposal and chapter 2 of the Staff Paper on multimedia, multipathway and background considerations of the Pb NAAQS review. As was true in the setting of the current standard, multimedia distribution of and multipathway exposure to Pb that has been emitted into the ambient air play a key role in the Agency's consideration of the Pb NAAQS. Some key multimedia and multipathway considerations in the review include:

(1) Lead is emitted into the air from many sources encompassing a wide variety of stationary and mobile source types. Lead emitted to the air is

predominantly in particulate form, with the particles occurring in various sizes. Once emitted, the particles can be transported long or short distances depending on their size, which influences the amount of time spent in aerosol phase. In general, larger particles tend to deposit more quickly, within shorter distances from emissions points, while smaller particles will remain in aerosol phase and travel longer distances before depositing. As summarized in sections II.A.1 and II.E.1 of the proposal, airborne concentrations of Pb at sites near sources are much higher, and the representation of larger particles is greater, than at sites not known to be directly influenced by sources.

(2) Once deposited out of the air, Pb can subsequently be resuspended into the ambient air and, because of the persistence of Pb, Pb emissions contribute to media concentrations for some years into the future.

(3) Exposure to Pb emitted into the ambient air (air-related Pb) can occur directly by inhalation, or indirectly by ingestion of Pb-contaminated food, water or other materials including dust and soil.¹⁰ This occurs as Pb emitted into the ambient air is distributed to other environmental media and can contribute to human exposures via indoor and outdoor dusts, outdoor soil, food and drinking water, as well as inhalation of air. These exposure pathways are described more fully in the proposal.

(4) Air-related exposure pathways are affected by changes to air quality, including changes in concentrations of Pb in air and changes in atmospheric deposition of Pb. Further, because of its persistence in the environment, Pb deposited from the air may contribute to human and ecological exposures for years into the future. Thus, because of the roles of both air concentration and air deposition in human exposure pathways, and because of the persistence of Pb once deposited, some pathways respond more quickly to changes in air quality than others. Pathways most directly involving Pb in ambient air and exchanges of ambient air with indoor air respond more quickly while pathways involving exposure to Pb deposited from ambient air into the environment generally respond more slowly.

Additionally, as when the standard was set, human exposures to Pb include nonair or background contributions in addition to air-related pathways. Some

key aspects of the consideration of air and nonair pathways in the review (described in more detail in the proposal) are summarized here:

(1) Human exposure pathways that are not air-related are those in which Pb does not pass through ambient air. These pathways as well as air-related human exposure pathways that involve natural sources of Pb to air are considered "policy-relevant background" in this review.

(2) The pathways of human exposure to Pb that are not air-related include ingestion of indoor Pb paint,¹¹ Pb in diet as a result of inadvertent additions during food processing, and Pb in drinking water attributable to Pb in distribution systems, as well as other generally less prevalent pathways, as described in the proposal (73 FR 29192) and Criteria Document (CD, pp. 3–50 to 3–51).

(3) Some amount of Pb in the air derives from background sources, such as volcanoes, sea salt, and windborne soil particles from areas free of anthropogenic activity and may also derive from anthropogenic sources of airborne Pb located outside of North America (which would also be considered policy-relevant background). In considering contributions from policy-relevant background to human exposures and associated health effects, however, policy-relevant background in air is likely insignificant in comparison to the contributions from exposures to nonair media.

(4) The relative contribution of Pb from different exposure media to human exposure varies, particularly for different age groups. For example, some studies have found that dietary intake of Pb may be a predominant source of Pb exposure among adults, greater than consumption of water and beverages or inhalation, while for young children, ingestion of indoor dust can be a significant Pb exposure pathway (e.g., via hand-to-mouth activity of very young children).

(5) Estimating separate contributions to human Pb exposure from air and nonair sources is complicated by the existence of multiple and varied air-related pathways, as well as the persistent nature of Pb. For example, Pb that is a soil or dust contaminant today may have been airborne yesterday or many years ago. The studies currently available and reviewed in the Criteria Document that evaluate the multiple pathways of Pb exposure, when considering exposure contributions from indoor dust or outdoor dust/soil,

¹⁰In general, air-related pathways include those pathways where Pb passes through ambient air on its path from a source to human exposure.

¹¹Weathering of outdoor Pb paint may also contribute to soil Pb levels adjacent to the house.

do not usually distinguish between air-related and other sources of Pb or between air-related Pb associated with historical emissions and that from recent emissions.¹²

(6) Relative contributions to a child's total Pb exposure from air-related exposure pathways compared to other (nonair-related) Pb exposures depends on many factors including ambient air concentrations and air deposition in the area where the child resides (as well as in the area from which the child's food derives) and access to other sources of Pb exposure such as Pb paint, tap water affected by plumbing containing Pb, and lead-tainted products. Studies indicate that in the absence of paint-related exposures, Pb from other sources such as stationary sources of Pb emissions may dominate a child's Pb exposures. In other cases, such as children living in older housing with peeling paint or where renovations have occurred, the dominant source of Pb exposure may be lead paint used in the house in the past. Depending on Pb levels in a home's tap water, drinking water can sometimes be a significant source. In still other cases, there may be more of a mixture of contributions from multiple sources, with no one source dominating.

2. Overview of Health Effects Information

This section summarizes information presented in section II.B of the proposal pertaining to health endpoints associated with the range of exposures considered to be most relevant to current exposure levels. In recognition of the role of multiple exposure pathways and routes and the use of an internal exposure or dose metric in evaluating health risk for Pb, the following section summarizes key aspects of the internal disposition or distribution of Pb, the use of blood Pb as an internal exposure or dose metric, and the evidence with regard to the quantitative relationship between air Pb and blood Pb levels (section II.A.2.a). This is followed first by a summary of the broad array of Pb-induced health effects and recognition of at-risk subpopulations (section II.A.2.b) and then by a summary of neurological effects in children and quantitative concentration-response relationships for blood Pb and IQ (section II.A.2.c).

¹² The exposure assessment for children performed for this review employed available data and methods to develop estimates intended to inform a characterization of these pathways (as described in the proposal and the final Risk Assessment Report).

a. Blood Lead

(i) Internal Disposition of Lead

Lead enters the body via the respiratory system and gastrointestinal tract, from which it is quickly absorbed into the blood stream and distributed throughout the body.¹³ Lead bioaccumulates in the body, with the bone serving as a large, long-term storage compartment; soft tissues (e.g., kidney, liver, brain, etc.) serve as smaller compartments, in which Pb may be more mobile (CD, sections 4.3.1.4 and 8.3.1). During childhood development, bone represents approximately 70% of a child's body burden of Pb, and this accumulation continues through adulthood, when more than 90% of the total Pb body burden is stored in the bone (CD, section 4.2.2). Throughout life, Pb in the body is exchanged between blood and bone, and between blood and soft tissues (CD, section 4.3.2), with variation in these exchanges reflecting "duration and intensity of the exposure, age and various physiological variables" (CD, p. 4–1).

The bone pool of Pb in children is thought to be much more labile than that in adults due to the more rapid turnover of bone mineral as a result of growth (CD, p. 4–27). As a result, changes in blood Pb concentration in children more closely parallel changes in total body burden (CD, pp. 4–20 and 4–27). This is in contrast to adults, whose bone has accumulated decades of Pb exposures (with past exposures often greater than current ones), and for whom the bone may be a significant source long after exposure has ended (CD, section 4.3.2.5).

(ii) Use of Blood Pb as Dose Metric

Blood Pb levels are extensively used as an index or biomarker of exposure by national and international health agencies, as well as in epidemiological (CD, sections 4.3.1.3 and 8.3.2) and toxicological studies of Pb health effects and dose-response relationships (CD, chapter 5). The U.S. Centers for Disease Control and Prevention (CDC), and its predecessor agencies, have for many years used blood Pb level as a metric for identifying children at risk of adverse health effects and for specifying particular public health recommendations (CDC, 1991; CDC, 2005a). Most recently, in 2005, with consideration of a review of the evidence by their advisory committee, CDC revised their statement on

¹³ Additionally, Pb freely crosses the placenta resulting in continued fetal exposure throughout pregnancy, with that exposure increasing during the latter half of pregnancy (CD, section 6.6.2).

Preventing Lead Poisoning in Young Children, specifically recognizing the evidence of adverse health effects in children with blood Pb levels below 10 µg/dL¹⁴ and the data demonstrating that no "safe" threshold for blood Pb had been identified, and emphasizing the importance of preventative measures (CDC, 2005a, ACCLPP, 2007).¹⁵

Since 1976, the CDC has been monitoring blood Pb levels in multiple age groups nationally through the National Health and Nutrition Examination Survey (NHANES).¹⁶ The NHANES information has documented the dramatic decline in mean blood Pb levels in the U.S. population that has occurred since the 1970s and that coincides with regulations regarding leaded fuels, leaded paint, and Pb-containing plumbing materials that have reduced Pb exposure among the general population (CD, sections 4.3.1.3 and 8.3.3; Schwemberger *et al.*, 2005). The

¹⁴ As described by the Advisory Committee on Childhood Lead Poisoning Prevention, "In 1991, CDC defined the blood lead level (BLL) that should prompt public health actions as 10 µg/dL. Concurrently, CDC also recognized that a BLL of 10 µg/dL did not define a threshold for the harmful effects of lead. Research conducted since 1991 has strengthened the evidence that children's physical and mental development can be affected at BLLs <10 µg/dL" (ACCLPP, 2007).

¹⁵ With the 2005 statement, CDC did not lower the 1991 level of concern and identified a variety of reasons, reflecting both scientific and practical considerations, for not doing so, including a lack of effective clinical or public health interventions to reliably and consistently reduce blood Pb levels that are below 10 µg/dL, the lack of a demonstrated threshold for adverse effects, and concerns for deflecting resources from children with higher blood Pb levels (CDC, 2005a, pp. 2–3). The preface for the CDC statement included the following: "Although there is evidence of adverse health effects in children with blood lead levels below 10 µg/dL, CDC has not changed its level of concern, which remains at levels >10 µg/dL. We believe it critical to focus available resources where the potential adverse effects remain the greatest. If no threshold level exists for adverse health effects, setting a new BLL of concern somewhere below 10 µg/dL would be based on an arbitrary decision. In addition, the feasibility and effectiveness of individual interventions to further reduce BLLs below 10 µg/dL has not been demonstrated." [CDC, 2005a, p. ix] CDC further stated "Nonetheless, the sources of lead exposure and the population-based interventions that can be expected to reduce lead exposure are similar in children with BLLs <10 µg/dL and >10 µg/dL, so preventive lead hazard control measures need not be deferred pending further research findings or consensus." [CDC, 2005a, p. 2] CDC's Advisory Committee on Childhood Lead Poisoning Prevention recently provided recommendations regarding interpreting and managing blood Pb levels below 10 µg/dL in children and reducing childhood exposures to Pb (ACCLPP, 2007).

¹⁶ This information documents a variation in mean blood Pb levels across the various age groups monitored. For example, mean blood Pb levels in 2001–2002 for ages 1–5, 6–11, 12–19 and greater than or equal to 20 years of age, are 1.70, 1.25, 0.94, and 1.56 µg/dL, respectively (CD, p. 4–22).

Criteria Document summarizes related information as follows (CD, p. E-6).

In the United States, decreases in mobile sources of Pb, resulting from the phasedown of Pb additives created a 98% decline in emissions from 1970 to 2003. NHANES data show a consequent parallel decline in blood-Pb levels in children aged 1 to 5 years from a geometric mean of ~15 µg/dL in 1976-1980 to ~1-2 µg/dL in the 2000-2004 period.

While blood Pb levels in the U.S. general population, including geometric mean levels in children aged 1-5, have declined significantly, levels have been found to vary among children of different socioeconomic status (SES) and other demographic characteristics (CD, p. 4-21), and racial/ethnic and income disparities in blood Pb levels in children persist. For example, as described in the proposal, blood Pb levels for lower income and African American children are higher than those for the general population. The recently released RRP rule (discussed above in section I.C) is expected to contribute to further reductions in blood Pb levels for children living in houses with Pb paint.

(iii) Air-to-Blood Relationships

As described in section II.A.1 above and discussed in section II.A of the proposal, Pb in ambient air contributes to Pb in blood by multiple pathways, with the pertinent exposure routes including both inhalation and ingestion (CD, sections 3.1.3.2, 4.2 and 4.4; Hilts, 2003). The quantitative relationship between ambient air Pb and blood Pb (discussed in section II.B.1.c of the proposal), which is often termed a slope or ratio, describes the increase in blood Pb (in µg/dL) estimated to be associated with each unit increase of air Pb (in µg/m³).¹⁷

The evidence on this quantitative relationship is now, as in the past, limited by the circumstances in which the data are collected. These estimates are generally developed from studies of populations in various Pb exposure circumstances. The 1986 Criteria Document discussed the studies available at that time that addressed the relationship between air Pb and blood Pb,¹⁸ recognizing that there is significant variability in air-to-blood ratios for different populations exposed

to Pb through different air-related exposure pathways and at different exposure levels.

In discussing the available evidence, the 1986 Criteria Document observed that estimates of air-to-blood ratios that included air-related ingestion pathways in addition to the inhalation pathway are "necessarily higher", in terms of blood Pb response, than those estimates based on inhalation alone (USEPA 1986a, p. 11-106). Thus, the extent to which studies account for the full set of air-related inhalation and ingestion exposure pathways affects the magnitude of the resultant air-to-blood estimates, such that fewer pathways included as "air-related" yields lower ratios. The 1986 Criteria Document also observed that ratios derived from studies focused only on inhalation pathways (e.g., chamber studies, occupational studies) have generally been on the order of 1:2 or lower, while ratios derived from studies including more air-related pathways were generally higher (USEPA, 1986a, p. 11-106). Further, the current evidence appears to indicate higher ratios for children as compared to those for adults (USEPA, 1986a), perhaps due to behavioral differences between the age groups.

Reflecting these considerations, the 1986 Criteria Document identified a range of air-to-blood ratios for children that reflected both inhalation and ingestion-related air Pb contributions as generally ranging from 1:3 to 1:5 based on the information available at that time (USEPA 1986a, p. 11-106). Table 11-36 (p. 11-100) in the 1986 Criteria Document (drawn from Table 1 in Brunekreef, 1984) presents air-to-blood ratios from a number of studies in children (i.e., those with identified air monitoring methods and reliable blood Pb data). For example, air-to-blood ratios from the subset of those studies that used quality control protocols and presented adjusted slopes¹⁹ include

adjusted ratios of 3.6 (Zielhuis *et al.*, 1979), 5.2 (Billick *et al.*, 1979, 1980); 2.9 (Billick *et al.*, 1983), and 8.5 (Brunekreef *et al.*, 1983).

Additionally, the 1986 Criteria Document noted that ratios derived from studies involving higher blood and air Pb levels are generally smaller than ratios from studies involving lower blood and air Pb levels (USEPA, 1986a, p. 11-99). In consideration of this factor, the proposal observed that the range of 1:3 to 1:5 in air-to-blood ratios for children noted in the 1986 Criteria Document generally reflected study populations with blood Pb levels in the range of approximately 10-30 µg/dL (USEPA 1986a, pp. 11-100; Brunekreef, 1984), much higher than those common in today's population. This observation suggests that air-to-blood ratios relevant for today's population of children would likely extend higher than the 1:3 to 1:5 range identified in the 1986 Criteria Document.

More recently, a study of changes in children's blood Pb levels associated with reduced Pb emissions and associated air concentrations near a Pb smelter in Canada (for children through age six in age) reports a ratio of 1:6, and additional analysis of the data by EPA for the initial time period of the study resulted in a ratio of 1:7 (CD, pp. 3-23 to 3-24; Hilts, 2003).²⁰ Ambient air and blood Pb levels associated with the Hilts (2003) study range from 1.1 to 0.03 µg/m³, and associated population mean blood Pb levels range from 11.5 to 4.7 µg/dL, which are lower than levels associated with the older studies cited in the 1986 Criteria Document (USEPA, 1986).

for underestimating ambient air Pb levels due to the use of low volume British Smoke air monitors and the potential for higher historical ambient air Pb levels to have influenced blood Pb levels (see Section V.B.1 of the 1989 Pb Staff Report for the Pb NAAQS review, EPA, 1989). In addition, the 1989 Staff Report notes that the higher air-to-blood ratios obtained from this study could reflect the relatively lower blood Pb levels seen across the study population (compared with blood Pb levels reported in other studies from that period).

²⁰This study considered changes in ambient air Pb levels and associated blood Pb levels over a five-year period which included closure of an older Pb smelter and subsequent opening of a newer facility in 1997 and a temporary (3 month) shutdown of all smelting activity in the summer of 2001. The author observed that the air-to-blood ratio for children in the area over the full period was approximately 1:6. The author noted limitations in the dataset associated with exposures in the second time period, after the temporary shutdown of the facility in 2001, including sampling of a different age group at that time and a shorter time period (3 months) at these lower ambient air Pb levels prior to collection of blood Pb levels. Consequently, EPA calculated an alternate air-to-blood Pb ratio based on consideration for ambient air Pb and blood Pb reductions in the first time period (after opening of the new facility in 1997).

¹⁷ Ratios are presented in the form of 1:x, with the 1 representing air Pb (in µg/m³) and x representing blood Pb (in µg/dL). Description of ratios as higher or lower refers to the values for x (i.e., the change in blood Pb per unit of air Pb). Slopes are presented as simply the value of x.

¹⁸ We note that the 2006 Criteria Document did not include a discussion of more recent studies relating to air-to-blood ratios; more recent studies were discussed in the Staff Paper, including discussion by CASAC in their review of those documents.

¹⁹ Brunekreef *et al.* (1984) discusses potential confounders to the relationship between air Pb and blood Pb, recognizing that ideally all possible confounders should be taken into account in deriving an adjusted air-to-blood relationship from a community study. The studies cited here adjusted for parental education (Zielhuis *et al.*, 1979), age and race (Billick *et al.*, 1979, 1980) and additionally measuring height of air Pb (Billick *et al.*, 1983); Brunekreef *et al.* (1984) used multiple regression to control for several confounders. The authors conclude that "presentation of both unadjusted and (stepwise) adjusted relationships is advisable, to allow insight in the range of possible values for the relationship" (p. 83). Unadjusted ratios were presented for two of these studies, including ratios of 4.0 (Zielhuis *et al.*, 1979) and 18.5 (Brunekreef *et al.*, 1983). The proposal noted that the Brunekreef *et al.*, 1983 study is subject to a number of sources of uncertainty that could result in air-to-blood Pb ratios that are biased high, including the potential

The proposal identified sources of uncertainty related to air-to-blood ratios obtained from Hiltz (2003). One such area of uncertainty relates to the pattern of changes in indoor Pb dustfall (presented in Table 3 in the article) which suggests a potentially significant decrease in Pb impacts to indoor dust prior to closure of an older Pb smelter and start-up of a newer facility in 1997. Some have suggested that this earlier reduction in indoor dustfall suggests that a significant portion of the reduction in Pb exposure (and therefore, the blood Pb reduction reflected in air-to-blood ratios) may have resulted from efforts to increase public awareness of the Pb contamination issue (e.g., through increased cleaning to reduce indoor dust levels) rather than reductions in ambient air Pb and associated indoor dust Pb contamination. In addition, notable fluctuations in blood Pb levels observed prior to 1997 (as seen in Figure 2 of the article) have raised questions as to whether factors other than ambient air Pb reduction could be influencing decreases in blood Pb.²¹

In addition to the study by Hiltz (2003), we are aware of two other studies published since the 1986 Criteria Document that report air-to-blood ratios for children (Tripathi *et al.*, 2001 and Hayes *et al.*, 1994). These studies were not cited in the 2006 Criteria Document, but were referenced in public comments received by EPA during this review.²² The study by Tripathi *et al.* (2001) reports an air-to-blood ratio of approximately 1:3.6 for an analysis of children aged six through ten in India. The ambient air and blood Pb levels in this study (geometric mean blood Pb levels generally ranged from 10 to 15 $\mu\text{g}/\text{dL}$) are similar to levels reported in older studies reviewed in the 1986 Criteria Document and are much higher than current conditions in the U.S. The study by Hayes *et al.* (1994) compared patterns of ambient air Pb

reductions and blood Pb reductions for large numbers of children in Chicago between 1971 and 1988, a period when significant reductions occurred in both measures. The study reports an air-to-blood ratio of 1:5.6 associated with ambient air Pb levels near 1 $\mu\text{g}/\text{m}^3$ and a ratio of 1:16 for ambient air Pb levels in the range of 0.25 $\mu\text{g}/\text{m}^3$, indicating a pattern of higher ratios with lower ambient air Pb and blood Pb levels consistent with conclusions in the 1986 Criteria Document.²³

In their advice to the Agency prior to the proposal, CASAC identified air-to-blood ratios of 1:5, as used by the World Health Organization (2000), and 1:10, as supported by an empirical analysis of changes in air Pb and changes in blood Pb between 1976 and the time when the phase-out of Pb from gasoline was completed (Henderson, 2007a).²⁴

In the proposal, beyond considering the evidence presented in the published literature and that reviewed in Pb Criteria Documents, we also considered air-to-blood ratios derived from the exposure assessment for this review (summarized below in section II.A.3 and described in detail in USEPA, 2007b). In that assessment, current modeling tools and information on children's activity patterns, behavior and physiology (e.g., CD, section 4.4) were used to estimate blood Pb levels associated with multimedia and multipathway Pb exposure. The results from the various case studies included in this assessment, with consideration of the context in which they were derived (e.g., the extent to which the range of air-related pathways were simulated), are also informative to our understanding of air-to-blood ratios.

For the general urban case study, air-to-blood ratios ranged from 1:2 to 1:9 across the alternative standard levels assessed, which ranged from the current standard of 1.5 $\mu\text{g}/\text{m}^3$ down to a level of 0.02 $\mu\text{g}/\text{m}^3$. This pattern of model-derived ratios generally supports the

range of ratios obtained from the literature and also supports the observation that lower ambient air Pb levels are associated with higher air-to-blood ratios. There are a number of sources of uncertainty associated with these model-derived ratios. The hybrid indoor dust Pb model, which is used in estimating indoor dust Pb levels for the urban case studies, uses a U.S. Department of Housing and Urban Development (HUD) survey dataset reflecting housing constructed before 1980 in establishing the relationship between dust loading and concentration, which is a key component in the hybrid dust model (as described in the Risk Assessment Report, Volume II, Appendix G, Attachment G-1). Given this application of the HUD dataset, there is the potential that the nonlinear relationship between indoor dust Pb loading and concentration (which is reflected in the structure of the hybrid dust model) could be driven more by the presence of indoor Pb paint than contributions from outdoor ambient air Pb. We also note that only recent air pathways were adjusted in modeling the impact of ambient air Pb reductions on blood Pb levels in the urban case studies, which could have implications for the air-to-blood ratios.

For the primary Pb smelter (subarea) case study, air-to-blood ratios ranged from 1:10 to 1:19 across the same range of alternative standard levels, from 1.5 down to 0.02 $\mu\text{g}/\text{m}^3$.²⁵ Because these ratios are based on regression modeling developed using empirical data, there is the potential for these ratios to capture more fully the impact of ambient air on indoor dust Pb, and ultimately blood Pb, including longer timeframe impacts resulting from changes in outdoor deposition. Therefore, given that these ratios are higher than ratios developed for the general urban case study using the hybrid indoor dust Pb model (which only considers reductions in recent air), the ratios estimated for the primary Pb smelter (subarea) support the evidence-based observation discussed above that consideration of more of the exposure pathways relating ambient air Pb to blood Pb, may result in higher air-to-blood Pb ratios. In considering this case study, some have suggested, however, that the regression modeling fails to accurately reflect the temporal relationship between reductions in ambient air Pb and indoor dust Pb, which could result in an over-estimate

²¹ In the publication, the author acknowledges that remedial programs (e.g., community and home-based dust control and education) may have been responsible for some of the blood Pb reduction seen during the study period (1997 to 2001). However, the author points out that these programs were in place in 1992 and he suggests that it is unlikely that they contributed to the sudden drop in blood Pb levels occurring after 1997. In addition, the author describes a number of aspects of the analysis which could have implications for air-to-blood ratios including a tendency over time for children with lower blood Pb levels to not return for testing, and inclusion of children aged 6 to 36 months in Pb screening in 2001 (in contrast to the wider age range up to 60 months as was done in previous years).

²² EPA is not basing its decisions on these two studies, but notes that these estimates are consistent with other studies that were included in the 1986 and 2006 Criteria Documents and considered by CASAC and the public.

²³ As with all studies, we note that there are strengths and limitations for these two studies which may affect the specific magnitudes of the reported ratios, but that the studies' findings and trends are generally consistent with the conclusions from the 1986 Criteria Document.

²⁴ The CASAC Panel stated "The Schwartz and Pitcher analysis showed that in 1978, the midpoint of the National Health and Nutrition Examination Survey (NHANES) II, gasoline Pb was responsible for 9.1 $\mu\text{g}/\text{dL}$ of blood Pb in children. Their estimate is based on their coefficient of 2.14 $\mu\text{g}/\text{dL}$ per 100 metric tons (MT) per day of gasoline use, and usage of 426 MT/day in 1976. Between 1976 and when the phase-out of Pb from gasoline was completed, air Pb concentrations in U.S. cities fell a little less than 1 $\mu\text{g}/\text{m}^3$ (24). These two facts imply a ratio of 9–10 $\mu\text{g}/\text{dL}$ per $\mu\text{g}/\text{m}^3$ reduction in air Pb, taking all pathways into account." (Henderson, 2007a, pp. D-2 to D-3).

²⁵ Air-to-blood ratios for the full study area of the primary Pb smelter range from 1:3 to 1:7 across the range of alternative standard levels from 1.5 down to 0.02 $\mu\text{g}/\text{m}^3$ (USEPA, 2007b).

of the degree of dust Pb reduction associated with a specified degree of ambient air Pb reduction, which in turn could produce air-to-blood Pb ratios that are biased high.

In summary, EPA's view in the proposal was that the current evidence in conjunction with the results and observations drawn from the exposure assessment, including related uncertainties, supports consideration of a range of air-to-blood ratios for children ranging from 1:3 to 1:7, reflecting multiple air-related pathways beyond simply inhalation and the lower air and blood Pb levels pertinent to this review. EPA invited comment on this range as well as the appropriate weight to place on specific ratios within this range. Advice from CASAC and comments from the public on this issue are discussed below in section II.C.3.

b. Array of Health Effects and At-Risk Subpopulations

Lead has been demonstrated to exert "a broad array of deleterious effects on multiple organ systems via widely diverse mechanisms of action" (CD, p. 8–24 and section 8.4.1). This array of health effects includes effects on heme biosynthesis and related functions; neurological development and function; reproduction and physical development; kidney function; cardiovascular function; and immune function. The weight of evidence varies across this array of effects and is comprehensively described in the Criteria Document. There is also some evidence of Pb carcinogenicity, primarily from animal studies, together with limited human evidence of suggestive associations (CD, sections 5.6.2, 6.7, and 8.4.10).²⁶

This review is focused on those effects most pertinent to ambient exposures, which, given the reductions in ambient Pb levels over the past 30 years, are generally those associated with individual blood Pb levels in children and adults in the range of 10 µg/dL and lower. These key effects include neurological, hematological and immune²⁷ effects for children, and

hematological, cardiovascular and renal effects for adults (CD, Tables 8–5 and 8–6, pp. 8–60 to 8–62). As evident from the discussions in chapters 5, 6 and 8 of the Criteria Document, "neurotoxic effects in children and cardiovascular effects in adults are among those best substantiated as occurring at blood Pb concentrations as low as 5 to 10 µg/dL (or possibly lower); and these categories are currently clearly of greatest public health concern" (CD, p. 8–60).^{28 29} The toxicological and epidemiological information available since the time of the last review "includes assessment of new evidence substantiating risks of deleterious effects on certain health endpoints being induced by distinctly lower than previously demonstrated Pb exposures indexed by blood Pb levels extending well below 10 µg/dL in children and/or adults" (CD, p. 8–25). Some health effects associated with individual blood Pb levels extend below 5 µg/dL, and some studies have observed these effects at the lowest blood levels considered. With regard to population mean levels, the Criteria Document points to studies reporting "Pb effects on the intellectual attainment of preschool and school age children at population mean concurrent blood-Pb levels ranging down to as low as 2 to 8 µg/dL" (CD, p. E–9).

We note that many studies over the past decade, in investigating effects at lower blood Pb levels, have utilized the CDC advisory level or level of concern for individual children (10 µg/dL)³⁰ as a benchmark for assessment, and this is reflected in the numerous references in the Criteria Document to 10 µg/dL. Individual study conclusions stated with regard to effects observed below 10 µg/dL are usually referring to individual blood Pb levels. In fact, many such study groups have been restricted to

individual blood Pb levels below 10 µg/dL or below levels lower than 10 µg/dL. We note that the mean blood Pb level for these groups will necessarily be lower than the blood Pb level they are restricted below.

Threshold levels, in terms of blood Pb levels in individual children, for neurological effects cannot be discerned from the currently available studies (CD, pp. 8–60 to 8–63). The Criteria Document states "There is no level of Pb exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects" (CD, p. 8–63). As discussed in the Criteria Document, "a threshold for Pb neurotoxic effects may exist at levels distinctly lower than the lowest exposures examined in these epidemiologic studies" (CD, p. 8–67).³¹

As described in the proposal, physiological, behavioral and demographic factors contribute to increased risk of Pb-related health effects. Potentially at-risk subpopulations, also referred to as sensitive sub-populations, include those with increased susceptibility (*i.e.*, physiological factors contributing to a greater response for the same exposure), as well as those with greater vulnerability (*i.e.*, those with increased exposure such as through exposure to higher media concentrations or resulting from behavior leading to increased contact with contaminated media), or those affected by socioeconomic factors, such as reduced access to health care or low socioeconomic status.

While adults are susceptible to Pb effects at lower blood Pb levels than previously understood (*e.g.*, CD, p. 8–25), the greater influence of past exposures on their current blood Pb levels (as summarized above in section II.A.2.a) leads us to give greater prominence to children as the sensitive subpopulation in this review. Children are at increased risk of Pb-related health effects due to various factors that enhance their exposures (*e.g.*, via the hand-to-mouth activity that is prevalent in very young children, CD, section 4.4.3) and susceptibility. While children are considered to be at a period of

²⁸ With regard to blood Pb levels in individual children associated with particular neurological effects, the Criteria Document states "Collectively, the prospective cohort and cross-sectional studies offer evidence that exposure to Pb affects the intellectual attainment of preschool and school age children at blood Pb levels <10 µg/dL (most clearly in the 5 to 10 µg/dL range, but, less definitively, possibly lower)." (p. 6–269)

²⁹ Epidemiological studies have consistently demonstrated associations between Pb exposure and enhanced risk of deleterious cardiovascular outcomes, including increased blood pressure and incidence of hypertension. A meta-analysis of numerous studies estimates that a doubling of blood-Pb level (*e.g.*, from 5 to 10 µg/dL) is associated with ~1.0 mm Hg increase in systolic blood pressure and ~0.6 mm Hg increase in diastolic pressure (CD, p. E–10).

³⁰ This level has variously been called an advisory level or level of concern (http://www.atsdr.cdc.gov/csem/lead/pb_standards2.html). In addressing children's blood Pb levels, CDC has stated "Specific strategies that target screening to high-risk children are essential to identify children with BLLs ≥ 10 µg/dL." (CDC, 2005, p.1)

³¹ In consideration of the evidence from experimental animal studies with regard to the issue of threshold for neurotoxic effects, the CD notes that there is little evidence that allows for clear delineation of a threshold, and that "blood-Pb levels associated with neurobehavioral effects appear to be reasonably parallel between humans and animals at reasonably comparable blood-Pb concentrations; and such effects appear likely to occur in humans ranging down at least to 5–10 µg/dL, or possibly lower (although the possibility of a threshold for such neurotoxic effects cannot be ruled out at lower blood-Pb concentrations)" (CD, p. 8–38).

²⁶ Lead has been classified as a probable human carcinogen by the International Agency for Research on Cancer (inorganic lead compounds), based mainly on sufficient animal evidence, and as reasonably anticipated to be a human carcinogen by the U.S. National Toxicology Program (lead and lead compounds) (CD, Section 6.7.2). U.S. EPA considers Pb a probable carcinogen (<http://www.epa.gov/iris/subst/0277.htm>; CD, p. 6–195).

²⁷ At mean blood Pb levels, in children, on the order of 10 µg/dL, and somewhat lower, associations have been found with effects to the immune system, including altered macrophage activation, increased IgE levels and associated increased risk for autoimmunity and asthma (CD, Sections 5.9, 6.8, and 8.4.6).

maximum exposure around 18–27 months, the current evidence has found even stronger associations between blood Pb at school age and IQ at school age. The evidence “supports the idea that Pb exposure continues to be toxic to children as they reach school age, and [does] not lend support to the interpretation that all the damage is done by the time the child reaches 2 to 3 years of age” (CD, section 6.2.12). The following physiological and demographic factors can further affect risk of Pb-related effects in some children.

- Children with particular genetic polymorphisms (e.g., presence of the δ -aminolevulinic acid dehydratase-2 [ALAD-2] allele) have increased sensitivity to Pb toxicity, which may be due to increased susceptibility to the same internal dose and/or to increased internal dose associated with same exposure (CD, p. 8–71, sections 6.3.5, 6.4.7.3 and 6.3.6).

- Some children may have blood Pb levels higher than those otherwise associated with a given Pb exposure (CD, section 8.5.3) as a result of nutritional status (e.g., iron deficiency, calcium intake), as well as genetic and other factors (CD, chapter 4 and sections 3.4, 5.3.7 and 8.5.3).

- Situations of elevated exposure, such as residing near sources of ambient Pb, as well as socioeconomic factors, such as reduced access to health care or low socioeconomic status (SES) (USEPA, 2003, 2005c) can also contribute to increased blood Pb levels and increased risk of associated health effects from air-related Pb.

- As described in the proposal (sections II.B.1.b and II.B.3), children in poverty and black, non-Hispanic children have notably higher blood Pb levels than do economically well-off children and white children, in general.

c. Neurological Effects in Children

Among the wide variety of health endpoints associated with Pb exposures, there is general consensus that the developing nervous system in children is among the, if not the, most sensitive. While blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with these more recent blood Pb levels (CD, chapter 6). Functional manifestations of Pb neurotoxicity during childhood include sensory, motor, cognitive and behavioral impacts. Numerous epidemiological studies have reported neurocognitive, neurobehavioral, sensory, and motor function effects in children with blood Pb levels below 10

$\mu\text{g}/\text{dL}$ (CD, sections 6.2 and 8.4).³² As discussed in the Criteria Document, “extensive experimental laboratory animal evidence has been generated that (a) substantiates well the plausibility of the epidemiologic findings observed in human children and adults and (b) expands our understanding of likely mechanisms underlying the neurotoxic effects” (CD, p. 8–25; section 5.3).

Cognitive effects associated with Pb exposures that have been observed in epidemiological studies have included decrements in intelligence test results, such as the widely used IQ score, and in academic achievement as assessed by various standardized tests as well as by class ranking and graduation rates (CD, section 6.2.16 and pp 8–29 to 8–30). As noted in the Criteria Document with regard to the latter, “Associations between Pb exposure and academic achievement observed in the above-noted studies were significant even after adjusting for IQ, suggesting that Pb-sensitive neuropsychological processing and learning factors not reflected by global intelligence indices might contribute to reduced performance on academic tasks” (CD, pp 8–29 to 8–30).

With regard to potential implications of Pb effects on IQ, the Criteria Document recognizes the “critical” distinction between population and individual risk, identifying issues regarding declines in IQ for an individual and for the population. The Criteria Document further states that a “point estimate indicating a modest mean change on a health index at the individual level can have substantial implications at the population level” (CD, p. 8–77).³³ A downward shift in the mean IQ value is associated with both substantial decreases in percentages achieving very high scores and substantial increases in the percentage of individuals achieving very low scores (CD, p. 8–81).³⁴ For an individual functioning in the low IQ range due to the influence of developmental risk

³² Further, neurological effects in general include behavioral effects, such as delinquent behavior (CD, sections 6.2.6 and 8.4.2.2), sensory effects, such as those related to hearing and vision (CD, sections 6.2.7 and 8.4.2.3), and deficits in neuromotor function (CD, p. 8–36).

³³ As an example, the Criteria Document states “although an increase of a few mmHg in blood pressure might not be of concern for an individual’s well-being, the same increase in the population mean might be associated with substantial increases in the percentages of individuals with values that are sufficiently extreme that they exceed the criteria used to diagnose hypertension” (CD, p. 8–77).

³⁴ For example, for a population mean IQ of 100 (and standard deviation of 15), 2.3% of the population would score above 130, but a shift of the population to a mean of 95 results in only 0.99% of the population scoring above 130 (CD, pp. 8–81 to 8–82).

factors other than Pb, a Pb-associated IQ decline of several points might be sufficient to drop that individual into the range associated with increased risk of educational, vocational, and social failure (CD, p. 8–77).

Other cognitive effects observed in studies of children have included effects on attention, executive functions, language, memory, learning and visuospatial processing (CD, sections 5.3.5, 6.2.5 and 8.4.2.1), with attention and executive function effects associated with Pb exposures indexed by blood Pb levels below 10 $\mu\text{g}/\text{dL}$ (CD, section 6.2.5 and pp. 8–30 to 8–31). The evidence for the role of Pb in this suite of effects includes experimental animal findings (discussed in CD, section 8.4.2.1; p. 8–31), which provide strong biological plausibility of Pb effects on learning ability, memory and attention (CD, section 5.3.5), as well as associated mechanistic findings.

The persistence of such Pb-induced effects is described in the proposal and the Criteria Document (e.g., CD, sections 5.3.5, 6.2.11, and 8.5.2). The persistence or irreversibility of such effects can be the result of damage occurring without adequate repair offsets or of the persistence of Pb in the body (CD, section 8.5.2). It is additionally important to note that there may be long-term consequences of such deficits over a lifetime. Poor academic skills and achievement can have “enduring and important effects on objective parameters of success in real life”, as well as increased risk of antisocial and delinquent behavior (CD, section 6.2.16).

Multiple epidemiologic studies of Pb and child development have demonstrated inverse associations between blood Pb concentrations and children’s IQ and other cognitive-related outcomes at successively lower Pb exposure levels over the past 30 years (as discussed in the CD, section 6.2.13). For example, the overall weight of the available evidence, described in the Criteria Document, provides clear substantiation of neurocognitive decrements being associated in children with mean blood Pb levels in the range of 5 to 10 $\mu\text{g}/\text{dL}$, and some analyses indicate Pb effects on intellectual attainment of children for which population mean blood Pb levels in the analysis ranged from 2 to 8 $\mu\text{g}/\text{dL}$ (CD, sections 6.2, 8.4.2 and 8.4.2.6). Thus, while blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with blood Pb levels similar to the more recent, lower blood Pb levels (CD,

chapter 6; and as discussed in section II.B.2.b of the proposal).

The current evidence reviewed in the Criteria Document with regard to the quantitative relationship between neurocognitive decrement, such as IQ, and blood Pb levels indicates that the slope for Pb effects on IQ is nonlinear and is steeper at lower blood Pb levels, such that each $\mu\text{g}/\text{dL}$ increase in blood Pb may have a greater effect on IQ at lower blood Pb levels (e.g., below $10 \mu\text{g}/\text{dL}$) than at higher levels (CD, section 6.2.13; pp. 8–63 to 8–64; Figure 8–7). As stated in the CD, “the most compelling evidence for effects at blood Pb levels $<10 \mu\text{g}/\text{dL}$, as well as a nonlinear relationship between blood Pb levels and IQ, comes from the international pooled analysis of seven prospective cohort studies ($n=1,333$) by Lanphear et al. (2005)” (CD, pp. 6–67 and 8–37 and section 6.2.3.1.11). Using the full pooled dataset with concurrent blood Pb level as the exposure metric and IQ as the response from the pooled dataset of seven international studies, Lanphear and others (2005) employed mathematical models of various forms, including linear, cubic spline, log-linear, and piece-wise linear, in their investigation of the blood Pb concentration-response relationship (CD, p. 6–29; Lanphear et al., 2005). They observed for this pooled dataset that the shape of the concentration-response relationship is nonlinear and the log-linear model provides a better fit over the full range of blood Pb measurements³⁵ than a linear one (CD, p. 6–29 and pp. 6–67 to 6–70; Lanphear et al., 2005). In addition, they found that no individual study among the seven was responsible for the estimated nonlinear relationship between Pb and deficits in IQ (CD p. 6–30). Others have also analyzed the same dataset and similarly concluded that, across the range of the dataset’s blood Pb levels, a log-linear relationship was a significantly better fit than the linear relationship ($p=0.009$) with little evidence of residual confounding from included model variables (CD, section 6.2.13; Rothenberg and Rothenberg, 2005).

As noted in the Criteria Document, a number of examples of non- or supralinear dose-response relationships exist in toxicology (CD, pp. 6–76 and 8–38 to 8–39). With regard to the effects of Pb on neurodevelopmental outcome such as IQ, the Criteria Document suggests that initial neurodevelopmental

effects at lower Pb levels may be disrupting very different biological mechanisms (e.g., early developmental processes in the central nervous system) than more severe effects of high exposures that result in symptomatic Pb poisoning and frank mental retardation (CD, p. 6–76). The Criteria Document describes this issue in detail with regard to Pb (summarized in CD at p. 8–39). Various findings within the toxicological evidence, presented in the Criteria Document (described in the proposal), provide biologic plausibility for a steeper IQ loss at low blood levels, with a potential explanation being that the predominant mechanism at very low blood-Pb levels is rapidly saturated and that a different, less-rapidly-saturated process, becomes predominant at blood-Pb levels greater than $10 \mu\text{g}/\text{dL}$.

The current evidence includes multiple studies that have examined the quantitative relationship between IQ and blood Pb level in analyses of children with individual blood Pb concentrations below $10 \mu\text{g}/\text{dL}$. In comparing across the individual epidemiological studies and the international pooled analysis, the Criteria Document observed that at higher blood Pb levels (e.g., above $10 \mu\text{g}/\text{dL}$), the slopes (for change in IQ with blood Pb) derived for log-linear and linear models are almost identical, and for studies with lower blood Pb levels, the slopes appear to be steeper than those observed in studies involving higher blood Pb levels (CD, p. 8–78, Figure 8–7). In making these observations, the Criteria Document focused on the curves from the models from the 10th percentile to the 90th percentile saying that the “curves are restricted to that range because log-linear curves become very steep at the lower end of the blood Pb levels, and this may be an artifact of the model chosen”.

The quantitative relationship between IQ and blood Pb level has been examined in the Criteria Document using studies where all or the majority of study subjects had blood Pb levels below $10 \mu\text{g}/\text{dL}$ and also where an analysis was performed on a subset of children whose blood Pb levels have never exceeded $10 \mu\text{g}/\text{dL}$ (CD, Table 6–1).³⁶ The datasets for three of these

studies included concurrent blood Pb levels above $10 \mu\text{g}/\text{dL}$; the concentration-response (C–R) relationship reported for one of the three was linear while it was log-linear for the other two. For the one study among these three that reported a linear C-R relationship, the highest blood Pb level was just below $12 \mu\text{g}/\text{dL}$ and the population mean was $7.9 \mu\text{g}/\text{dL}$ (Kordas et al., 2006). Of the two studies with log-linear functions, one reported 69% of the children with blood Pb levels below $10 \mu\text{g}/\text{dL}$ and a population mean blood Pb level of $7.44 \mu\text{g}/\text{dL}$ (Al-Saleh et al., 2001), and the second reported a population median blood Pb level of $9.7 \mu\text{g}/\text{dL}$ and a 95th percentile of $33.2 \mu\text{g}/\text{dL}$ (Lanphear et al., 2005). In order to compare slopes across all of these studies (linear and log-linear) in the Criteria Document, EPA estimated, for each, the average slope of change in IQ with change in blood Pb between the 10th percentile³⁷ blood Pb level and $10 \mu\text{g}/\text{dL}$ (CD, Table 6–1). The resultant group of reported and estimated average linear slopes for IQ change with blood Pb levels up to $10 \mu\text{g}/\text{dL}$ range from -0.4 to -1.8 IQ points per $\mu\text{g}/\text{dL}$ blood Pb (CD, Tables 6–1 and 8–7), with a median of -0.9 IQ points per $\mu\text{g}/\text{dL}$ blood Pb (CD, p. 8–80).³⁸ These slopes from

appropriate for children under age three. For such children, studies generally use the age-appropriate Bayley Scales of Infant Development as a measure of cognitive development.

³⁷ In the Criteria Document analysis, the 10th percentile was chosen as a common point of comparison for the loglinear (and linear) models at a point prior to the lowest end of the blood Pb levels.

³⁸ One of these slopes (CD, Table 6–1) is for the IQ-blood Pb (concurrent) relationship for children whose peak blood Pb levels are below $10 \mu\text{g}/\text{dL}$ in the international pooled dataset studied by Lanphear and others (2005); these authors reported this slope along with the companion slope, from the same (piece-wise) model, for the remaining children whose peak blood Pb level equals or is above $10 \mu\text{g}/\text{dL}$ (Lanphear et al., 2005). In the economic analysis for EPA’s recent Lead Renovation, Repair and Painting (RRP) Program rule (described above in section I.C) for children living in houses with lead-based paint, changes in IQ were estimated as a function of changes in lifetime average blood Pb level using the corresponding piece-wise model for lifetime average blood Pb derived from the pooled dataset (USEPA, 2008; USEPA, 2007d). The piecewise models that gave greater weight to impacts in this blood Pb range were chosen because peak blood Pb levels are likely to be less than $10 \mu\text{g}/\text{dL}$ for the vast majority of children exposed to Pb during renovation activities. Further, while Lanphear et al. (2005) used peak blood Pb concentrations to determine which segment of a model to apply, for the hypothetical children to whom the approach is discussed in the RRP Program rule, only lifetime averages were used (in the RRP analysis). To counter the impact of assigning additional hypothetical RRP children to the steeper of the two slopes than would have been the case if they could be assigned based on peak blood Pb levels (as a child’s lifetime average blood Pb is lower than peak blood Pb), the RRP analysis

Continued

³⁵ The median of the concurrent blood Pb levels modeled was $9.7 \mu\text{g}/\text{dL}$; the 5th and 95th percentile values were 2.5 and $33.2 \mu\text{g}/\text{dL}$, respectively (Lanphear et al., 2005).

³⁶ The tests for cognitive function in these studies include age-appropriate Wechsler intelligence tests (Lanphear et al., 2005; Bellinger and Needleman, 2003), the Stanford-Binet intelligence test (Canfield et al., 2003), the Test of Non-Verbal Intelligence (Al-Saleh et al., 2001), an abbreviated form of the Wechsler tests (Kordas et al., 2006) and the Bayley Scales of Infant Development (Tellez-Rojo et al., 2006). The Wechsler and Stanford-Binet tests are widely used to assess neurocognitive function in children and adults, however, these tests are not

Tables 6–1 and 8–7 of the Criteria Document are presented in the second set of slopes in Table 1 below (adapted from Table 1 of the proposal). In this second set are studies (included in the Criteria Document Table 6–1) that examined the quantitative relationships of IQ and blood Pb in study populations for which most blood Pb levels were below 10 µg/dL and for which a linear slope restricted to blood Pb levels below about 10 µg/dL could be estimated.

Among this group of quantitative IQ-blood Pb relationships examined in the Criteria Document (CD, Tables 6–1 and 8–7), the steepest slopes for change in IQ with change in blood Pb level are those derived for the subsets of children in the Rochester and Boston cohorts for which peak blood Pb levels were <10 µg/dL; these slopes, in terms of IQ points per µg/dL blood Pb, are –1.8 (for concurrent blood Pb influence on IQ)

and –1.6 (for 24-month blood Pb influence on IQ), respectively. The mean blood Pb levels for children in these subsets of the Rochester and Boston cohorts are 3.32 (Canfield, 2008) and 3.8 µg/dL (Bellinger, 2008), respectively, which are the lowest population mean levels among the datasets included in the table. Other studies with analyses involving similarly low blood Pb levels (e.g., mean levels below 4 µg/dL) also had slopes steeper than –1.5 points per µg/dL blood Pb. These include the slope of –1.71 points per µg/dL blood Pb³⁹ for the subset of 24-month old children in the Mexico City cohort with blood Pb levels less than 5 µg/dL (n=193), for which the mean concurrent blood Pb level was 2.9 µg/dL (Tellez-Rojo *et al.* 2006, 2008),⁴⁰ and the slope of –2.94 points per µg/dL blood Pb for the subset

of 6–10 year old children whose peak blood Pb levels never exceeded 7.5 µg/dL (n=112), and for which the mean concurrent blood Pb level was 3.24 µg/dL (Lanphear *et al.* 2005; Hornung 2008a). Thus, from these subset analyses, the slopes range from –1.71 to –2.94 IQ points per µg/dL of concurrent blood Pb, as shown in the first set of slopes in Table 1. In this first set are studies that included quantitative relationships for IQ and blood Pb that focused on lower individual blood Pb levels (below 7.5 µg/dL). We also note that for blood Pb levels up to approximately 3.7 µg/dL, the slope of the nonlinear C–R function in which greatest confidence is placed in estimating IQ loss in the quantitative risk assessment (the LLL function)⁴¹ falls intermediate between these two values.

TABLE 1—SUMMARY OF QUANTITATIVE RELATIONSHIPS OF IQ AND BLOOD Pb FOR TWO SETS OF STUDIES DISCUSSED ABOVE

Study/analysis	Study cohort	Analysis dataset	N	Range BLL ^A (µg/dL)	Geometric mean BLL ^A (µg/dL)	Form of model from which average slope derived	Average linear slope ^B (points per µg/dL)
Set of studies from which steeper slopes are drawn in the proposal							
Tellez-Rojo <5 subgroup.	Mexico City, age 24 mo.	Children—BLL<5 µg/dL.	193	0.8–4.9	2.9	Linear	–1.71
based on Lanphear <i>et al.</i> 2005 ^C , Log-linear with low-exposure linearization (LLL).	Dataset from which the log-linear function is derived is the pooled International dataset of 1333 children, age 6–10 yr, having median blood Pb of 9.7 µg/dL and 5th–95th percentile of 2.5–33.2 µg/dL.					LLL ^D : –2.29 at 2 µg/dL –1.89 at 3 µg/dL	
Lanphear <i>et al.</i> 2005 ^C , <7.5 peak subgroup.	Pooled International, age 6–10 yr.	Children—peak BLL <7.5 µg/dL.	103	0.9–7.4	3.24	Linear	–2.94

used the piece-wise model with node at 10 µg/dL, for which the steeper of the two slopes is less steep than it is for the model with node at 7.5 µg/dL. As stated in the RRP economic analysis document, “[s]electing a model with a node, or changing one segment to the other, at a lifetime average blood Pb concentration of 10 µg/dL rather than at 7.5 µg/dL, is a small protection against applying an incorrectly rapid change (steep slope with increasingly smaller effect as concentrations lower) to the calculation” (USEPA, 2008). We note here that the slope for the less-than-10-µg/dL portion of the model used in the RRP analysis (-0.88) is similar to the median for the slopes included in the Criteria Document analysis of quantitative relationships for studies in which the majority of blood Pb levels were below 10 µg/dL.

³⁹This slope reflects effects on cognitive development in this cohort of 24-month old children based on the age-appropriate test described earlier, and is similar in magnitude to slopes for the cohorts of older children described here. The strengths and limitations of this age-appropriate test, the Mental Development Index (MDI) of the Bayley Scales of Infant Development (BSID), were

discussed in a letter to the editor by Black and Baqui (2005). The letter states that “the MDI is a well-standardized, psychometrically strong measure of infant mental development.” The MDI represents a complex integration of empirically-derived cognitive skills, for example, sensory/perceptual acuties, discriminations, and response; acquisition of object constancy; memory learning and problem solving; vocalization and beginning of verbal communication; and basis of abstract thinking. Black and Baqui additionally state that although the MDI is one of the most well-standardized, widely used assessment of infant mental development, evidence indicates low predictive validity of the MDI for infants younger than 24 months to subsequent measures of intelligence. They explain that the lack of continuity may be partially explained by “the multidimensional and rapidly changing aspects of infant mental development and by variations in performance during infancy, variations in tasks used to measure intellectual functioning throughout childhood, and variations in environmental challenges and opportunities that may influence development.” Martin and Volkmar (2007) also noted that correlations between BSID

performance and subsequent IQ assessments were variable, but they also reported high test-retest reliability and validity, as indicated by the correlation coefficients of 0.83 to 0.91, as well as high interrater reliability, correlation coefficient of 0.96, for the MDI. Therefore, the BSID has been found to be a reliable indicator of current development and cognitive functioning of the infant. Martin and Volkmar (2007) further note that “for the most part, performance on the BSID does not consistently predict later cognitive measures, particularly when socioeconomic status and level of functioning are controlled”.

⁴⁰In this study, the slope for blood Pb levels between 5 and 10 µg/dL (population mean blood Pb of 6.9 µg/dL; n=101) was –0.94 points per µg/dL blood Pb but was not statistically significant, with a p value of 0.12. The difference in the slope between the <5 µg/dL and the 5–10 µg/dL groups was not statistically significant (Tellez-Rojo *et al.*, 2006; Tellez-Rojo, 2008).

⁴¹The LLL function is the loglinear function from Lampshear *et al.* (2005), with linearization at low exposures (as described in sections 2.1.5 and 4.1.1.2 of the Risk Assessment Report).

TABLE 1—SUMMARY OF QUANTITATIVE RELATIONSHIPS OF IQ AND BLOOD Pb FOR TWO SETS OF STUDIES DISCUSSED ABOVE—Continued

Study/analysis	Study cohort	Analysis dataset	N	Range BLL ^A (µg/dL)	Geometric mean BLL ^A (µg/dL)	Form of model from which average slope derived	Average linear slope ^B (points per µg/dL)
Set of studies with shallower slopes (Criteria Document Table 6–1) presented in the proposal^E							
Canfield et al 2003 ^C , <10 peak subgroup.	Rochester, age 5 yr	Children—peak BLL <10 µg/dL.	71	0.5–8.4	3.32	Linear	– 1.79
Bellinger and Needleman 2003 ^C .	Boston ^{B F}	Children—peak BLL <10 µg/dL.	48	1–9.3 ^F	^F 3.8	Linear	– 1.56
Tellez-Rojo et al. 2006.	Mexico City, age 24 mo.	Full dataset	294	0.8–9.8	4.28	Linear	– 1.04
Tellez-Rojo et al. 2006 full—loglinear.	Mexico City, age 24 mo.	Full dataset	294	0.8–9.8	4.28	Log-linear	^G – 0.94
Lanphear et al. 2005 ^C , <10 peak ^C subgroup.	Pooled International, age 6–10 yr.	Children—peak BLL <10 µg/dL.	244	0.1–9.8	4.30	Linear	– 0.80
Al-Saleh et al 2001 full—loglinear.	Saudi Arabia, age 6–12 yr.	Full dataset	533	2.3–27.36 ^H ..	7.44	Log-linear	^G – 0.76
Kordas et al 2006, <12 subgroup.	Torreon, Mexico, age 7 yr.	Children—BLL <12 µg/dL.	377	2.3–<12	7.9	Linear	– 0.40
Lanphear et al 2005 ^C full—loglinear.	Pooled International, age 6–10 yr.	Full dataset	1333	0.1–71.7	9.7 (median)	Log-linear	^G – 0.41
Median value							^D – 0.9

^A Blood Pb level (BLL) information provided here is drawn from publications listed in table, in some cases augmented by study authors (Bellinger, 2008; Canfield, 2008a,b; Hornung, 2008a,b; Kordas, 2008; Tellez-Rojo, 2008).

^B Average linear slope estimates here are for relationship between IQ and concurrent blood Pb levels (BLL), except for Bellinger & Needleman which used 24 month BLLs with 10 year old IQ.

^C The Lanphear et al. 2005 pooled International study includes blood Pb data from the Rochester and Boston cohorts, although for different ages (6 and 5 years, respectively) than the ages analyzed in Canfield et al 2003 and Bellinger and Needleman 2003.

^D The LLL function (described in section II.C.2.b) was developed from Lanphear et al 2005 loglinear model with a linearization of the slope at BLL below 1 µg/dL. In estimating IQ loss with this function in the risk assessment (section II.A.3) the nonlinear form of the model with varying slope was used for all BLL above 1 µg/dL. The slopes shown are the average slopes (IQ points per µg/dL blood Pb) associated with application of the LLL functions from zero to the blood Pb levels identified (2 and 3 µg/dL).

^E These studies and quantitative relationships are discussed in the Criteria Document (CD, sections 6.2, 6.2.1.3 and 8.6.2).

^F The BLL for Bellinger and Needleman (2003) are for age 24 months.

^G For nonlinear models, this is the estimated average slope for change in IQ with change in blood Pb over the range from the 10th percentile blood Pb value in study to 10 µg/dL (CD, p. 6–65). The shape of these models is such that the average slopes from the 10th percentiles to a value lower than 10 µg/dL are larger negative values than those shown here (e.g., the slopes to 5 µg/dL are 50% larger negative values).

^H 69% of children in Al-Saleh et al. (2001) study had BLL <10 µg/dL.

3. Overview of Human Exposure and Health Risk Assessments

To put judgments about risk associated with exposure to air-related Pb in a broader public health context, EPA developed and applied models to estimate human exposures to air-related Pb and associated health risk for various air quality scenarios and alternative standards. The design and implementation of the risk assessment needed to address significant limitations and complexity that go far beyond the situation for similar assessments typically performed for other criteria pollutants. The multimedia and persistent nature of Pb and the role of multiple exposure pathways add significant complexity as compared with other criteria pollutants that focus only on the inhalation exposure. Not only was the risk assessment

constrained by the timeframe allowed for this review in the context of the breadth of information to address, it was also constrained by significant limitations in data and modeling tools for the assessment, as described in section II.C.2.h of the proposal.

The scope and methodology for this assessment were developed over the last few years with considerable input from the CASAC Pb Panel and the public, as described in the proposal (section II.C.2.a).⁴² The following sections

⁴² In their review of the final risk assessment, CASAC expressed strong support, stating that “[t]he Final Risk Assessment report captures the breadth of issues related to assessing the potential public health risk associated with lead exposures; it competently documents the universe of knowledge and interpretations of the literature on lead toxicity, exposures, blood lead modeling and approaches for conducting risk assessments for lead” (Henderson, 2008a, p. 4).

provide a brief summary of the quantitative exposure and risk assessment and key findings. The complete full-scale assessment, including the associated uncertainties, is more fully summarized in section II.C of the proposal and described in detail in the Risk Assessment Report (USEPA, 2007b).

a. Design Aspects and Associated Uncertainties

As discussed in section II.C.2 of the proposal, EPA conducted exposure and risk analyses to estimate blood Pb and associated IQ loss in children exposed to air-related Pb. As recognized in section II.A.2 above and discussed in the proposal notice and Criteria Document, among the wide variety of health endpoints associated with Pb exposures, there is general consensus

that the developing nervous system in children is among, if not, the most sensitive, and that neurobehavioral effects (specifically neurocognitive deficits), including IQ decrements, appear to occur at lower blood Pb levels than previously believed. The selection of children's IQ for the quantitative risk assessment reflects consideration of the evidence presented in the Criteria Document as well as advice received from CASAC (Henderson, 2006, 2007a).⁴³

The brief summary provided here focuses on blood Pb and risk estimates for five case studies⁴⁴ that generally represent two types of population exposures: (1) More highly air-pathway exposed children (as described below) residing in small neighborhoods or localized residential areas with air concentrations somewhat near the standard being evaluated, and (2) location-specific urban populations with a broader range of air-related exposures.

The case studies representing the more highly air-pathway exposed children are the general urban case study and the primary Pb smelter case study. The general urban case study is not based on a specific geographic location and reflects several simplifications in representing exposure including uniform ambient air Pb levels associated with the standard of interest across the hypothetical study area and a uniform study population. Additionally, the method for simulating temporal variability in air Pb concentrations in this case study relied on national average estimates of the relationships between air concentrations in terms of the statistics considered for different forms of the standard being assessed and the annual ambient air concentrations required for input to the blood Pb model.⁴⁵ Thus, while this case study provides characterization of risk to children that are relatively more highly air pathway exposed (as

compared to the location-specific case studies), this case study is not considered to represent a high-end scenario with regard to the characterization of ambient air Pb levels and associated risk. The primary Pb smelter case study provides risk estimates for children living in a specific area that is currently not in attainment with the current NAAQS. We have focused on a subarea within 1.5 km of the facility where airborne Pb concentrations are closest to the current standard and where children's air-related exposures are most impacted by emissions associated with the Pb smelter from which air Pb concentrations were estimated.

The three location-specific urban case studies focus on specific residential areas within Cleveland, Chicago, and Los Angeles to provide representations of urban populations with a broader range of air-related exposures due to spatial gradients in both ambient air Pb levels and population density. For example, the highest air concentrations in these case studies (*i.e.*, those closest to the standard being assessed) are found in very small parts of the study areas, while a large majority of the case study populations reside in areas with much lower air concentrations.

Based on the nature of the population exposures represented by the two categories of case study, the first category (the general urban and primary Pb smelter case studies) relates more closely to the air-related IQ loss evidence-based framework described in the proposal (sections II.D.2.a.ii and II.E.3.a) with regard to estimates of air-related IQ loss. As mentioned above, these case studies, as compared to the other category of case studies, include populations that are relatively more highly exposed by way of air pathways to air Pb concentrations somewhat near the standard level evaluated.

The air quality scenarios assessed include (a) the current NAAQS (for all five case studies);⁴⁶ (b) current

conditions for the location-specific⁴⁷ and general urban case studies (which are below the current NAAQS); and (c) a range of alternate standard levels (for all case studies). The alternative NAAQS scenarios included levels of 0.50, 0.20, 0.05 and 0.02 $\mu\text{g}/\text{m}^3$, with a form of maximum monthly average, as well as a level of 0.20 $\mu\text{g}/\text{m}^3$, with a form of maximum quarterly average. Details of the assessment scenarios, including the Pb concentrations for other media are presented in Sections 2.3 and 5.1.1 of the Risk Assessment Report (USEPA, 2007b).

Exposure and associated blood Pb levels were simulated using the IEUBK model, as more fully described and presented in the Risk Assessment Report (USEPA, 2007b). Because of the nonlinear response of blood Pb to exposure and also the nonlinearity reflected in the C-R functions for estimation of IQ loss, this assessment first estimated total blood Pb and risk (air- and nonair-related), and then separated out those estimates of blood Pb and associated risk associated with the pathways of interest in this review. We separated out the estimates of total (all-pathway) blood Pb and IQ loss into a background category and two air-related categories (referred to as "recent air" and "past air"). However, significant limitations in our modeling tools and data resulted in an inability to parse specific risk estimates into specific pathways, such that we have approximated estimates for the air-related and background categories.

Those Pb exposure pathways tied most directly to ambient air, which consequently have the potential to respond relatively more quickly to changes in air Pb (*i.e.*, inhalation and ingestion of indoor dust Pb derived from the infiltration of ambient air Pb indoors), were placed into the "recent air" category. The other air-related Pb exposure pathways, all of which are associated with atmospheric deposition, were placed into the "past air" category. These include ingestion of Pb in outdoor dust/soil and ingestion of the portion of Pb in indoor dust that after deposition from ambient air outdoors is carried indoors with humans (as noted in section II.A.1 above).

Among the limitations affecting our estimates for the air-related and background categories is the apportionment of background (nonair) pathways. For example, while conceptually indoor Pb paint

⁴³ CASAC advice on the design of the risk assessment is summarized in section II.C.2.a of the proposal.

⁴⁴ A sixth case study (the secondary Pb smelter case study) is also described in the Risk Assessment Report. However, as discussed in Section 4.3.1 of that document (USEPA, 2007a), significant limitations in the approaches have contributed to large uncertainties in the corresponding estimates.

⁴⁵ As the blood Pb model used in the risk assessment was limited in that it did not accept inputs of a temporal time step shorter than annual average, ratios of relationships in the available air monitoring data between different statistical forms being considered for the standard and an annual average were employed for the urban case studies (that did not rely on dispersion modeling) as a method of simulating the temporal variability in air Pb concentrations that occurs as a result of meteorology, source and emissions characteristics.

⁴⁶ The current NAAQS scenario for the urban case studies assumes ambient air Pb concentrations higher than those currently occurring in nearly all urban areas nationally. While it is extremely unlikely that Pb concentrations in urban areas would rise to meet the current NAAQS and there are limitations and uncertainties associated with the roll-up procedure used for the location-specific urban case studies (as described in Section II.C.2.h of the proposal), this scenario was included for those case studies to provide perspective on potential risks associated with raising levels to the point that the highest level across the study area just meets the current NAAQS. This scenario was simulated for the location-specific urban case studies using a proportional roll-up procedure. For the general urban case study, the maximum quarterly average ambient air concentration was set equal to the current NAAQS.

⁴⁷ Current conditions for the three location-specific urban case studies in terms of maximum quarterly average air Pb concentrations were 0.09, 0.14 and 0.36 $\mu\text{g}/\text{m}^3$ for the study areas in Los Angeles, Chicago and Cleveland, respectively.

contributions to indoor dust Pb would be considered background and included in the "background" category for this assessment, due to technical limitations related to indoor dust Pb modeling, dust from Pb paint was included as part of "other" indoor dust Pb (*i.e.*, as part of past air exposure). The inclusion of indoor paint Pb as a component of "other" indoor dust Pb (and consequently as a component of the "past air" category) represents a source of potential high bias in our prediction of exposure and risk associated with the "past air" category because conceptually, exposure to indoor paint Pb is considered part of background exposure. At the same time, Pb in ambient air does contribute to the exposure pathways included in the "background" category (drinking water and diet), and is likely a substantial contribution to diet (CD, p. 3–48). We could not separate the air contribution from the nonair contributions, and the total contribution from both the drinking water and diet pathways are categorized as "background" in this assessment. As a result, our "background" risk estimate includes some air-related risk representing a source of potential low bias in our predictions of air-related risk.

Further, we note that in simulating reductions in exposure associated with reducing ambient air Pb levels through alternative NAAQS (and increases in exposure if the current NAAQS was reached in certain case studies) only the exposure pathways categorized as "recent air" (inhalation and ingestion of that portion of indoor dust associated with outdoor ambient air) were varied with changes in air concentration. The assessment did not simulate decreases in "past air" exposure pathways (*e.g.*, reductions in outdoor soil Pb levels following reduction in ambient air Pb levels and a subsequent decrease in exposure through incidental soil ingestion and the contribution of outdoor soil to indoor dust).⁴⁸ These exposures were held constant across all air quality scenarios.⁴⁹

In summary, because of limitations in the assessment design, data and modeling tools, our risk estimates for

the "past air" category include both risks that are truly air-related and potentially, some background risk. Because we could not sharply separate Pb linked to ambient air from Pb that is background, some of the three categories of risk are underestimated and others overestimated. On balance, we believe this limitation leads to a slight overestimate of the risks in the "past air" category. At the same time, as discussed above, the "recent air" category does not fully represent the risk associated with all air-related pathways. Thus, we consider the risk attributable to air-related exposure pathways to be bounded on the low end by the risk estimated for the "recent air" category and on the upper end by the risk estimated for the "recent air" plus "past air" categories.

As discussed in the proposal notice and in greater detail in the Staff Paper and Risk Assessment Report, exposure and risk modeling conducted for this analysis was complex and subject to significant uncertainties due to limitations, data, models and time available. Key assumptions, limitations and uncertainties, which were recognized in various ways in the assessment and presentation of results, are listed here, beginning with those related to design of the assessment or case studies, followed by those related to estimation of Pb concentrations in ambient air, indoor dust, outdoor soil/dust, and blood, and estimation of Pb-related IQ loss.

- *Temporal Aspects:* During the 7-year exposure period, media concentrations remain fixed and the simulated child remains at the same residence (while exposure factors and physiological parameters are adjusted to match the age of the child).

- *General Urban Case Study:* The design for this case study employs assumptions regarding uniformity that are reasonable in the context of a small neighborhood population, but would contribute significant uncertainty to extrapolation of these estimates to a specific urban location, particularly a relatively large one. Thus, the risk estimates for this general urban case study, while generally representative of an urban residential population exposed to the specified ambient air Pb levels, cannot be readily related to a specific large urban population.

- *Location-Specific Urban Case Studies:* Limitations in the ambient air monitoring network limit our characterization of spatial gradients of ambient air Pb levels in these case studies.

- *Air Quality Simulation:* The proportional roll-up and roll-down

procedures used in some case studies to simulate current NAAQS and alternate NAAQS levels, respectively, assume proportional changes in air concentrations across the study area in those scenarios for those case studies. EPA recognizes that it is extremely unlikely that Pb concentrations would rise to just meet the current NAAQS in urban areas nationwide and that there is substantial uncertainty with our simulation of such conditions in the urban location-specific case studies. There is also significant uncertainty in simulation conditions associated with the implementation of emissions reduction actions to meet a lower standard.

- *Outdoor Soil/Dust Pb Concentrations:* Uncertainty regarding soil/dust Pb levels and the inability to simulate the influence of changing air Pb levels related to lowering the NAAQS contributes uncertainty to air-related risk estimates.

- *Indoor Dust Pb Concentrations:* Limitations and uncertainty in modeling of indoor dust Pb levels, including the impact of reductions in ambient air Pb levels, contributes uncertainty to air-related risk estimates.

- *Interindividual Variability in Blood Pb Levels:* Uncertainty related to population variability in blood Pb levels and limitations in modeling of this introduces significant uncertainty into blood Pb and IQ loss estimates for the 95th percentile of the population.

- *Pathway Apportionment for Higher Percentile Blood Pb and IQ Loss:* Limitations in data, modeling tools and assessment design introduce uncertainty into estimates of air-related blood Pb and IQ loss for the upper ends of population distribution.

- *IQ Loss Concentration-Response Functions:* Specification of the quantitative relationship between blood Pb level and IQ loss is subject to significant uncertainty at lower blood Pb levels (*e.g.*, below 5 µg/dL concurrent blood Pb).

b. Summary of Blood Pb Estimates

Key observations regarding the blood Pb estimates from this analysis are noted here:

- As shown in Table 2 of the proposal (73 FR 29215), median blood Pb levels for the current conditions air quality scenario in the urban case studies ranged from 1.7–1.8 µg/dL for the location-specific case studies up to 1.9 µg/dL for the general urban case study. These values are slightly larger than the median value from NHANES for children aged 1–5 years old in 2003–2004 of 1.6 µg/dL (http://www.epa.gov/envirohealth/children/body_burdens/

⁴⁸ Similarly, since dietary Pb was included within "background", reductions in dietary Pb, *e.g.*, as a result of reduced deposition to crops, were also not simulated.

⁴⁹ In comparing total risk estimates between alternate NAAQS scenarios, this aspect of the analysis will tend to underestimate the reductions in risk associated with alternative NAAQS. However, this does not mean that overall risk has been underestimated. The net effect of all sources of uncertainty or bias in the analysis, which may also tend to under- or overestimate risk, could not be quantified.

b1-table.htm). Blood Pb level estimates for the 90th percentile in the urban case studies are also higher than the NHANES 90th percentile blood Pb levels. We note, however, that ambient air Pb levels in the urban case studies are higher than those at most monitoring sites in the U.S., as described in section II.C.3.a of the proposal.

- With regard to air-to-blood ratios, estimates for the general urban case study ranged from 1:2 to 1:9 with the majority of the estimates ranging from 1:4 to 1:6.⁵⁰ Because the risk assessment only reflects the impact of reductions on recent air-related pathways in predicting changes in indoor dust Pb for the general urban case study (as noted in section II.C.3.a of the proposal), however, the ratios generated are lower than they would be if they had also reflected other air-related pathways (e.g., changes in outdoor surface soil/dust and dietary Pb with changes in ambient air Pb).

- Air-to-blood ratios estimated for the primary Pb smelter subarea ranged from 1:10 and higher.⁵¹ One reason for these estimates being higher than those for the urban case study may be that the dust Pb model used may somewhat reflect ambient air-related pathways other than that of ambient air infiltrating a home.

c. Summary of IQ Loss Estimates

As described more fully in the proposal notice and in the Risk Assessment Report (USEPA, 2007b, section 5.3.1), four sets of IQ loss estimates were derived from the blood Pb estimates, one for each of four concentration-response functions derived from the international pooled analysis by Lanphear and others (2005). Each of these four functions utilizes a

different approach for characterizing low-exposure IQ loss, thereby providing a range of estimates intended to reflect the uncertainty in this key aspect of the risk assessment. As described in section II.C.2.b of the proposal (and in more detail in section 2.1.5 of the Risk Assessment Report), we have placed greater confidence in the log-linear function with low-exposure linearization (LLL) and present risk estimates based on that function here.⁵²

The risk estimates summarized here are those considered most relevant to the review in considering whether the current NAAQS and potential alternative NAAQS provide protection of public health with an adequate margin of safety (i.e., estimates of IQ loss associated with air-related Pb exposure). In considering these estimates, we note that IQ loss associated with air-related Pb is bounded on the low end by risk associated with the *recent air* category of exposure pathways and on the upper end by the *recent plus past air* categories of pathways (as described above in section II.A.3.a). Key observations regarding the median estimates⁵³ of air-related risk for the current NAAQS and alternative standards include:

- As shown in Table 2 below (Table 3 in the proposal), in all five case studies, the lower bound of population median air-related risk associated with the current NAAQS exceeds 2 points IQ loss, and the upper bound is near or above 4 points.⁵⁴

- Alternate standards provide substantial reduction in estimates of air-related risk across the full set of alternative NAAQS considered, particularly for the lower bound of air-

related risk which includes only the pathways that were varied with changes in air concentrations (as shown in Table 2).

- In the general urban case study, the estimated population median air-related risk falls between 1.9 and 3.6 points IQ loss for an alternative NAAQS of 0.50 µg/m³, maximum monthly average, between 1.2 and 3.2 points IQ loss for an alternative NAAQS of 0.20 µg/m³ and between 0.5 and 2.8 points IQ loss for an alternate NAAQS of 0.05 µg/m³, maximum monthly average, (as shown in Table 2). Higher risk estimates are associated with a maximum quarterly averaging time (USEPA, 2007b).

- At each NAAQS level assessed, the upper bound of population median air-related risk for the primary Pb smelter subarea, which due to limitations in modeling is the only air-related risk estimate for this case study, is generally higher than that for the general urban case study, likely due to differences in the indoor dust models used for the two case studies (as discussed in section II.C.3.b of the proposal).

- Compared to the other case studies, the air-related risk for the location-specific case studies is smaller because of the broader range of air-related exposures and the population distribution. For example, the majority of the populations in each of the location-specific case studies resides in areas with ambient air Pb levels well below each standard level assessed, particularly for standard levels above 0.05 µg/m³, maximum monthly average. Consequently, risk estimates for these case studies indicate little response to alternative standard levels above 0.05 µg/m³ maximum monthly average (as shown in Table 2).

TABLE 2—SUMMARY OF RISK ATTRIBUTABLE TO AIR-RELATED Pb EXPOSURE

NAAQS level simulated (µg/m ³ max monthly, except as noted below)	Median air-related IQ loss ^A				
	General urban case study	Primary Pb smelter (sub-area) case study ^{B C}	Location-specific urban case studies		
			Cleveland (0.56 µg/m ³)	Chicago (0.31 µg/m ³)	Los Angeles (0.17 µg/m ³)
1.5 max quarterly ^D	3.5–4.8 (1.5–7.7)	<6 <(3.2–9.4)	2.8–3.9 ^E (0.6–4.6)	3.4–4.7 ^E (1.4–7.4)	2.7–4.2 ^E (1.1–6.2)
0.5	1.9–3.6 (0.7–4.8)	<4.5 <(2.1–7.7)	0.6–2.9 (0.2–3.9)	(^F)	(^F)
0.2	1.2–3.2 (0.4–4.0)	<3.7 <(1.2–5.1)	0.6–2.8 (0.1–3.2)	0.6–2.9 (0.3–3.6)	0.7–2.9 ^G (0.2–3.5)

⁵⁰The ratios increase as the level of the alternate standard decreases. This reflects the nonlinearity in the Pb response, which is greater on a per-unit basis for lower ambient air Pb levels.

⁵¹For the primary Pb smelter (full study area), for which limitations are noted in section II.C.2.c of the proposal, the air-to-blood ratio estimates, presented in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b), ranged from 1:3 to 1:7. As in the other case studies, ratios are higher at lower

ambient air Pb levels. It is noted that the underlying changes in both ambient air Pb and blood Pb across standard levels are extremely small, introducing uncertainty into ratios derived using these data.

⁵²As shown in the presentation in the Staff Paper (section 4.4), risk estimates for the LLL function are generally bounded by estimates based on the other three C–R functions included in the assessment.

⁵³Because of greater uncertainty in characterizing high-end population risk, and specifically related to

pathway apportionment of IQ loss estimates for high-end percentiles, results discussed here focus on those for the population median.

⁵⁴As noted in Table 2 below and sections II.C.2.d and II.C.2.h of the proposal, with regard to associated limitations and uncertainties, a proportional roll-up procedure was used to estimate air Pb concentrations in this scenario for the location-specific case studies.

TABLE 2—SUMMARY OF RISK ATTRIBUTABLE TO AIR-RELATED Pb EXPOSURE—Continued

NAAQS level simulated ($\mu\text{g}/\text{m}^3$ max monthly, except as noted below)	Median air-related IQ loss ^A				
	General urban case study	Primary Pb smelter (sub-area) case study ^{B C}	Location-specific urban case studies		
			Cleveland (0.56 $\mu\text{g}/\text{m}^3$)	Chicago (0.31 $\mu\text{g}/\text{m}^3$)	Los Angeles (0.17 $\mu\text{g}/\text{m}^3$)
0.05	0.5–2.8 (0.2–3.3)	<2.8 <(0.9–3.4)	0.1–2.6 (<0.1–3.1)	0.2–2.6 (0.1–3.2)	0.3–2.7 (0.1–3.2)
0.02	0.3–2.6 (0.1–3.1)	<2.9 <(0.9–3.3)	<0.1–2.6 (<0.1–3.0)	0.1–2.6 (<0.1–3.1)	0.1–2.6 (<0.1–3.1)

^A—Air-related risk is bracketed by “recent air” (lower bound of presented range) and “recent” plus “past air” (upper bound of presented range). While differences between standard levels are better distinguished by differences in the “recent” plus “past air” estimates (upper bounds shown here), these differences are inherently underestimates. The term “past air” includes contributions from the outdoor soil/dust contribution to indoor dust, historical air contribution to indoor dust, and outdoor soil/dust pathways; “recent air” refers to contributions from inhalation of ambient air Pb or ingestion of indoor dust Pb predicted to be associated with outdoor ambient air Pb levels, with outdoor ambient air also potentially including resuspended, previously deposited Pb (see section II.C.2.e of the proposal). Boldface values are estimates generated using the log-linear with low-exposure linearization function. Values in parentheses reflect the range of estimates associated with all four concentration-response functions.

^B—In the case of the primary Pb smelter case study, only recent plus past air estimates are available.

^C—In the case of the primary Pb smelter case study, only recent plus past air estimates are available.

^C—Median air-related IQ loss estimates for the primary Pb smelter (full study area) range from <1.7 to <2.9 points, with no consistent pattern across simulated NAAQS levels. This lack of a pattern reflects inclusion of a large fraction of the study population with relatively low ambient air impacts such that there is lower variation (at the population median) across standard levels (see section 4.2 of the Risk Assessment, Volume 1).

^D—This corresponds to roughly 0.7–1.0 $\mu\text{g}/\text{m}^3$ maximum monthly mean, across the urban case studies.

^E—A “roll-up” was performed so that the highest monitor in the study area is increased to just meet this level.

^F—A “roll-up” to this level was not performed.

^G—A “roll-up” to this level was not performed; these estimates are based on current conditions in this area.

B. Need for Revision of the Current Primary Standard

The initial issue to be addressed in the current review of the primary Pb standard is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standard should be revised. In evaluating whether it is appropriate to revise the current standard, the Administrator builds on the general approach used in the initial setting of the standard, as well as that used in the last review, and reflects the broader body of evidence and information now available. The approach used is based on an integration of information on health effects associated with exposure to ambient Pb; expert judgment on the adversity of such effects on individuals; and policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety, which are informed by air quality and related analyses, quantitative exposure and risk assessments when possible, and qualitative assessment of impacts that could not be quantified. The Administrator has taken into account both evidence-based and quantitative exposure- and risk-based considerations in developing conclusions on the adequacy of the current primary Pb standard.

The Administrator’s proposed conclusions on the adequacy of the current primary standard are summarized below in the Introduction (section II.B.1), followed by

consideration of comments received on the proposal (section II.B.2) and the Administrator’s final decision with regard to the need for revision of the current primary standard (II.B.3).

1. Introduction

As described in section II.D.1.a of the proposal, the current standard was set in 1978 to provide protection to the public, especially children as the particularly sensitive population subgroup, against Pb-induced adverse health effects (43 FR 46246). The standard was set to provide protection against anemia (as well as effects associated with higher exposures), with consideration of impacts on the heme synthesis pathway leading to anemia (43 FR 46252–46253). In setting the standard, EPA determined that “the maximum safe level of blood lead for an individual child” should be no higher than 30 $\mu\text{g}/\text{dL}$, and described 15 $\mu\text{g}/\text{dL}$ Pb as “the maximum safe blood lead level (geometric mean) for a population of young children” (43 FR 46247, 46253). The basis for the level, averaging time, form and indicator are described in section II.D.1.a of the proposal.

As noted in the proposal, the body of available evidence today, summarized above in section II.A.2 and in section II.B of the proposal, and discussed in the Criteria Document, is substantially expanded from that available when the current standard was set three decades ago. The Criteria Document presents evidence of the occurrence of health effects at appreciably lower blood Pb

levels than those demonstrated by the evidence at the time the standard was set. Further, subsequent to the setting of the standard, the Pb NAAQS criteria review during the 1980s and the current review have provided “(a) increasingly stronger evidence that substantiated still lower fetal and/or postnatal Pb-exposure levels (indexed by blood-Pb levels extending to as low as 10 to 15 $\mu\text{g}/\text{dL}$ or, possibly, below) as being associated with slowed physical and neurobehavioral development, lower IQ, impaired learning, and/or other indicators of adverse neurological impacts; and (b) other pathophysiological effects of Pb on cardiovascular function, immune system components, calcium and vitamin D metabolism and other selected health endpoints” (CD, pp. 8–24 to 8–25). This evidence is discussed fully in the Criteria Document.

In the proposal, EPA explained its evidence-based considerations regarding the adequacy of the current standard. With regard to the sensitive population, while the sensitivity of the elderly and other particular subgroups is recognized, as at the time the current standard was set, young children continue to be recognized as a key sensitive population for Pb exposures.

With regard to the exposure levels at which adverse health effects occur, the proposal noted that the current evidence demonstrates the occurrence of adverse health effects at appreciably lower blood Pb levels than those demonstrated by the evidence at the time the standard was set. This evidence is reflected in

changes over the intervening years in the CDC's identification and description of their advisory level for Pb in individual children's blood (as described above in section II.A.2.a). The current evidence indicates the occurrence of a variety of health effects, including neurological effects in children, associated with blood Pb levels extending well below 10 µg/dL (CD, sections 6.2, 8.4 and 8.5). For example, as noted in the Criteria Document with regard to the neurocognitive effects in children, the "weight of overall evidence strongly substantiates likely occurrence of [this] type of effect in association with blood-Pb concentrations in range of 5–10 µg/dL, or possibly lower * * * Although no evident threshold has yet been clearly established for those effects, the existence of such effects at still lower blood-Pb levels cannot be ruled out based on available data." (CD, p. 8–61). The Criteria Document further notes that any such threshold may exist "at levels distinctly lower than the lowest exposures examined in these epidemiological studies" (CD, p. 8–67).

In considering the adequacy of the current standard, the Staff Paper considered the evidence in the context of the framework used to determine the standard in 1978, as adapted to reflect the current evidence. In so doing, the Staff Paper recognized that the health effects evidence with regard to characterization of a threshold for adverse effects has changed since the standard was set in 1978, as have the Agency's views on the characterization of a safe blood Pb level. As summarized in the proposal (73 FR 29237–38) and described in the Staff Paper (section 5.4.1), parameters for this framework include estimates for average nonair blood Pb level, and air-to-blood ratio, as well as a maximum safe individual and/or geometric mean blood Pb level. For this last parameter, the Staff Paper for the purposes of this evaluation considered the lowest population mean blood Pb levels with which some neurocognitive effects have been associated in the evidence.

Based on the current evidence, the Staff Paper first concluded that young children remain the sensitive population of primary focus in this review and that "there is now no recognized safe level of Pb in children's blood and studies appear to show adverse effects at population mean concurrent blood Pb levels as low as approximately 2 µg/dL (CD, pp. 6–31 to 6–32; Lanphear *et al.*, 2000)" (USEPA, 2007c). The Staff Paper further stated that "while the nonair contribution to blood Pb has declined, perhaps to a

range of 1.0–1.4 µg/dL, the air-to-blood ratio appears to be higher at today's lower blood Pb levels than the estimates at the time the standard was set, with current estimates on the order of 1:3 to 1:5 and perhaps up to 1:10" (USEPA, 2007c). Adapting the framework employed in setting the standard in 1978, the Staff Paper concluded that "the more recently available evidence suggests a level for the standard that is lower by an order of magnitude or more" (USEPA, 2007c, p. 5–17).

Since completion of the Staff Paper and ANPR, the Agency further considered the evidence with regard to adequacy of the current standard using an approach other than the adapted 1978 framework considered in the Staff Paper. This alternative evidence-based⁵⁵ framework, referred to as the air-related IQ loss framework, shifts focus from identifying an appropriate target population mean blood lead level and instead focuses on the magnitude of effects of air-related Pb on neurocognitive functions. This framework builds on a recommendation by the CASAC Pb Panel to consider the evidence in a more quantitative manner, and is discussed in more detail in section II.E.3.a.ii of the proposal.

In this air-related IQ loss framework, EPA draws from the entire body of evidence as a basis for concluding that there are causal associations between air-related Pb exposures and population IQ loss.⁵⁶ We also draw more quantitatively from the evidence by using evidence-based C–R functions to quantify the association between air Pb concentrations and air-related population mean IQ loss. Thus, this framework more fully considers the evidence with regard to the concentration-response relationship for the effect of Pb on IQ than does the adapted 1978 framework, and it also

⁵⁵ The term "evidence-based" as used here refers to the drawing of information directly from published studies, with specific attention to those reviewed and described in the Criteria Document, and is distinct from considerations that draw from the results of the quantitative exposure and risk assessment.

⁵⁶ For example, as stated in the Criteria Document, "Fortunately, there exists a large database of high quality studies on which to base inferences regarding the relationship between Pb exposure and neurodevelopment. In addition, Pb has been extensively studied in animal models at doses that closely approximate the human situation. Experimental animal studies are not compromised by the possibility of confounding by such factors as social class and correlated environmental factors. The enormous experimental animal literature that proves that Pb at low levels causes neurobehavioral deficits and provides insights into mechanisms must be considered when drawing causal inferences (Bellinger, 2004; Davis *et al.*, 1990; U.S. Environmental Protection Agency, 1986a, 1990)." (CD, p. 6–75).

draws from estimates for air-to-blood ratios.

In the proposal, while we noted the evidence of steeper slope for the C–R relationship for blood Pb concentration and IQ loss at lower blood Pb levels (described above in sections II.A.2.c), we stated that for purposes of consideration of the adequacy of the current standard we were concerned with the C–R relationship for blood Pb levels that would be associated with exposure to air-related Pb at the level of the current standard. For this purpose, we focused on a median linear estimate of the slope of the C–R function from study populations for which most blood Pb levels were below 10 µg/dL and for which a linear slope restricted to blood Pb levels below about 10 µg/dL could be estimated (described in CD, pp. 6–65 to 6–66 and summarized in section II.B.2.b of the proposal). The median slope estimate is –0.9 IQ points per µg/dL blood Pb (CD, p. 8–80). Applying estimates of air-to-blood ratios ranging from 1:3 to 1:5, drawing from the discussion of air-to-blood ratios in section II.B.1.c of the proposal, to a population of children exposed at the current level of the standard is estimated to result in an average air-related blood Pb level above 4 µg/dL.⁵⁷ Multiplying these blood Pb levels by the slope estimate, identified above, for blood Pb levels extending up to 10 µg/dL (–0.9 IQ points per µg/dL), would imply an average air-related IQ loss for such a group of children on the order of 4 or more IQ points.

In the proposal, EPA also explained its exposure- and risk-based considerations regarding the adequacy of the current standard. EPA estimated exposures and health risks associated with air quality that just meets the current standard (as described in the Risk Assessment Report) to help inform judgments about whether or not the current standard provides adequate protection of public health, taking into account key uncertainties associated with the estimated exposures and risks (summarized above in section II.C of the proposal and more fully in the Risk Assessment Report). In considering the adequacy of the standard, the Staff Paper considered exposure and risk estimates from the quantitative risk assessment, taking into account associated uncertainties. The Staff Paper

⁵⁷ This is based on the calculation in which 1.5 µg/m³ is multiplied by a ratio of 3 µg blood Pb per 1 µg/m³ air Pb to yield an air-related blood Pb estimates of 4.5 µg/dL; using a 1:5 ratio yields an estimate of 7.5 µg/dL. As with the 1978 framework considered in the Staff Paper, the context for use of the air-to-blood ratio here is a population being exposed at the level of the standard.

first considered exposure/risk estimates associated with air-related risk, which as recognized in section II.A.3 above (and summarized in section II.C.2.e of the proposal and described more fully in the Risk Assessment Report) are approximated estimates, provided in terms of upper and lower bounds. The Staff Paper described the magnitude of these estimates for the current NAAQS as being indicative of levels of IQ loss associated with air-related risk that may “reasonably be judged to be highly significant from a public health perspective” (USEPA, 2007c).

As discussed in section II.D.2.b of the proposal, the Staff Paper also describes a different risk metric that estimated differences in the numbers of children with different amounts of Pb-related IQ loss between air quality scenarios for current conditions and for the current NAAQS in the three location-specific urban case studies. The Staff Paper concluded that these estimated differences “indicate the potential for significant numbers of children to be negatively affected if air Pb concentrations increased to levels just meeting the current standard” (USEPA, 2007c). Beyond the findings related to quantified IQ loss, the Staff Paper recognized the potential for other, unquantified adverse effects that may occur at similarly low exposures as those quantitatively assessed in the risk assessment. In summary, the Staff Paper concluded that taken together, “the quantified IQ effects associated with the current NAAQS and other, nonquantified effects are important from a public health perspective, indicating a need for consideration of revision of the standard to provide an appreciable increase in public health protection” (USEPA, 2007c).

In their letter to the Administrator subsequent to consideration of the ANPR, the Staff Paper and the Risk Assessment Report, the CASAC Pb Panel advised the Administrator that they unanimously and fully supported “Agency staff’s scientific analyses in recommending the need to substantially lower the level of the primary (public-health based) Lead NAAQS, to an upper bound of no higher than 0.2 $\mu\text{g}/\text{m}^3$ with a monthly averaging time” (Henderson, 2008a, p. 1). The Panel additionally advised that the current Pb NAAQS “are totally inadequate for assuring the necessary decreases of lead exposures in sensitive U.S. populations below those current health hazard markers identified by a wealth of new epidemiological, experimental and mechanistic studies”, and that “it is the CASAC Lead Review Panel’s considered judgment that the NAAQS for Lead must be decreased to

fully-protect both the health of children and adult populations” (Henderson, 2007a, p. 5). CASAC drew support for their recommendation from the current evidence, described in the Criteria Document, of health effects occurring at dramatically lower blood Pb levels than those indicated by the evidence available when the standard was set and of a recognition of effects that extend beyond children to adults.

At the time of proposal, in considering whether the current primary standard should be revised, the Administrator carefully considered the conclusions contained in the Criteria Document, the information, exposure/risk assessments, conclusions and recommendations presented in the Staff Paper, the advice and recommendations from CASAC, and public comments received on the ANPR and other documents to date. In so doing, the Administrator noted the following: (1) A substantially expanded body of available evidence, described briefly in section II.A above and more fully in section II.B of the proposal and discussed in the Criteria Document, from that available when the current standard was set three decades ago; (2) evidence of the occurrence of health effects at appreciably lower blood Pb levels than those demonstrated by the evidence at the time the standard was set in 1978; (3) the currently available robust evidence of neurotoxic effects of Pb exposure in children, both with regard to epidemiological and toxicological studies; (4) associations of effects on the neurodevelopment of children with blood Pb levels notably decreased from those in the late 1970s;⁵⁸ (5) toxicological evidence including extensive experimental laboratory animal evidence that substantiates well the plausibility of the epidemiologic findings observed in human children; (6) current evidence that suggests a steeper dose-response relationship at recent lower blood Pb levels than at higher blood Pb levels, indicating the potential for greater incremental impact associated with exposure at these lower levels.

In addition to the evidence of health effects occurring at significantly lower blood Pb levels, the Administrator recognized in the proposal that, as at the time the standard was set, the current health effects evidence together with findings from the exposure and risk assessments (summarized above in

section II.A.3) supports a finding that air-related Pb exposure pathways contribute to blood Pb levels in young children by inhalation and ingestion. Furthermore, the Administrator took note of the information that suggests that the air-to-blood ratio (i.e., the quantitative relationship between air concentrations and blood concentrations) is now likely larger, when air inhalation and ingestion are considered, than that estimated when the standard was set.

At the time of proposal, the Administrator first considered the current evidence in the context of an adaptation of the 1978 framework, as presented in the Staff Paper, recognizing that the health effects evidence with regard to characterization of a threshold for adverse effects has changed dramatically since the standard was set in 1978. As discussed in the proposal, however, limitations in the application of that framework to the current situation, where (unlike when the standard was set in 1978) there is not an evidentiary basis to determine a safe level for individual children with respect to the identified health effect, led the Administrator to focus primarily instead on the air-related IQ loss evidence-based framework, described in section II.D.2.a.ii of the proposal, in considering the adequacy of the current standard.

As discussed in the proposal, the Administrator judged that air-related IQ loss associated with exposure at the level of the current standard is large from a public health perspective and that this evidence-based framework supports a conclusion that the current standard does not protect public health with an adequate margin of safety. Further, the Administrator provisionally concluded that the current evidence indicates the need for a standard level that is substantially lower than the current level to provide increased public health protection, especially for at-risk groups, including most notably children, against an array of effects, most importantly including effects on the developing nervous system.

At the time of proposal, the Administrator also considered the results of the exposure and risk assessments conducted for this review as providing some further perspective on the potential magnitude of air-related IQ loss, although, noting uncertainties and limitations in the assessments, the Administrator did not place primary reliance on the exposure and risk assessments. Nonetheless, the Administrator observed that in areas projected to just meet the current standard, the quantitative estimates of

⁵⁸ As noted in the proposal (73 FR 29228), while blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with these more recent blood Pb levels.

IQ loss associated with air-related Pb indicate risk of a magnitude that in his judgment is significant from a public health perspective and also recognized that, although the current monitoring data indicate few areas with airborne Pb near or just exceeding the current standard, there are significant limitations with the current monitoring network and thus there exists the potential that the prevalence of such Pb concentrations may be underestimated by currently available data.

Based on all of these considerations, the Administrator provisionally concluded that the current Pb standard is not requisite to protect public health with an adequate margin of safety because it does not provide sufficient protection, and that the standard should be revised to provide increased public health protection, especially for members of at-risk groups.

2. Comments on the Need for Revision

In considering comments on the need for revision, the Administrator first notes the advice and recommendations from CASAC with regard to the adequacy of the current standard. In the four letters that CASAC has sent the Agency providing advice on the Pb standard, including the most recent one on the proposal, all have repeated their unanimous view regarding the need for substantial revision of the Pb NAAQS (Henderson, 2007a, 2007b, 2008a, 2008b). For example, as stated in their letter of March 2007, the *“unanimous judgment of the Lead Panel is that * * * both the primary and secondary NAAQS should be substantially lowered”* (Henderson, 2007a).

General comments based on relevant factors that either support or oppose any change to the current Pb primary standard are addressed in this section. Comments on elements of the proposed primary standard and on studies that relate to consideration of the appropriate indicator, averaging time and form, and level are addressed below in sections II.C.1, II.C.2, and II.C.3, respectively. Other specific comments related to the standard setting, as well as general comments based on implementation-related factors that are not a permissible basis for considering the need to revise the current standards are addressed in the Response to Comments document.

The vast majority of public comments received on the proposal generally asserted that, based on the available scientific information, the current Pb standard is insufficient to protect public health with an adequate margin of safety and revisions to the standard are appropriate. Among those calling for

revisions to the current standards are medical groups, including the American Academy of Pediatrics, the American Medical Association and the American Thoracic Society, as well as two groups of concerned physicians and scientists, and the Agency's external Children's Health Protection Advisory Committee (Marty, 2008). Similar conclusions were also submitted in comments from many national, state, and local environmental and public health organizations, including, for example, the Natural Resources Defense Council (NRDC), the Sierra Club, and the Coalition to End Childhood Lead Poisoning. All of these medical, public health and environmental commenters stated that the current Pb standard needs to be revised to a level well below the current level to protect the health of sensitive population groups. Many individual commenters also expressed such views. Additionally, regional organizations of state agencies, including the National Association of Clean Air Agencies (NACAA), and Northeast States for Coordinated Air Use Management (NESCAUM) urged that EPA revise the Pb standard. State and local air pollution control authorities or public health agencies who commented on the Pb standard also supported revision of the current Pb standard, including the New York Departments of Health and Environmental Conservation, Iowa Departments of Natural Resources and Public Health, the Missouri Departments of Natural Resources and Health and Senior Services, as well as the Missouri Office of the Attorney General, among others. All tribal governments and tribal air and environmental agencies commenting on the standard, including the InterTribal Council of Arizona, Inc. (an organization of 20 tribal governments in Arizona), the Lone Pine Paiute-Shoshone Reservation, as well as the Fond du Lac Band of Lake Superior Chippewa, commented in support of revision of the Pb NAAQS.

In general, all of these commenters agreed with EPA's proposed conclusions on the importance of results from the large body of scientific studies reviewed in the Criteria Document and on the need to revise the primary Pb standard as articulated in EPA's proposal. Many commenters cited CASAC advice on this point. The EPA generally agrees with CASAC and these public commenters' conclusions regarding the need to revise the primary Pb standard. EPA agrees that the evidence assessed in the Criteria Document and the Staff Paper provides a basis for concluding that the current

Pb standard does not protect public health with an adequate margin of safety. Comments on specific aspects of the level for a revised standard are discussed below in section II.C.3 below.

Some of these commenters also identified “new” studies that were not included in the Criteria Document as providing further support for the need to revise the Pb standards. As noted above in section I.C, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the Pb air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next Pb NAAQS review. Nonetheless, in considering these comments related to these more recent studies (further discussed in the Response to Comments document), EPA notes that our provisional consideration of these studies concludes that this new information and findings do not materially change any of the broad scientific conclusions regarding neurotoxic and other health effects of lead exposure made in the 2006 Criteria Document. For example, “new” studies cited by commenters on neurocognitive and neurobehavioral effects add to the overall weight of evidence and focus on findings of such effects beyond IQ in study groups with some studies including lower blood Pb levels than were available for review in the Criteria Document.

Three industry associations (National Association of Manufacturers, Non-Ferrous Founders' Society, and Wisconsin Manufacturers & Commerce) commented in support of retaining the current primary Pb standard. These commenters generally state that most health risks associated with Pb exposures are more likely to result from past air emissions or nonair sources of Pb, such as lead-based paint, and that reduction of the Pb standard will not provide meaningful benefits to public health. They additionally cite costs to those industries on whose part action will be required to meet a reduced standard. While EPA recognizes that nonair sources contribute Pb exposure to today's population, EPA disagrees with the commenters' premise that Pb exposures associated with any past air emissions are not relevant to consider in judging the adequacy of the current standard. Further, EPA disagrees with commenters, regarding the significance of health risk associated with air-related Pb exposures allowed by the current standard. As discussed in summarized in section II.B.1 above and discussed in section II.B.3 below, EPA has concluded

that the health risk associated with air-related Pb exposures allowed by the current standard is of such a significant magnitude that a revision to the standard is needed to protect public health with an adequate margin of safety. EPA further notes that, as discussed above in section I.B, under the CAA, EPA may not consider the costs of compliance in determining what standard is requisite to protect public health with an adequate margin of safety.

3. Conclusions Regarding the Need for Revision

Having carefully considered the public comments, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of Pb reached in the Criteria Document and Staff Paper, briefly summarized above in section II.B.1, remain valid. In considering whether the primary Pb standard should be revised, the Administrator places primary consideration on the large body of scientific evidence available in this review concerning the public health impacts of Pb, including significant new evidence concerning effects at blood Pb concentrations substantially below those identified when the current standard was set. As summarized in section II.A.2.b, Pb has been demonstrated to exert a broad array of adverse effects on multiple organ systems, with the evidence across this array of effects much expanded since the standard was set, with the key effects most pertinent to ambient exposures today including neurological, hematological and immune effects for children and hematological, cardiovascular and renal effects for adults. The Administrator particularly notes the robust evidence of neurotoxic effects of Pb exposure in children, both with regard to epidemiological and toxicological studies. While blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with these more recent blood Pb levels. The toxicological evidence includes extensive experimental laboratory animal evidence that substantiates well the plausibility of the epidemiologic findings observed in human children and expands our understanding of likely mechanisms underlying the neurotoxic effects. Further, the Administrator notes the current evidence that suggests a steeper dose-response relationship at these lower blood Pb levels than at higher blood Pb levels, indicating the potential for greater incremental impact

associated with exposure at these lower levels.

In addition to the evidence of health effects occurring at significantly lower blood Pb levels, the Administrator recognizes that the current health effects evidence together with findings from the exposure and risk assessments (summarized above in section II.A.3), like the information available at the time the standard was set, supports our finding that air-related Pb exposure pathways contribute to blood Pb levels in young children, by inhalation and ingestion. Furthermore, the Administrator takes note of the information that suggests that the air-to-blood ratio (i.e., the quantitative relationship between air concentrations and blood concentrations) is now likely larger, when all air inhalation and ingestion pathways are considered, than that estimated when the standard was set.

The Administrator has considered the evidence in the record, and discussed above, in the context of an adaptation of the 1978 framework, as presented in the Staff Paper, recognizing that the health effects evidence with regard to characterization of a threshold for adverse effects has changed dramatically since the standard was set in 1978. As discussed in the proposal (73 FR 29229), however, the Administrator recognizes limitations to this approach and has focused primarily instead on the air-related IQ loss evidence-based framework described in section II.B.1 above, in considering the adequacy of the current standard.

In considering the application of the air-related IQ loss framework to the current evidence as discussed above in section II.B.1, the Administrator concludes that in areas projected to just meet the current standard, the quantitative estimates of IQ loss associated with air-related Pb indicate risk of a magnitude that in his judgment is significant from a public health perspective, and that this evidence-based framework supports a conclusion that the current standard does not protect public health with an adequate margin of safety. Further, the Administrator believes that the current evidence indicates the need for a standard level that is substantially lower than the current level to provide increased public health protection, especially for at-risk groups, including most notably children, against an array of effects, most importantly including effects on the developing nervous system.

In addition to the primary consideration given to the available evidence, the Administrator has also

taken into consideration the Agency's exposure and risk assessments to help inform his evaluation of the adequacy of the current standard. As at the time of proposal, the Administrator believes the results of those assessments provide some further perspective on the potential magnitude of air-related IQ loss and thus inform his judgment on the adequacy of the current standard to protect against health effects of concern. While taking into consideration the uncertainties and limitations in the risk assessments, the Administrator again observes that in areas projected to just meet the current standard, the quantitative estimates of IQ loss associated with air-related Pb indicate risk of a magnitude that in his judgment is significant from a public health perspective. Further, although the current monitoring data indicate few areas with airborne Pb near or just exceeding the current standard, the Administrator recognizes significant limitations with the current monitoring network and thus there is the potential that the prevalence of such Pb concentrations may be underestimated by currently available data. The Administrator thus finds that the exposure and risk estimates provide additional support to the evidence-based conclusion, reached above, that the current standard needs to be revised.

Based on these considerations, and consistent with the CASAC Panel's unanimous conclusion that EPA needed to substantially lower the level of the primary Pb NAAQS to fully protect the health of children and adult populations, the Administrator agrees with the vast majority of public commenters that the current standard is not sufficient and thus not requisite to protect public health with an adequate margin of safety and that revision is needed to provide increased public health protection, especially for members of at-risk groups.

C. Conclusions on the Elements of the Standard

The four elements of the standard—indicator, averaging time, form, and level—serve to define the standard and must be considered collectively in evaluating the health and welfare protection afforded by the standard. In considering comments on the proposed revisions to the current primary Pb standard, as discussed in the following sections, EPA considers each of the four elements of the standard as to how they might be revised to provide a primary standard for Pb that is requisite to protect public health with an adequate margin of safety. The basis for the proposed decision, comments on the

proposal, and the Administrator's final decision on indicator are discussed in section II.C.1, on averaging time and form in section II.C.2, and on a level for the primary Pb NAAQS in section II.C.3.

1. Indicator

a. Basis for Proposed Decision

In setting the current standard in 1978, EPA established Pb-TSP as the indicator.⁵⁹ In comments on the 1977 proposal, EPA received comments expressing concern that because only a fraction of airborne particulate matter is respirable, an air standard based on total air Pb would be unnecessarily stringent and therefore the standard should be limited to respirable size Pb particulate matter. Such a standard might have led to a Pb NAAQS with an indicator of Pb in particulate matter less than or equal to 10 μm in diameter (Pb-PM₁₀)⁶⁰ as the indicator. The Agency considered this recommendation, but did not accept it. Rather, EPA reemphasized that larger particles of air-related Pb contribute to Pb exposure through ingestion pathways, and that ingestion pathways, including those associated with deposition of Pb from the air, can be a significant component of Pb exposures. In addition to these ingestion exposure pathways, nonrespirable Pb that has been emitted to the ambient air may, at some point, become respirable through weathering or mechanical action, thus subsequently contributing to inhalation exposures. EPA concluded that total airborne Pb, both respirable and nonrespirable fractions, should be addressed by the air standard (43 FR 46251). The federal reference method (FRM) for Pb-TSP specifies the use of the high-volume sampler.

In the 1990 Staff Paper, this issue was again considered in light of information regarding limitations of the high-volume sampler used for the Pb-TSP measurements, such as the variability

⁵⁹The current standard specifies the measurement of airborne Pb with a high-volume TSP federal reference method (FRM) sampler with atomic absorption spectrometry of a nitric acid extract from the filter for Pb, or with an approved equivalent method (40 CFR 50.12, Appendix G).

⁶⁰For simplicity, the discussion in this notice speaks as if PM₁₀ samplers have a sharp size cut-off. In reality, they have a size selection behavior in which 50% of particles 10 microns in size are captured, with a progressively higher capture rate for smaller particles and a progressively lower capture rate for larger particles. The ideal capture efficiency curve for PM₁₀ samplers specifies that particles above 15 microns not be captured at all, although real samplers may capture a very small percentage of particles above 15 microns. TSP samplers have 50% capture points in the range of 25 to 50 microns (Wedding *et al.*, 1977), which is broad enough to include virtually all sizes of particles capable of being transported any significant distance from their source except under extreme wind events.

discussed below. The continued use of Pb-TSP as the indicator was recommended in the Staff Paper (USEPA, 1990b):

Given that exposure to lead occurs not only via direct inhalation, but via ingestion of deposited particles as well, especially among young children, the hi-vol provides a more complete measure of the total impact of ambient air lead. * * * Despite its shortcomings, the staff believes the high-volume sampler will provide a reasonable indicator for determination of compliance * * *

As in the past, and discussed in the proposal, the evidence available today indicates that Pb in all particle size fractions, not just respirable Pb particles, contributes to Pb in blood and to associated health effects. Further, the evidence and exposure/risk estimates in the current review indicate that ingestion pathways dominate air-related exposure. Lead is unlike other criteria pollutants, where inhalation of the airborne pollutant is the key contributor to exposure. For Pb it is the quantity of Pb in ambient particles with the potential to deposit indoors or outdoors, thereby leading to a role in ingestion pathways, that is the key contributor to air-related exposure. The evidence additionally indicates that airborne Pb particles are transported long or short distances depending on their size, such that the representation of larger particles is greater at locations near sources than at sites not directly influenced by sources.

In the current review, the Staff Paper evaluated the evidence with regard to the indicator for a revised primary standard. This evaluation included consideration of the basis for using Pb-TSP as the current indicator, information regarding the sampling methodology for the current indicator, and CASAC advice with regard to indicator (described below). Based on this evaluation, the Staff Paper recommended retaining Pb-TSP as the indicator for the primary standard. The Staff Paper also recommended activities intended to encourage collection and development of datasets that will improve our understanding of national and site-specific relationships between Pb-PM₁₀ (collected by low-volume sampler)⁶¹ and Pb-TSP to support a more informed consideration of indicator during the next review. The Staff Paper suggested that such activities might include describing a federal

⁶¹"Low-volume PM₁₀ sampling" refers to sampling using any of a number of monitor models that draw 16.67 liters/minute (1 m³/hour) of air through the filter, in contrast to "high-volume" sampling of either TSP or PM₁₀ in which the monitor draws 1500 liters/minute (90 m³/hour).

equivalence method (FEM) in terms of PM₁₀ and allowing its use for a TSP-based standard in certain situations, such as where sufficient data are available to adequately demonstrate a relationship between Pb-TSP and Pb-PM₁₀ or, in combination with more limited Pb-TSP monitoring, in areas where Pb-TSP data indicate Pb levels well below the NAAQS level.

The ANPR further identified issues and options associated with consideration of the potential use of Pb-PM₁₀ data for judging attainment or nonattainment with a Pb-TSP NAAQS. These issues included the impact of controlling Pb-PM₁₀ for sources predominantly emitting Pb in particles larger than those captured by PM₁₀ monitors (i.e., ultra-coarse)⁶², and the options included potential application of Pb-PM₁₀ FRM/FEMs at sites with established relationships between Pb-TSP and Pb-PM₁₀, and use of Pb-PM₁₀ data, with adjustment, as a surrogate for Pb-TSP data. The ANPR broadly solicited comment in these areas.

As noted in the proposal, the Agency in setting the standard and CASAC in providing their advice (described below) both recognized that ingestion pathways are important to air-related Pb exposures and that Pb particles contributing to these pathways include ultra-coarse particles. Thus, as noted in the proposal, choosing the appropriate indicator requires consideration of the impact of the indicator on the protection provided from exposure to air-related Pb of all particle sizes, including ultra-coarse particles, by both the inhalation and ingestion pathways.

As discussed in the proposal (sections II.E.1 and V.A.), the Agency recognizes the body of evidence indicating that the high-volume Pb-TSP sampling methodology contributes to imprecision in resultant Pb measurements due to variability in the efficiency of capture of particles of different sizes and thus, in the mass of Pb measured. Variability is most substantial in samples with a large portion of Pb particles greater than 10 microns, such as those samples collected near sources with emissions of ultra-coarse particles. As noted in the proposal, this variability contributes to a clear risk of underestimating the ambient level of total Pb in the air,

⁶²In this notice, we use "ultra-coarse" to refer to particles collected by a TSP sampler but not by a PM₁₀ sampler. We note that CASAC has variously also referred to these particles as "very coarse" or "larger coarse-mode" particles. This terminology is consistent with the traditional usage of "fine" to refer to particles collected by a PM_{2.5} sampler, and "coarse" to refer to particles collected by a PM₁₀ sampler but not by a PM_{2.5} sampler, recognizing that there will be some overlap in the particle sizes in the three types of collected material.

especially in areas near sources of ultra-coarse particles, by underestimating the amount of the ultra-coarse particles. This variability also contributes to a risk of not consistently identifying sites that fail to achieve the standard.

The Agency also recognizes, as discussed in the proposal, that the low-volume PM₁₀ sampling methodology does not exhibit such variability⁶³ due both to increased precision of the monitor and the decreased spatial variation of Pb-PM₁₀ concentrations, associated with both the more widespread distribution of PM₁₀ sources and aerodynamic characteristics of particles of this size class which contribute to broader distribution from sources. Accordingly, there is a lower risk of error in measuring the ambient Pb in the PM₁₀ size class than there is risk of error in measuring the ambient Pb in the TSP size class using Pb TSP samplers. We additionally noted in the proposal that, since Pb-PM₁₀ concentrations have less spatial variability, such monitoring data may be representative of Pb-PM₁₀ air quality conditions over a larger geographic area (and larger populations) than would Pb-TSP measurements. The larger scale of representation for Pb-PM₁₀ would mean that reported measurements of this indicator, and hence designation outcomes, would be less sensitive to exact monitor siting than with Pb-TSP as the indicator.

As discussed in the proposal, however, there is a different source of error associated with the use of Pb-PM₁₀ as the indicator, in that larger Pb particles not captured by PM₁₀ samplers would not be measured. As noted above, these particles contribute to the health risks posed by air-related Pb, especially in areas influenced by sources of ultra-coarse particles. As discussed in the proposal, there is uncertainty as to the degree to which control strategies put in place to meet a NAAQS with a Pb-PM₁₀ indicator would be effective in controlling ultra-coarse Pb-containing particles. Additionally, the fraction of Pb collected with a TSP sampler that would not be collected by a PM₁₀ sampler varies depending on proximity to sources of ultra-coarse Pb particles and the size mix of the particles they emit, as well as the sampling variability inherent in the method discussed above.

⁶³ Low-volume PM₁₀ samplers are equipped with an omni-directional (cylindrical) inlet, which reduces the effect of wind direction, and a sharp particle separator which excludes most of the particles greater than 10–15 microns in diameter whose collection efficiency is most sensitive to wind speed. Also, in low-volume samplers, the filter is protected from post-sampling contamination.

Thus, this error is of most concern in locations in closer proximity to such sources, which may also be locations with some of the highest ambient air levels.

Accordingly, we stated in the proposal that it is reasonable to consider continued use of a Pb-TSP indicator, focusing on the fact that it specifically includes ultra-coarse Pb particles among the particles collected, all of which are of concern and need to be addressed in protecting public health from air-related exposures. We additionally recognized that some State, local, or tribal monitoring agencies, or other organizations, for the sake of the advantages noted above, and described more fully in the proposal, may wish to deploy low-volume Pb-PM₁₀ samplers rather than Pb-TSP samplers. Thus, we also considered several approaches that would allow the use of Pb-PM₁₀ data in conjunction with retaining Pb-TSP as the indicator. These approaches, discussed more fully in the proposal (sections II.E.1 and IV), include the development and use of site-specific scaling factors and the use of default scaling factors for particular categories of monitoring sites (e.g., source-oriented, non-source-oriented). Additionally, we solicited comment on changing the indicator to Pb in PM₁₀, in recognition of the potential benefits of such a revision discussed above.

In their advice to the Agency during the current review, the CASAC Pb Panel provided recommendations to the Agency on the indicator for a revised standard in conjunction with their recommendations for revisions to level and averaging time. As noted above in section II.B and below in section II.C.3, the Panel recommended a significant lowering of the level for the standard, which they noted would lead to a requirement for additional monitoring over that currently required, with distribution of monitors over a much larger area. In consideration of this, prior to the proposal, the CASAC Pb Panel, as well as the majority of the CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee, recommended that EPA consider a change in the indicator to PM₁₀, utilizing low-volume PM₁₀ sampling (Henderson, 2007a, 2007b, 2008a, 2008b; Russell, 2008a). They found support for their recommendation in a range of areas, as summarized in the proposal (73 FR 29230). In advising a revision to the indicator, CASAC also stated that they “recognize the importance of coarse dust contributions to total Pb ingestion and acknowledge that TSP sampling is likely to capture additional very coarse particles which

are excluded by PM₁₀ samplers” (Henderson 2007b). They suggested that an adjustment of the NAAQS level would accommodate the loss of these ultra-coarse Pb particles, and that development of such a quantitative adjustment might appropriately be based on concurrent Pb-PM₁₀ and Pb-TSP sampling data⁶⁴ (Henderson, 2007a, 2007b, 2008a).

For reasons discussed in the proposal and recognized above, and taking into account information and assessments presented in the Criteria Document, Staff Paper, and ANPR, the advice and recommendations of CASAC and of members of the CASAC AAMM Subcommittee, and public comments received prior to proposal, the Administrator proposed to retain the current indicator of Pb-TSP, measured by the current FRM, a current FEM, or an FEM approved under the proposed revisions to 40 CFR part 53. The Administrator also proposed an expansion of the measurements accepted for determining attainment or nonattainment of the Pb NAAQS to provide an allowance for use of Pb-PM₁₀ data, measured by the new low-volume Pb-PM₁₀ FRM specified in the proposed appendix Q to 40 CFR part 50 or by a FEM approved under the proposed revisions to 40 CFR part 53, with site-specific scaling factors. The Administrator also solicited comment on providing States the option of using default scaling factors instead of conducting the testing that would be needed to develop the site-specific scaling factors. Additionally, the Administrator invited comment on an alternative option of revising the indicator to Pb-PM₁₀.

b. Comments on Indicator

In considering comments received on the proposal, EPA first notes the advice provided by CASAC concerning the proposal in a July 2008 letter to the Administrator (Henderson, 2008b). In that advice, CASAC repeated their prior recommendations regarding the indicator and level of the revised standard, and emphasized that these recommendations “were based, in part on an *assumption* that the level of the primary Pb NAAQS would be ‘substantially’ lowered to the EPA Staff-

⁶⁴ In their advice, CASAC recognized the potential for site-to-site variability in the relationship between Pb-TSP and Pb-PM₁₀ (Henderson, 2007a, 2007b). They also stated in their September 2007 letter, “The Panel urges that PM₁₀ monitors, with appropriate adjustments, be used to supplement the data. * * * A single quantitative adjustment factor could be developed from a short period of collocated sampling at multiple sites; or PM₁₀ Pb/TSP Pb ‘equivalency ratio’ could be determined on a regional or site-specific basis”.

recommended range (with an TSP indicator) of between 0.1 to 0.2 $\mu\text{g}/\text{m}^3$ as an upper bound and 0.02 to 0.05 $\mu\text{g}/\text{m}^3$ as a lower bound (with the added consideration that the selection be made somewhat 'conservatively' within this range to accommodate the potential loss of ultra-coarse lead with a PM_{10} Pb indicator)" (emphasis in original) (Henderson, 2008b). They additionally noted that "at most population-oriented monitoring sites, levels of PM_{10} Pb are essentially the same as TSP Pb, but at source-oriented monitoring sites with high coarse mode particulate lead emissions, TSP Pb was roughly twice as high as PM_{10} Pb" and that this "factor-of-two difference * * * could be readily accommodated by considering a slightly more conservative upper bound of 0.1 $\mu\text{g}/\text{m}^3$ rather than 0.2 $\mu\text{g}/\text{m}^3$ " (Henderson, 2008b). The CASAC panel concluded that "a transition to a PM_{10} indicator would be preferable, but only at a level conservatively below an upper bound of 0.2 $\mu\text{g}/\text{m}^3$ or lower" (Henderson, 2008b). EPA interprets this advice on the whole to be supportive of Pb-TSP as the indicator for any standard level greater than 0.10 $\mu\text{g}/\text{m}^3$, particularly when the level has been selected with recognition of the inclusion of ultra-coarse particles in Pb-TSP measurements.

The EPA received many public comments on issues related to the indicator for Pb. The large majority of public comments were in support of EPA's proposal to retain Pb-TSP as the indicator for Pb. Represented in this group were many state agencies, as well as some Tribes and tribal environmental agencies, and local environmental agencies. Many commenters supported Pb-TSP as the indicator regardless of a level for the standard, variously citing evidence also cited by EPA in the proposal notice, such as the relevance of all sizes of Pb particles to exposures, blood Pb levels and effects and the omission of ultra-coarse particles with PM_{10} samples. In support of Pb-TSP as the indicator, a few commenters also stated that air-to-blood ratios used in the evidence-based framework for considering a level for the standard are generally based on Pb-TSP data. Some comments, similar to CASAC, supported Pb-TSP as the indicator for levels above the lower end of the proposed range (*i.e.*, above 0.10 $\mu\text{g}/\text{m}^3$), including a level of 0.15 $\mu\text{g}/\text{m}^3$. One commenter (NESCAUM) specifically recommended an indicator of Pb-TSP for a NAAQS with a level of 0.15 $\mu\text{g}/\text{m}^3$, recommending a revision to Pb- PM_{10} only if some other, much lower, level (0.05 $\mu\text{g}/\text{m}^3$) was selected.

EPA generally agrees with CASAC and the large number of public commenters with regard to the appropriateness of a Pb-TSP indicator for the level of the standard identified below. This conclusion is supported by the current scientific evidence, discussed above in section II.C.1.a, recognizing the range of particle sizes inclusive of ultra-coarse particles which contribute to Pb exposures, evidence of the presence of ultra-coarse particles in some areas, particularly near sources, and variation in the relationship between Pb-TSP and Pb- PM_{10} at such sites, which together contribute to uncertainty about the sufficiency of public health protection associated with a Pb- PM_{10} standard at the level of 0.15 $\mu\text{g}/\text{m}^3$.

A few commenters (including the National Association of Clean Air Agencies) recommended transition to a Pb- PM_{10} indicator for the standard at levels below 0.2 $\mu\text{g}/\text{m}^3$. These commenters stated that low-volume PM_{10} samplers measure Pb much more accurately than high-volume TSP samplers, referring to EPA's discussion in the proposal that recognized the variability of Pb-TSP measurements associated with wind speed and direction, and also referred to support among CASAC AAMM members and the July 2008 comments from CASAC on indicator. These commenters, however, did not provide rationales as to why a Pb- PM_{10} indicator might be justified in light of the health considerations identified by EPA in the proposal. Further, as noted above, EPA interprets CASAC's July 2008 comments on the whole to be supportive of Pb-TSP as the indicator for any standard level greater than 0.10 $\mu\text{g}/\text{m}^3$.

A few commenters, including both state and industry commenters, recommended transition to Pb- PM_{10} without reference to a particular level. Some of these commenters, like CASAC, noted concerns with the high-volume TSP sampling methodology and advantages of the PM_{10} monitoring method in reduced variability of the measurements. Two industry commenters additionally suggested consideration of an indicator based on Pb- $\text{PM}_{2.5}$, stating as their rationale that almost all airborne Pb in air is in "the small size fraction", ambient sampling for PM_{10} and $\text{PM}_{2.5}$ size fractions is already required, and precision which might be greater with PM_{10} monitors is needed for "lower" standards. None of this group of commenters provided a rationale as to why a Pb- PM_{10} indicator might be justified in light of the health

considerations identified by EPA in the proposal.

EPA disagrees with this group of commenters, noting the potential presence at some sites of particles that would not be captured by PM_{10} or $\text{PM}_{2.5}$ samplers yet would contribute to human exposure to Pb and associated health effects. As discussed below, EPA believes that, in light of the evidence of all particle sizes of Pb contributing to blood Pb and health effects by both ingestion and inhalation pathways, the available data on relationships between Pb-TSP and Pb- PM_{10} (discussed in section II.E.1 of the proposal and in section IV.C below) are inadequate to support development of a Pb- PM_{10} -based NAAQS that would provide sufficient but not more than necessary protection of public health, with an adequate margin of safety, across the wide variety of ambient Pb circumstances affecting this relationship, and at the level selected by the Administrator. Although, EPA did not consider relationships between Pb-TSP and Pb- $\text{PM}_{2.5}$ in the proposal, EPA notes the more restricted particle size range associated with $\text{PM}_{2.5}$ measurements than with PM_{10} measurements, and the associated omission of substantially more Pb that contributes to blood Pb and associated health effects.⁶⁵

A number of comments were received regarding the potential use of site-specific or default scaling factors to relate Pb- PM_{10} data to a Pb-TSP-based standard, with the large majority of these comments being opposed to these options. With regard to site-specific scaling factors, commenters note the temporal variability of the relationship between Pb-TSP and Pb- PM_{10} at individual sites, raise concerns about defensibility of attainment and nonattainment decisions based on the use of scaling factors, and question whether there are benefits associated with allowance of such scaling factors.

As discussed below in section IV, EPA generally agrees with these commenters and has not adopted a provision allowing the use of site-specific scaling factors. A few commenters supported the use of default scaling factors that would be developed by EPA, as an approach that would be most easily implemented. EPA, however, concludes that the limited available data on relationships between Pb-TSP and Pb- PM_{10} are inadequate to support development of

⁶⁵ Data from collocated TSP and $\text{PM}_{2.5}$ monitors are generally presented in the Staff Paper (section 2.3.5).

appropriate default scaling factors as described below in section IV.

Although commenters generally opposed the use of scaling factors that would relate Pb-PM₁₀ data to specific corresponding levels of Pb-TSP for all levels of Pb-PM₁₀ and for all purposes related to implementation of the standard, many commenters supported some uses of Pb-PM₁₀ monitoring with a Pb-TSP-based NAAQS. One example of such a use that was suggested by commenters is at sites well below the standard and in areas without ultra-coarse particle sources. EPA agrees with these commenters that such a limited use of Pb-PM₁₀ data in such areas is desirable in light of the advantages of Pb-PM₁₀ monitoring described in section II.C.1.a above, and does not raise the concerns discussed above about sufficiency of public health protection when considering ambient air Pb concentrations that are closer to the level of the standard. Such uses allowed by this rulemaking are recognized below in section II.C.1.c and discussed more fully in sections IV and V below.

Some States noted agreement with the view expressed by EPA in the proposal that low-volume TSP sampling offers advantages over high-volume TSP sampling (the federal reference method for Pb). Issues regarding the sample collection method for the TSP indicator are discussed in section V below.

c. Conclusions on Indicator

Having carefully considered the public comments, as discussed above, and advice and recommendations from CASAC on this issue, the Administrator concludes that it is appropriate to retain Pb-TSP as the indicator for the Pb NAAQS at this time. The Administrator agrees with CASAC that use of a Pb-TSP indicator is necessary to provide sufficient public health protection from the range of particle sizes of ambient air Pb, including ultra-coarse particles, in conjunction with the selected level (see section II.C.3 below). The Administrator recognizes that Pb in all particle sizes contributes to Pb in blood and associated health effects (as discussed in section II.E.1 of the proposal and II.C.1.a above). The Administrator additionally notes that selection of the standard level does not include an adjustment or accommodation for the difference in Pb particles captured by TSP and PM₁₀ monitors which, as discussed elsewhere (section II.E.1 of the proposal, section II.C.1.a above, and section IV.D below) may be on the order of a factor of two in some areas. The Administrator also recognizes the quite limited dataset,

particularly for source-oriented sites,⁶⁶ that is available to the Agency from which to characterize the relationship between Pb-TSP and Pb-PM₁₀ for purposes of identifying the appropriate level for a Pb-PM₁₀ based standard. Further, the Administrator recognizes there is uncertainty with regard to whether a Pb-PM₁₀-based NAAQS would also effectively control ultra-coarse Pb particles, which, as noted above, may have a greater presence in areas near sources where Pb concentrations are highest. In light of these considerations, the Administrator concludes that it is appropriate to retain Pb-TSP as the indicator to protect against health risks from ultra coarse particulate Pb emitted to ambient air.

With regard to the use of scaling factors to relate Pb-PM₁₀ data to a Pb-TSP indicator, the Administrator concludes that the limited available data on relationships between Pb-TSP and Pb-PM₁₀ are inadequate to support a use of scaling factors to relate all valid Pb-PM₁₀ measurements to specific levels of Pb-TSP concentrations for all purposes of a Pb-TSP-based standard.

The Administrator concurs with the comments from CASAC and public commenters that recognize the potential value of providing a role for Pb-PM₁₀ in the monitoring required for a Pb-TSP standard. Such comments emphasize the similarity of Pb-TSP and Pb-PM₁₀ measurements at non-source-oriented locations, while recognizing the potential for differences at sites near sources, and recognize the sufficiency of public health protection when Pb-PM₁₀ levels are well below the level of the standard. EPA believes that use of Pb-PM₁₀ measurements at sites not influenced by sources of ultra-coarse Pb and where Pb concentrations are well below the standard would take advantage of the increased precision of these measurements and decreased spatial variation of Pb-PM₁₀ concentrations, without raising the same concerns over a lack of protection against health risks from all particulate Pb emitted to the ambient air that support retention of Pb-TSP as the indicator. Accordingly, the Administrator is expanding the types of measurements which may be considered with regard to implementation of the Pb NAAQS. This expansion, as discussed more fully in sections IV and V below, provides a role for Pb-PM₁₀ data under

certain limited circumstances and with certain conditions. The circumstances and conditions under which such data are allowed, as described in sections IV and V below, are those in which the Pb concentrations are expected to be substantially below the standard and ultra-coarse particles are not expected to be present.

2. Averaging Time and Form

a. Basis for Proposed Decision

The averaging time and form of the current standard is a not-to-be-exceeded or maximum value, averaged over a calendar quarter. The basis for this averaging time and form reflects consideration of the evidence available when the Pb NAAQS were promulgated in 1978. At that time, the Agency had concluded that the level of the standard, 1.5 µg/m³, would be a "safe ceiling for indefinite exposure of young children" (43 FR 46250), and that the slightly greater possibility of elevated air Pb levels for shorter periods within the quarterly averaging period, as contrasted to the monthly averaging period proposed in 1977 (43 FR 63076), was not significant for health. These conclusions were based in part on the Agency's interpretation of the health effects evidence as indicating that 30 µg/dL was the maximum safe level of blood Pb for an individual child, and the Agency's views that the distribution of air concentrations made it unlikely there could be sustained periods greatly above the average value and that the multipathway nature of Pb exposure lessened the impact of short-term changes in air concentrations of Pb.

In the 1990 Staff Paper, this issue was again considered in light of the evidence available at that time. The 1990 Staff Paper concluded that "[a] monthly averaging period would better capture short-term increases in lead exposure and would more fully protect children's health than the current quarterly average" (USEPA, 1990b). The 1990 Staff Paper further concluded that "[t]he most appropriate form of the standard appears to be the second highest monthly average in a 3-year span. This form would be nearly as stringent as a form that does not permit any exceedances and allows for discounting of one 'bad' month in 3 years which may be caused, for example, by unusual meteorology." In their review of the 1990 Staff Paper, the CASAC Pb Panel concurred with the staff recommendation to express the lead

NAAQS as a monthly standard not to be exceeded more than once in three years.

As summarized in section II.A above and discussed in detail in the Criteria

⁶⁶ As described in the proposal (73 FR29233), collocated data from source-oriented sites were available from just three locations near three different types of sources and include data from as long ago as 1988 (Schmidt and Cavender, 2008). A limited amount of additional data has been provided in comments on the proposal.

Document, the currently available health effects evidence⁶⁷ indicates a wider variety of neurological effects, as well as immune system and hematological effects, associated with substantially lower blood Pb levels in children than were recognized when the standard was set in 1978. Further, the health effects evidence with regard to characterization of a threshold for adverse effects has changed since the standard was set in 1978, as have the Agency's views on the characterization of a safe blood Pb level.⁶⁸

In the proposal (section II.E.2), we noted various aspects of the current evidence that are pertinent to consideration of the averaging time and form for the Pb standard. We noted those aspects pertaining to the human physiological response to changes in Pb exposures and also aspects pertaining to the response of air-related Pb exposure pathways to changes in airborne Pb. The latter aspects are more complex for Pb than for other criteria pollutants because the exposure pathways for air-related Pb include both inhalation pathways and deposition-related ingestion pathways, which is not the case for other criteria pollutants. The persistence of Pb in multiple media and in the body⁶⁹ provides an additional complication in the case of Pb.

With regard to the human physiological response to changes in Pb exposures, as summarized in the Staff Paper and discussed in more detail in the Criteria Document, the evidence indicates that blood Pb levels respond quickly to increased Pb exposures, such that an abrupt increase in Pb uptake results in increased blood Pb levels. Contributing to this response is the absorption through the lungs and the gastrointestinal tract (which is both greater and faster in children as compared to adults), and the rapid distribution (within days), once absorbed, from plasma to red blood cells and throughout the body. As noted in the proposal, while the evidence with regard to sensitive neurological effects is limited in what it indicates regarding the specific duration of exposures associated with effects, it indicates both the sensitivity of the first three years of

life and a sustained sensitivity throughout the lifespan as the human central nervous system continues to mature and be vulnerable to neurotoxicants (CD, section 8.4.2.7). In general, the evidence indicates the potential importance of exposures on the order of months (CD, section 5.3). The evidence also indicates increased vulnerability during some developmental periods (e.g., prenatal), the length of which indicates a potential importance of exposures as short as weeks to months.

As noted in the proposal with regard to the response of human exposure pathways to changes in airborne Pb, data from NHANES II and an analysis of the temporal relationship between gasoline consumption and blood Pb indicate a month lag between changes in Pb emissions from leaded gasoline and the response of children's blood Pb levels and the number of children with elevated blood Pb levels (EPA, 1986a, p. 11–39; Rabinowitz and Needleman, 1983; Schwartz and Pitcher, 1989; USEPA, 1990b). As noted in the proposal with regard to consideration of air-related Pb exposure pathways, the evidence described in the Criteria Document and the quantitative risk assessment indicate that today ingestion of dust can be a predominant exposure pathway for young children to air-related Pb. Further, the proposal noted that a recent study of dustfall near an open window in New York City indicates the potential for a response of indoor dust Pb loading to ambient airborne Pb on the order of weeks (Caravanos *et al.*, 2006; CD, p. 3–28).

In the proposal, we additionally noted that the health effects evidence identifies varying durations in exposure that may be relevant and important to the selection of averaging time. In light of uncertainties in aspects such as response times of children's exposure to airborne Pb, we recognized, as in the past, that this evidence provides a basis for consideration of both quarterly and monthly averaging times.

In considering both averaging time and form in the proposal, EPA combined the current calendar quarter averaging time with the current not-to-be exceeded (maximum) form and also combined a monthly averaging time with a second maximum form, so as to provide an appropriate degree of year-to-year stability that a maximum monthly form would not provide. We also observed in the proposal (73 FR 29235) that the second maximum monthly form provides a roughly comparable degree of protection on a broad national scale to the current maximum calendar quarter averaging

time and form. This observation was based on an analysis of the 2003–2005 monitoring data set that found a roughly similar number of areas not likely to attain alternate levels of the standard for these two combinations of averaging time and form (although a slightly greater number of sites would likely exceed the levels based on the second maximum monthly average). We also noted, however, that the relative protection provided by these two averaging times and forms may differ from area to area. Moreover, we noted that control programs to reduce average Pb concentrations across a calendar quarter may not have the same protective effect as control programs aimed at reducing average Pb concentrations on a monthly basis. Given the limited scope of the current monitoring network, which lacks monitors near many significant Pb sources, and uncertainty about Pb source emissions and possible controls, the proposal noted that it is difficult to more quantitatively compare the protectiveness of standards defined in terms of the maximum calendar quarter average versus the second maximum monthly average.

In their advice to the Agency prior to the proposal, CASAC recommended that consideration be given to changing from a calendar quarter to a monthly averaging time (Henderson, 2007a, 2007b, 2008a). In making that recommendation, CASAC has emphasized support from studies that suggest that blood Pb concentrations respond at shorter time scales than would be captured completely by a quarterly average. With regard to form of the standard, CASAC has stated that one could “consider having the lead standards based on the second highest monthly average, a form that appears to correlate well with using the maximum quarterly value”, while also indicating that “the most protective form would be the highest monthly average in a year” (Henderson, 2007a). Among the public comments the Agency received on the discussion of averaging time in the ANPR, the majority concurred with the CASAC recommendation for a revision to a monthly averaging time.

On an additional point related to form, the 1990 Staff Paper and the Staff Paper for this review both recommended that the Administrator consider specifying that compliance with the NAAQS be evaluated over a 3-year period. As described in the proposal, a monitor would be considered to be in violation of the NAAQS based on a 3-year period, if, in any of the three previous calendar years with sufficiently complete data (as

⁶⁷ The differing evidence and associated strength of the evidence for these different effects is described in the Criteria Document.

⁶⁸ For example, EPA recognizes today that “there is no level of Pb exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects” (CD, p. 8–63).

⁶⁹ Lead accumulates in the body and is only slowly removed, with bone Pb serving as a blood Pb source for years after exposure and as a source of fetal Pb exposure during pregnancy (CD, sections 4.3.1.4 and 4.3.1.5).

explained in detail in section IV of the proposal), the value of the selected averaging time and form statistic (e.g., second maximum monthly average or maximum quarterly average) exceeded the level of the NAAQS. Thus, a monitor, initially or after once having violated the NAAQS, would not be considered to have attained the NAAQS until three years have passed without the level of the standard being exceeded. In discussing the merits of this approach in the proposal, we noted that variations in Pb source emissions and in meteorological conditions contribute to the potential for a monitor to record an exceedance of a particular level in one period but not in another, even if no permanent controls have been applied to the nearby source(s). We further noted that it would potentially reduce the public health protection afforded by the standard if areas fluctuated in and out of nonattainment status so frequently that States do not have opportunity and incentive to identify sources in need of more emission control and to require those controls to be put in place. We noted that the 3-year approach would help ensure that areas initially found to be violating the NAAQS have effectively controlled the contributing lead emissions before being redesignated to attainment.

At the time of proposal, the Administrator considered the information summarized above (described in more detail in Criteria Document and Staff Paper), as well as the advice from CASAC and public comments on the ANPR. The Administrator recognized that there is support in the evidence for an averaging time as short as monthly consistent with the following observations: (1) The health evidence indicates that very short exposures can lead to increases in blood Pb levels, (2) the time period of response of indoor dust Pb to airborne Pb can be on the order of weeks, and (3) the health evidence indicates that adverse effects may occur with exposures during relatively short windows of susceptibility, such as prenatally and in developing infants.⁷⁰ The Administrator also recognized

limitations and uncertainties in the evidence including the limited available evidence specific to the consideration of the particular duration of sustained airborne Pb levels having the potential to contribute to the adverse health effects identified as most relevant to this review, as well as variability in the response time of indoor dust Pb loading to ambient airborne Pb.

Based on these considerations and the air quality analyses summarized above, the Administrator concluded that this information provided support for an averaging time no longer than a calendar quarter. Further, the Administrator recognized that if substantial weight is given to the evidence of even shorter times for response of key exposure pathways, blood Pb, and associated effects to airborne Pb, a monthly averaging time may be appropriate. Accordingly, the Administrator proposed two options with regard to the form and averaging time for the standard, and with both he proposed that three years be the time period evaluated in considering attainment. One option was to retain the current not-to-be-exceeded form with an averaging time of a calendar quarter, and the second option was to revise the averaging time to a calendar month and the form to the second highest monthly average.

b. Comments on Averaging Time and Form

In considering comments on averaging time for the revised standard, the Administrator first notes that the CASAC Pb Panel, in their comments on the proposal, restated their previous recommendation to reduce the averaging time from calendar quarter to monthly (Henderson, 2008b). In repeating this recommendation in their July 2008 letter, CASAC noted that “adverse effects could result from exposures over as few as 30 days’ duration” (Henderson, 2008b). Many public commenters also supported the option of a monthly averaging time, generally placing great weight on the recommendation of CASAC. Some of these commenters also provided additional reasons for their support for a monthly averaging time. These reasons variously included concerns regarding the lack of a “safe” blood Pb level; evidence that children’s blood Pb concentrations respond over time periods shorter than three months; evidence for very short windows of susceptibility to some effects during prenatal and infant development; concerns that dust Pb responds relatively quickly to air Pb; and concerns for large near-source temporal

variability in airborne Pb concentrations and the exposure and risk contributed by “high” months, which, given the persistence of Pb, may occur for some time subsequent to the “high” month.

Some other commenters supported retaining the current quarterly averaging time stating that the proposed option of a monthly averaging time is not well founded in the evidence. In supporting this view, the commenters variously stated that no evidence has been presented to show a relationship between a shorter-term air concentration and air-related blood Pb levels contributing to neurological effects; there is little known regarding the relationship between neurocognitive effects such as IQ and a monthly exposure period; there is uncertainty regarding the time over which indoor dust, a key pathway for air-related Pb, responds to indoor air; and, the World Health Organization and European Community air criteria or guidelines for Pb are based on a yearly average.

In considering advice from CASAC and comments from the public, EPA recognizes that the evidence indicates the potential for effects pertinent to this review to result from Pb exposures (e.g., from ingestion and inhalation routes) on the order of one to three months, as summarized in section II.C.2.a and described more fully in the proposal. EPA additionally notes the greater complexity inherent in considering the averaging time for the primary Pb standard, as compared to other criteria pollutants, due to the persistence and multimedia nature of Pb and its multiple pathways of human exposure. Accordingly, in considering averaging time in this review, in addition to considering the evidence with regard to exposure durations related to blood Pb levels associated with neurological effects, a key consideration for the Agency is how closely Pb exposures via the major air-related Pb exposure pathways reflect temporal changes in ambient air Pb concentrations, recognizing that the averaging period involves the duration over time of ambient air concentrations, and is not a direct measure of the duration or degree of exposure.

With regard to exposure durations related to blood Pb levels associated with neurocognitive effects, EPA notes that, as described in section II.A.2.c above, the concurrent blood Pb metric (i.e., blood Pb measured at the time of IQ test) has been found to have the strongest association with IQ response. Further, a concurrent blood Pb measurement is most strongly related to a child’s exposure events within the past few (e.g., one to three) months. This

⁷⁰The health evidence with regard to the susceptibility of the developing fetus and infants is well documented in the evidence as described in the 1986 Criteria Document, the 1990 Supplement (e.g. chapter III) and the 2006 Criteria Document. For example, “[n]eurobehavioral effects of Pb-exposure early in development (during fetal, neonatal, and later postnatal periods) in young infants and children ≤7 years old) have been observed with remarkable consistency across numerous studies involving varying study designs, different developmental assessment protocols, and diverse populations.” (CD, p. E-9)

is supported by multiple aspects of the evidence (e.g., CD, chapter 4; USEPA, 1986a, chapter 11), including evidence cited by CASAC and commenters, such as the findings of the significant contribution to blood Pb of gasoline Pb sales in the past month (e.g., Schwartz and Pitcher, 1989; Rabinowitz and Needleman, 1983).

EPA also recognizes, as noted by some commenters and discussed in the Criteria Document and summarized in the Staff Paper, ANPR and proposal, that the evidence demonstrates sensitivity of the early years of life and increased vulnerability of specific types of effects during some developmental periods (e.g., prenatal) which may be shorter than a calendar quarter. EPA notes uncertainty, however in some aspects of the linkages between airborne Pb concentrations and these physiological responses, including time-related aspects of the exposure pathways contributing to such effects.

In considering the evidence regarding how blood Pb levels respond to changes in ambient air Pb concentrations along the multiple exposure pathways to blood, EPA recognizes several pertinent aspects of the evidence. First, the evidence in this area does not specify the duration of a sustained air concentration associated with a particular blood Pb contribution. Accordingly, we are uncertain as to the precise duration of air concentration(s) reflected in any one air-to-blood ratio and the ways in which an air-to-blood ratio may vary with the duration of the air Pb concentration. However, as discussed in section II.C.2.a above, the evidence supports the importance of time periods on the order of three months or less, and as discussed below, in light of the prominent role of deposition-related pathways today, EPA concludes the evidence most strongly supports a time period of approximately three months.

Given the varying complexities of the multiple air-related exposure pathways summarized in section II.A.1 above, exposure durations pertinent for each pathway may be expected to vary. The most immediate and direct exposure pathway is the inhalation pathway, while the ingestion pathways are more indirect and to varying degrees (across the range of pathways) less immediate. For example, as mentioned above, when leaded gasoline was a predominant source of air-related exposure for people in the U.S., the evidence indicates that blood Pb levels were strongly associated with average sales of leaded gasoline during the previous month (e.g., Schwartz and Pitcher, 1989). We note that exposures to the generally fine

particles produced by combustion of leaded gasoline, which remain suspended in the atmosphere for many days (USEPA, 1986a, p. 5–10), provide a greater role for inhalation pathways (e.g., as compared to deposition-related ingestion pathways, such as indoor dust ingestion) than would exposures to generally larger Pb particles (which tend to more readily deposit). Further, as recognized in the Staff Paper and the proposal, air-related ingestion pathways are necessarily slower to respond to changes in air concentrations than the immediate and direct pathway of inhalation. The ingestion pathways are affected by a variety of factors that play a lesser, if any, role in inhalation exposure. For example, human behavior (e.g., activity, cleaning practices and frequency) and other building characteristics (e.g., number of windows, presence of screens, air conditioning) would be expected to modulate the response of indoor dust to changes in ambient air Pb (Caravanos *et al.*, 2006; CD, p. 3–28).

As noted previously, the evidence and the results of the quantitative risk assessment indicate a greater role for ingestion pathways than inhalation pathways in contributing to the air-related exposures of children today. Accordingly, the relatively greater focus today (than at the time of leaded gasoline usage) on deposition-related pathways of exposure to air-related Pb such as indoor dust ingestion would tend to support consideration of an averaging time longer than a month. We additionally note results from dust Pb modeling analyses performed as part of the quantitative risk assessment. These results provide an estimate of approximately four months as the time over which an increase in air Pb will reach 90% of the final steady-state change in dust Pb (USEPA, 2007b, section G.3.2.2). Additionally, we note that multiple studies have observed blood Pb levels to exhibit seasonal patterns, perhaps related to seasonality in exposure variables (e.g., Rabinowitz *et al.*, 1985).

Some commenters who supported a monthly averaging time cited concern for the potential for the occurrence of single month average air Pb concentration, within a quarter that met the standard, to be substantially above the level of the standard. For example, one commenter suggested that a monthly averaging time would be more likely to capture exceedances related to periodic activities (such as industrial activity, construction or demolition). Another commenter submitted examples of such temporal variability in ambient air concentrations at specific

monitoring sites, one of which indicated a quarter in which the current standard of 1.5 $\mu\text{g}/\text{m}^3$ was met, while a single month within that quarter was some 30% percent higher (2.07 $\mu\text{g}/\text{m}^3$). In considering this example, we consider the likelihood of differing blood Pb responses between children in two different situations: one in which the 3-month average Pb concentration just met the level of the standard but a single month within the quarter was 30% higher than that level (with the other two months below the standard level), and the other in which each of three consecutive monthly average Pb concentrations just met the level of the standard. The current evidence is limited with regard to the consideration of this issue. Given the range of air-related blood Pb exposure pathways and the processes involved in their relationships with airborne Pb (e.g., the response of indoor dust Pb to ambient air Pb), it is highly uncertain, based on the evidence available today, whether there would be appreciable differences in blood Pb levels between the children in these two scenarios as a result of these different 3-month periods. That is, in this example, we consider it unlikely that a single relatively higher month of air Pb followed by two months of relatively lower air Pb would translate into a similar single high month of blood Pb followed by two months of relatively low blood Pb. Rather, it is expected that the high month would tend to be modulated into a more extended and less pronounced month-to-month change in blood Pb levels.

In considering this issue, however, we recognize that greater month-to-month variability in air concentrations than that described by this example is possible, and as such variability increases, it becomes more likely that a month's air Pb concentration might result in a more pronounced impact on blood Pb concentrations.

Another example offered by the commenter described more extreme month-to-month variability in a quarter in which the current standard was met. This example indicated a monthly average that was more than 3 times the average for the quarter. The allowance for this seemingly implausible occurrence results from the current calculation method for the current quarterly average standard. The current method takes an average across all valid measurements in a quarter, without according equal weight to each month's measurements. In situations where a significantly different number of measurements occur in each month of the quarter, the current method can have the effect of giving greater weight

to multiple measurements occurring over a relatively short period. In the specific example cited by the commenter, the few very high measurements in a single month were outweighed by a much larger number of lower measurements occurring in each of the other two months of the quarter, thus biasing the resulting quarterly average. EPA agrees with the commenter that the allowance of such significant month-to-month variability within a 3-month period is inappropriate and may not provide appropriate protection of public health. In consideration of this issue, the Agency has identified changes to the method used to derive the 3-month average that would yield an average that is more representative of air quality over the 3-month period and lessen the likelihood and frequency of occurrence of cases where such extremely high months would be allowed in a 3-month averaging period that met the standard. More specifically, as discussed below in section IV, the Agency considers it appropriate to average the measurements within each month prior to deriving the 3-month average as a way to avoid the allowance of such large monthly variability as noted by the commenter.

In considering comments specifically on the current use of a block calendar quarter average, the Administrator first notes that the CASAC Pb Panel, in their comments on the proposal, stated that “there is no logic for averaging only by ‘calendar’ quarter as there is nothing unique about effects that may occur exclusively during the four calendar seasons” and that a “‘rolling’ three-month (or 90-day) average would be more logical than a ‘calendar’ quarter” (Henderson, 2008b). Comments from a state environmental agency also recommended use of a 3-month rolling average, rather than the current block calendar quarter average.

EPA agrees with CASAC as to the stronger basis for a “rolling” 3-month average as compared to a block calendar quarter. A 3-month average not constrained to calendar quarters would consider each of the twelve 3-month periods associated with a given year, not just the four calendar years within that year. We agree with CASAC that the averaging time of calendar quarter inappropriately separates air concentrations occurring in months such as March and April that span two calendar quarters. For example, under the calendar quarter approach, two consecutive “high” months that occur in different calendar quarters (e.g., March and April) may be mitigated by “low” months in those calendar quarters (i.e., January and February for

March, May and June for April). Thus, the same air quality data could cause an exceedance of the calendar quarter standard if it occurred in February and March but could meet the calendar quarter standard if it occurred in March and April. EPA believes there is no evidence-based justification for this potential disparity in outcomes. By contrast, with a rolling 3-month averaging time, each month contributes to three separate 3-month periods, through separate combinations with three different pairs of months (e.g. January-March, February-April, and March-June), thus providing a more complete consideration of air quality during that month and the periods in which it falls. EPA also notes that analyses of air quality data for 2005–2007 indicate a greater degree of protection is afforded by a rolling 3-month average as compared to a block calendar quarter average (Schmidt, 2008).

CASAC also provided advice on a form for a monthly average standard, noting that a “monthly or ‘rolling’ 30-day averaging time with a ‘not to be exceeded’ form would be more protective against adverse short-term effects than a form (such as a ‘second-highest month in three years’) that periodically allows a month of exposures to much higher concentrations” (Henderson, 2008b). Public comments also included recommendations for a not-to-be-exceeded maximum form for a monthly average (e.g., NACAA), as well as some recommendations for a second maximum monthly average (e.g., NESCAUM). While these comments are instructive on the relative merits of a maximum and a second maximum form for a monthly averaging time, given the Administrator’s selection of a 3-month averaging time (as described in section II.C.2.c below), and his reasons for this selection, including his consideration of the issue of short-term changes in ambient air concentrations over the 3-month averaging time, EPA believes it is unnecessary to address comments on the appropriate form for a monthly averaging time further here.

EPA notes, however, that a maximum rolling 3-month average would be expected to provide greater protection from deposition-related pathways in an area of highly variable air concentrations than the proposed second maximum monthly average because the former does not allow for the “discounting” or omitting of airborne Pb in any month. While the averaging time for a maximum rolling 3-month average is longer than the monthly averaging time recommended

by CASAC and several commenters, the combination of a rolling 3-month averaging time with a maximum form would be expected to offer greater protection from deposition-related exposure pathways than the proposed option of a second maximum monthly average, because each month contributes to three 3-month averages and no month is omitted from the calculation of averages for comparison to the standard. Results of analyses of air quality data for 2005–2007 are consistent with this view, in that a greater percentage of monitors meeting data completeness criteria are not likely to meet the revised standard based on a maximum rolling 3-month average as compared to a second maximum monthly average (Schmidt, 2008).⁷¹

More detailed responses to some of the public comments described above, as well as responses to other comments related to averaging time and form not considered here, are provided in the Response to Comments document.

c. Conclusions on Averaging Time and Form

Having carefully considered CASAC’s advice and the public comments on the appropriate averaging time and form for the standard, the Administrator concludes that the fundamental scientific conclusions pertaining to averaging time described in the Criteria Document and Staff Paper, briefly summarized above in section II.C.2.a and discussed more fully in section II.E.2 of the proposal remain valid. In light of all of the evidence, the Administrator concludes that the appropriate averaging time for the standard is no longer than a 3-month period.

In considering the option of a monthly averaging time, the Administrator recognizes the complexity inherent in considering the averaging time and form for the primary Pb standard, which is greater than in the case of the other criteria pollutants, due to the multimedia nature of Pb and its multiple pathways of human exposure. Accordingly, while the Administrator recognizes there are some factors that might support a period as short as a month for the averaging time, other factors support use of a longer averaging time, as discussed in section II.C.2.b above. The Administrator believes that in the complex multimedia, multi-pathway situation for Pb, it is necessary to consider all of the relevant factors, both those pertaining to the human

⁷¹ These analyses incorporate the revised averaging method identified above and discussed more fully in section IV below.

physiological response to changes in Pb exposures and those pertaining to the response of air-related Pb exposure pathways to changes in airborne Pb, in an integrated manner.

The Administrator recognizes that the evidence as well as the results of the quantitative risk assessment for this review indicate a greater role for ingestion pathways than inhalation pathways in contributing to children's air-related exposure. He further recognizes that ingestion pathways are influenced by more factors than inhalation pathways, and those factors are considered likely to lessen the impact of month-to-month variations in airborne Pb concentrations on levels of air-related Pb in children's blood. Accordingly, while the evidence is limited as to our ability to characterize these impacts, this evidence suggests that the multiple factors affecting ingestion pathways, such as ingestion of indoor dust, are likely to lead to response times (e.g., for the response of blood to air Pb via these pathways) extending longer than a month. In addition, there remains uncertainty over the period of time needed for air Pb concentrations to lead to the health effects most at issue in this review.

Further, it is important to note, as discussed above, that a rolling 3-month averaging time is likely to be somewhat more protective from a broad national perspective than a calendar quarter averaging time. Over a 3-year time frame, the rolling 3-month averaging time is also likely to be more protective with regard to air-related Pb exposures than would be a form that allows one month in three years to be greater than the level of the standard (i.e., a monthly averaging time with a second maximum form). In combination with the additional changes in form discussed below, this means that a rolling 3-month average can be expected to provide a high degree of control over all of the months of a three-year period, with few individual months exceeding the level of the standard. This expectation appears to be generally supported by analyses of air quality data for 2005–2007 comparing percentages of monitors not likely to meet a revised standard with different averaging times and forms (Schmidt, 2008).

The Administrator further notes that, as discussed in section II.C.2.b above, the rolling three-month average eliminates the possibility for two consecutive "high" months falling in two separate calendar quarters to be considered independently (perhaps being mitigated by "low" months falling in each of the same calendar quarters). Rather, the same month, in the rolling

three-month approach, would contribute to three different 3-month periods through separate combinations with three different pairs of months, thus providing a more complete consideration of air quality during that month and the 3-month periods in which it falls. Taking these considerations into account, the Administrator concludes that a rolling 3-month averaging time is appropriate. This conclusion to revise from a block calendar quarter average to a rolling 3-month average is consistent with the views of CASAC and some commenters on this issue.

In recognition of the uncertainty in the information on which the decision to select a 3-month averaging time is based, the Administrator further concludes that the month-to-month variability allowed by the current method by which the 3-month average metric is derived is not sufficiently protective of public health. Accordingly, he concludes it is appropriate to modify the method by which the 3-month average metric is derived, as described in section IV below, to be the average of three monthly average concentrations, as compared to the current practice by which the average is derived across the full dataset for a quarter, without equally weighting each month within the quarter. Thus, in consideration of the uncertainty associated with the evidence pertinent to averaging time discussed above, the Administrator notes that the two changes in form for the standard (to a rolling 3-month average and to providing equal weighting to each month in deriving the 3-month average) both afford greater weight to each individual month than does the current form, tending to control both the likelihood that any month will exceed the level of the standard and the magnitude of any such exceedance.

Based on the evidence and air quality considerations discussed above, EPA concludes that a monthly averaging time is not warranted. Furthermore, the Administrator concludes that the appropriate averaging time and form for the revised primary Pb standard is a not-to-be-exceeded (maximum) 3-month rolling average evaluated over a 3-year span, derived in accordance with calculation methods described below in section IV.

3. Level

As noted in the proposal, EPA recognizes that in the case of Pb there are several aspects to the body of epidemiological evidence that add complexity to the selection of an appropriate level for the primary standard. As summarized above and

discussed in greater depth in the Criteria Document (CD, sections 4.3 and 6.1.3), the epidemiological evidence that associates Pb exposures with health effects generally focuses on blood Pb for the dose metric.⁷² In addition, exposure to Pb comes from various media, only some of which are air-related, and through both inhalation and ingestion pathways. These complexities are in contrast to the issues faced in the reviews for other air pollutants, such as particulate matter and ozone, which involve only inhalation exposures. Further, for the health effects receiving greatest emphasis in this review (neurological effects, particularly neurocognitive and neurobehavioral effects, in children), no threshold levels can be discerned from the evidence. As was recognized at the time of the last review, estimating a threshold for toxic effects of Pb on the central nervous system entails a number of difficulties (CD, pp. 6–10 to 6–11). The task is made still more complex by support in the evidence for a nonlinear rather than linear relationship between blood Pb and neurocognitive decrement, with greater risk of decrement-associated changes per $\mu\text{g}/\text{dL}$ of blood Pb at the lower levels of blood Pb in the exposed population (CD, section 6.2.13). In this context EPA notes that the health effects evidence most useful in determining the appropriate level of the NAAQS is the large body of epidemiological studies discussed in the Criteria Document. The discussion in the proposal and below therefore focuses on the epidemiological studies, recognizing and taking into consideration the complexity and resulting uncertainty in using this body of evidence to determine the appropriate level for the NAAQS.

The Administrator's proposed conclusions on range of levels for the primary standard are summarized below in the Introduction (section II.C.3.a), followed by consideration of comments received on the proposal (section II.C.3.b) and the Administrator's final decision with regard to level for the current primary standard (II.C.3.c).

a. Basis for Proposed Range

For the reasons discussed in the proposal and summarized below, and taking into account information and assessments presented in the Criteria Document, Staff Paper, and ANPR, the advice and recommendations of CASAC, and the public comments received prior to proposal, the

⁷² Among the studies of Pb health effects, in which blood Pb level is generally used as an index of exposure, the sources of exposure vary and are inclusive of air-related sources of Pb such as smelters (e.g., CD, chapter 6).

Administrator proposed to revise the existing primary Pb standard. Specifically, the Administrator proposed to revise the level of the primary Pb standard, defined in terms of the current Pb-TSP indicator, to within the range of 0.10 to 0.30 $\mu\text{g}/\text{m}^3$, conditional on judgments as to the appropriate values of key parameters to use in the context of the air-related IQ loss evidence-based framework summarized below (and discussed in section II.E.3.a.ii of the proposal). Further, in recognition of alternative views of the science, the exposure and risk assessments, the uncertainties inherent in the science and these assessments, and the appropriate public health policy responses based on the currently available information, the Administrator solicited comments on alternative levels of a primary Pb-TSP standard within ranges from above 0.30 $\mu\text{g}/\text{m}^3$ up to 0.50 $\mu\text{g}/\text{m}^3$ and below 0.10 $\mu\text{g}/\text{m}^3$. In addition, the Administrator solicited comments on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero.

The Administrator's consideration of alternative levels of the primary Pb-TSP standard built on his proposed conclusion, discussed above in section II.B.1, that the overall body of evidence indicates that the current Pb standard is not requisite to protect public health with an adequate margin of safety and that the standard should be revised to provide increased public health protection, especially for members of at-risk groups, notably including children, against an array of adverse health effects. These effects include IQ loss, decrements in other neurocognitive functions, other neurological effects and immune system effects, as well as cardiovascular and renal effects in adults, with IQ loss the health outcome quantified in the risk assessment. In reaching a proposed decision about the level of the Pb primary standard, the Administrator considered: The evidence-based considerations from the Criteria Document, Staff Paper, and ANPR, and those based on the air-related IQ loss evidence-based framework discussed in the proposal; the results of the exposure and risk assessments summarized in section II.A.3 above and in the Staff Paper, giving weight to the exposure and risk assessments as judged appropriate; CASAC advice and recommendations, as reflected in discussions of the Criteria Document, Staff Paper, and ANPR at public meetings, in separate written comments, and in CASAC's letters to the Administrator; EPA staff recommendations; and public

comments received during the development of these documents, either in connection with CASAC meetings or separately. In considering what standard is requisite to protect public health with an adequate margin of safety, the Administrator noted at the time of proposal that he was mindful that this choice requires judgment based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn.

In reaching a proposed decision on a range of levels for a revised standard, as in reaching a proposed decision on the adequacy of the current standard, the Administrator primarily considered the evidence in the context of the air-related IQ loss evidence-based framework as described in the proposal (section II.E.3.a.ii). The air-related IQ loss evidence-based framework considered by the Administrator in the proposal focuses on the contribution of air-related Pb to the neurocognitive effect of IQ loss in children, with a public health goal of identifying the appropriate ambient air level of Pb to protect exposed children from health effects that are considered adverse, and are associated with their exposure to air-related Pb. In this air-related IQ loss evidence-based framework, the Agency drew from the entire body of evidence as a basis for concluding that there are causal associations between air-related Pb exposures and IQ loss in children. Building on recommendations from CASAC to consider the body of evidence in a more quantitative manner, the framework additionally draws more quantitatively from the evidence by combining air-to-blood ratios with evidence-based C-R functions from the epidemiological studies to quantify the association between air Pb concentrations and air-related population mean IQ loss in exposed children. This framework was also premised on a public health goal of selecting a proposed standard level that would prevent air-related IQ loss (and related effects) of a magnitude judged by the Administrator to be of concern in populations of children exposed to the level of the standard. The framework explicitly links a public health goal regarding IQ loss with two key parameters—a C-R function for population IQ response associated with blood Pb level and an air-to-blood ratio.

As a general matter, in considering this evidence-based framework, the Administrator recognized that in the case of Pb there are several aspects to the body of epidemiological evidence that add complexity to the selection of

an appropriate level for the primary standard. As discussed above, these complexities include evidence based on blood Pb as the dose metric, multimedia exposure pathways for both air-related and nonair-related Pb, and the absence of any discernible threshold levels in the health effects evidence. Further, the Administrator recognized that there are a number of important uncertainties and limitations inherent in the available health effects evidence and related information, including uncertainties in the evidence of associations between total blood Pb and neurocognitive effects in children, especially at the lowest blood Pb levels evaluated in such studies, as well as uncertainties in key parameters used in the evidence-based framework, including C-R functions and air-to-blood ratios. In addition, the Administrator recognized that there are currently no commonly accepted guidelines or criteria within the public health community that would provide a clear basis for reaching a judgment as to the appropriate degree of public health protection that should be afforded to neurocognitive effects in sensitive populations, such as IQ loss in children.

Based on the discussion of the key parameters used in the framework, as discussed in the proposal, the Administrator concluded that, in considering alternative standard levels below the level of the current standard, it was appropriate to take into account two sets of C-R functions (described in section II.E.3.a.ii of the proposal), recognizing uncertainties in the related evidence. In the proposal, the first set of C-R functions was described as reflecting the evidence indicative of steeper slopes in relationships between blood Pb and IQ in children, and the second set of C-R functions as reflecting relationships with shallower slopes between blood Pb and IQ in children.⁷³ In addition, the Administrator concluded that it was appropriate to consider various air-to-blood ratios within a range of values considered to be generally supported by the available evidence, again recognizing the uncertainties in the relevant evidence.⁷⁴

⁷³ As described in section II.E.3.a.ii of the proposal, the first set focused on C-R functions from analyses involving population mean concurrent blood Pb levels of approximately 3 $\mu\text{g}/\text{dL}$ (closer to current mean blood Pb levels in U.S. children). The second set (CD, pp. 8-78 to 8-80) considered functions descriptive of the C-R relationship from a larger set of studies that include population mean blood Pb levels ranging from a mean of 3.3 up to a median of 9.7 $\mu\text{g}/\text{dL}$ (see Table 1).

⁷⁴ In considering alternative levels for the standard within the air-related IQ loss framework, the Agency focused on estimates using an air-to-

With regard to making a public health policy judgment as to the appropriate level of protection against air-related IQ loss and related effects, the Administrator first noted that ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur. The Administrator recognized, however, that in the case of setting a NAAQS, he is required to make a judgment as to what degree of protection is requisite to protect public health with an adequate margin of safety. The NAAQS must be sufficient but not more stringent than necessary to achieve that result, and does not require a zero-risk standard. Considering the advice of CASAC and public comments on this issue, notably including the comments of the American Academy of Pediatrics (AAP, 2008), the Administrator proposed to conclude that an air-related population mean IQ loss within the range of 1 to 2 points could be significant from a public health perspective, and that a standard level should be selected to provide protection from air-related population mean IQ loss in excess of this range.

In reaching his proposed decision, the Administrator considered the application of this air-related IQ loss framework with this target degree of protection in mind, drawing from the information presented in Table 7 of the proposal (section II.E.3.a.ii) which addresses a broad range of standard levels. In so doing, the Administrator considered estimates associated with both sets of C-R functions and the range of air-to-blood ratios identified in the proposal, and noted those that would limit the estimated degree of impact on population mean IQ loss from air-related Pb to the proposed range of protection.

Taking these considerations into account, and based on the full range of information presented in Table 7 of the proposal on estimates of air-related IQ loss in children over a broad range of alternative standard levels, the Administrator concluded that it was appropriate to propose a range of standard levels, and that a range of levels from 0.10 to 0.30 $\mu\text{g}/\text{m}^3$ would be consistent with the target for protection from air-related IQ loss in children identified in the proposal. In recognition of the uncertainties in the key parameters of air-to-blood ratio and C-R functions, the Administrator stated that the selection of a standard level from within this range was conditional

blood ratio of 1:5 and also provided IQ loss estimates using higher and lower estimates (i.e., 1:3 and 1:7).

on judgments as to the most appropriate parameter values to use in the context of this evidence-based framework. He noted that placing more weight on the use of a C-R function with a relatively steeper slope would tend to support a standard level in the lower part of the proposed range, while placing more weight on a C-R function with a shallower slope would tend to support a level in the upper part of the proposed range. Similarly, placing more weight on a higher air-to-blood ratio would tend to support a standard level in the lower part of the proposed range, whereas placing more weight on a lower ratio would tend to support a level in the upper part of the range. In soliciting comment on a standard level within this proposed range, the Administrator specifically solicited comment on the appropriate values to use for these key parameters in the context of this evidence-based framework.

The Administrator also considered the results of the exposure and risk assessments conducted for this review to provide some further perspective on the potential magnitude of air-related IQ loss.⁷⁵ The Administrator found these quantitative assessments to provide a useful perspective on the risk from air-related Pb. However, in light of the important uncertainties and limitations associated with these assessments, as discussed in sections II.A.3 above and section II.E.3.b of the proposal, for purposes of evaluating potential new standards, the Administrator placed less weight on the risk estimates than on the evidence-based assessments. Nonetheless, the Administrator found the risk estimates to be roughly consistent with and generally supportive of the evidence-based air-related IQ loss estimates discussed in section II.E.3.b of the proposal, lending support to the proposed range based on this evidence-based framework.

In the proposal, the Administrator noted his view that the above considerations, taken together, provided no evidence- or risk-based bright line that indicates a single appropriate level. Instead, he noted, there is a collection of scientific evidence and judgments

⁷⁵ In considering the risk estimates in light of IQ loss estimates based on the air-related IQ loss evidence-based framework in the proposal, the Agency focused on risk estimates for the general urban and primary Pb smelter subarea case studies as these case studies generally represent population exposures for more highly air-pathway exposed children residing in small neighborhoods or localized residential areas with air concentrations nearer the standard level being evaluated, as compared to, the location-specific case studies in which populations have a broader range of air-related exposures including many well below the standard level being evaluated.

and other information, including information about the uncertainties inherent in many relevant factors, which needs to be considered together in making this public health policy judgment and in selecting a standard level from a range of reasonable values. Based on consideration of the entire body of evidence and information available at the time of proposal, as well as the recommendations of CASAC and public comments, the Administrator proposed that a standard level within the range of 0.10 to 0.30 $\mu\text{g}/\text{m}^3$ would be requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety. He also recognized that selection of a level from within this range was conditional on judgments as to what C-R function and what air-to-blood ratio are most appropriate to use within the context of the air-related IQ loss framework. The Administrator noted that this proposed range encompasses the specific level of 0.20 $\mu\text{g}/\text{m}^3$, the upper end of the range recommended by CASAC and by many public commenters on the ANPR. The Administrator provisionally concluded that a standard level selected from within this range would reduce the risk of a variety of health effects associated with exposure to Pb, including effects indicated in the epidemiological studies at low blood Pb levels, particularly including neurological effects in children, and cardiovascular and renal effects in adults.

The proposal noted that there is no bright line clearly directing the choice of level within this reasonable range, and therefore the choice of what is appropriate, considering the strengths and limitations of the evidence, and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments, is a public health policy judgment. To further inform this judgment, the Administrator solicited comment on the air-related IQ loss evidence-based framework considered by the Agency and on appropriate parameter values to be considered in the application of this framework. More specifically, we solicited comment on the appropriate C-R function and air-to-blood ratio to be used in the context of the air-related IQ loss framework. The Administrator also solicited comment on the degree of impact of air-related Pb on IQ loss and other related neurocognitive effects in children considered to be significant from a public health perspective, and on the use of this framework as a basis for selecting a standard level.

The Administrator further noted that the evidence-based framework, with the inputs illustrated at the time of

proposal, indicated that for standard levels above 0.30 $\mu\text{g}/\text{m}^3$ up to 0.50 $\mu\text{g}/\text{m}^3$, the estimated degree of impact on population mean IQ loss from air-related Pb would range from approximately 2 points to 5 points or more with the use of the first set of C–R functions and the full range of air-to-blood ratios considered, and would extend from somewhere within the proposed range of 1 to 2 points IQ loss to above that range when using the second set of C–R functions and the full range of air-to-blood ratios considered. The Administrator proposed to conclude in light of his consideration of the evidence in the framework discussed above that the magnitude of air-related Pb effects at the higher blood Pb levels that would be allowed by standards above 0.30 up to 0.50 $\mu\text{g}/\text{m}^3$ would be greater than what is requisite to protect public health with an adequate margin of safety.

In addition, the Administrator noted that for standard levels below 0.10 $\mu\text{g}/\text{m}^3$, the estimated degree of impact on population mean IQ loss from air-related Pb would generally be somewhat to well below the proposed range of 1 to 2 points air-related population mean IQ loss regardless of which set of C–R functions or which air-to-blood ratio within the range of ratios considered are used. The Administrator proposed to conclude that the degree of public health protection that standards below 0.10 $\mu\text{g}/\text{m}^3$ would likely afford would be greater than what is requisite to protect public health with an adequate margin of safety.

Having reached these proposed decisions based on the interpretation of the evidence, the evidence-based frameworks, the exposure/risk assessment, and the public health policy judgments described above, the Administrator recognized that other interpretations, frameworks, assessments, and judgments are possible. There are also potential alternative views as to the range of values for relevant parameters (e.g., C–R function, air-to-blood ratio) in the evidence-based framework that might be considered supportable and the relative weight that might appropriately be placed on any specific value for these parameters within such ranges. In addition, the Administrator recognized that there may be other views as to the appropriate degree of public health protection that should be afforded in terms of air-related population mean IQ loss in children that would provide support for alternative standard levels different from the proposed range. Further, there may be other views as to the appropriate weight and

interpretation to give to the exposure/risk assessment conducted for this review. Consistent with the goal of soliciting comment on a wide array of issues, the Administrator solicited comment on these and other issues.

In the proposal, the Administrator also recognized that Pb can be considered a non-threshold pollutant⁷⁶ and that, as discussed in section I.B above, the CAA does not require that NAAQS be established at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. However, expecting that, as time goes on, future scientific studies will continue to enhance our understanding of Pb, and that such studies might lead to a situation where there is very little if any remaining uncertainty about human health impacts from even extremely low levels of Pb in the ambient air, the Administrator recognized that there is the potential in the future for fundamental questions to arise as to how the Agency could continue to reconcile such evidence with the statutory provision calling for the NAAQS to be set at a level that is requisite to protect public health with an adequate margin of safety. In light of such considerations, EPA solicited comment on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero.

b. Comments on Level

In this section we discuss advice and recommendations received from CASAC and the public on the proposed range of levels for the primary Pb standard with a Pb-TSP indicator,⁷⁷ including comments on specific levels and ranges appropriate for the standard, comments pertaining to the use of the evidence-based framework and inputs to the framework, and comments related to the risk assessment. More detailed responses to some of the public comments on level described below, as well as responses to other comments related to level not discussed here, are provided in the Response to Comments document.

⁷⁶ Similarly, in the most recent reviews of the NAAQS for ozone and PM, EPA recognized that the available epidemiological evidence neither supports nor refutes the existence of thresholds at the population level, while noting uncertainties and limitations in studies that make discerning thresholds in populations difficult (e.g., 73 FR 16444, March 27, 2008; 71 FR 61158, October 17, 2006).

⁷⁷ Some commenters provided recommendations with regard to a level for a Pb-PM₁₀-based standard. While these comments are instructive on that issue, the Administrator has decided to retain the current indicator of Pb-TSP, and therefore they do not need to be addressed here.

(i) General Comments on Range of Levels

In considering comments received on the proposal related to the standard level, EPA first notes the general advice provided by CASAC concerning the proposal in a July 2008 letter to the Administrator (Henderson, 2008b). In that letter, CASAC emphasized their unanimous recommendation (initially stated in their March 2007 letter) regarding “*the need to substantially lower the level*” of the primary Pb standard such that the upper bound should be “*no higher than 0.2 $\mu\text{g}/\text{m}^3$* ” (emphasis in originals).

The vast majority of public comments that addressed a level for the standard recommended standard levels below, or no higher than 0.2 $\mu\text{g}/\text{m}^3$. Many of these commenters noted the advice of CASAC and recommended that EPA follow this advice. Specific rationales provided by this large group of commenters included various considerations, such as recognition that the current evidence indicates Pb effects at much lower exposure levels than when the current standard was set and in multiple systems (e.g., neurological effects in children, cardiovascular and renal effects in adults), and does not indicate a threshold; impacts associated with some neurological effects can persist into adulthood; and there is now evidence of a greater air-to-blood ratio than was considered when the standard was set. Many of these commenters recommended a specific level or range of levels for the standard that was equal to or below 0.2 $\mu\text{g}/\text{m}^3$. In recommending levels below 0.2 $\mu\text{g}/\text{m}^3$, some of these stated that CASAC’s recommendation for an upper bound of 0.2 $\mu\text{g}/\text{m}^3$ should not be read to imply that CASAC supported a standard level of 0.2 $\mu\text{g}/\text{m}^3$ if that level did not account for CASAC’s other specific recommendations on the framework and its inputs. Some commenters’ specific recommendations for level (including a standard level of 0.15 $\mu\text{g}/\text{m}^3$) were based on consideration of the air-related IQ loss evidence-based framework and their application of it using their recommended parameter inputs and public health policy goal. The specific recommendations on application of the framework are discussed separately below. Some commenters (including EPA’s Children’s Health Protection Advisory Committee, NESCAUM, several States and Tribes, and several environmental or public health organizations) specified levels below 0.2 $\mu\text{g}/\text{m}^3$ as necessary to protect public health with an adequate margin of safety, with some of these additionally

stating that in assuring this level of protection, EPA must take into account susceptible or vulnerable subgroups. In discussing these subgroups, some commenters noted factors such as nutritional deficiencies as contributing to susceptibility and identified minority and low-income children as a sensitive subpopulation for Pb exposures. Some of these commenters recommended much lower levels, such as $0.02 \mu\text{g}/\text{m}^3$, based on their views as to the level needed to protect public health with an adequate margin of safety in light of their interpretation of the advice of CASAC and EPA Staff and the evidence, including the lack of identifiable threshold. Some of these commenters recommending much lower levels expressed the view that the standard should be as protective as possible.

A second, much smaller, group of comments (including some industry comments and some state agency comments), recommended levels for the standard that are higher than $0.2 \mu\text{g}/\text{m}^3$. Among this group, some commenters provide little or no health-based rationale for their comment. Other commenters, in recommending various levels above $0.2 \mu\text{g}/\text{m}^3$, generally state that there is no benefit to be gained by setting a lower level for the standard. In support of this general conclusion, the commenters variously stated that there is substantial uncertainty associated with the slope of the blood Pb-IQ loss concentration-response function at lower blood Pb levels, such that EPA should not rely on estimates that indicate a steeper slope at lower blood Pb levels; that the risk assessment results for total risk at alternative standard levels indicate no benefit to be achieved from a standard level below $0.5 \mu\text{g}/\text{m}^3$; that levels derived from the evidence-based framework need upward adjustment for use with an averaging time less than a year and that IQ loss estimates derived from the evidence-based framework presented in the proposal for levels from 0.10 to $0.50 \mu\text{g}/\text{m}^3$ do not differ much (e.g., from 2 to 4.1 points IQ loss [steeper slopes] and from 1.1 to 2.2 points IQ loss [shallower slope] for the two sets of C-R functions).

For the range of reasons summarized in section II.C.3.a above, and the reasons described more fully in section II.C.3.c below, EPA does not believe that a level for the standard above $0.2 \mu\text{g}/\text{m}^3$ would protect public health with an adequate margin of safety. Rather, EPA concludes that such a level for the standard would not be protective of public health with an adequate margin of safety. Further, EPA disagrees with the industry comment that levels identified using the evidence-based framework should be

adjusted upward; this and other specific aspects of comments summarized above are discussed further in the Response to Comments document.

(ii) Use of Air-related IQ Loss Evidence-based Framework

As noted above, EPA received advice and recommendations from CASAC and comments from the public with regard to application of the air-related IQ loss evidence-based framework in the selection of a level for the primary standard. In the discussion that follows, we first describe CASAC advice and public comments on the appropriate degree of public health protection that should be afforded to at-risk populations in terms of IQ loss in children as estimated by this framework. We then describe CASAC advice and public comments on the specific parameters of C-R function and air-to-blood ratio.

In their July 2008 advice to the Agency on the proposal notice, CASAC characterized the target degree of protection proposed for use with the air-related IQ loss framework to be inadequate (Henderson, 2008a). As basis for this characterization, they repeat the advice they conveyed with their March 2007 letter, that they considered that “a population loss of 1–2 IQ points is highly significant from a public health perspective” and that “the primary lead standard should be set so as to protect 99.5% of the population from exceeding that IQ loss” (emphasis in original). They further emphasized their view that an IQ loss of 1–2 points should be “prevented in all but a small percentile of the population—and certainly not accepted as a reasonable change in mean IQ scores across the entire population” (emphasis in original).

Recommendations from several commenters, including the American Academy of Pediatrics, and state health agencies that commented on this issue, are in general agreement with the view emphasized by CASAC that air-related IQ loss of a specific magnitude, such as on the order of 1 or 2 points, should be prevented in a very high percentage (e.g., 99.5%) of the population.

EPA generally agrees with CASAC and the commenters that emphasize that the NAAQS should prevent air-related IQ loss of a significant magnitude in all but a small percentile of the population. However, it is important to note that in selecting a target degree of public health protection from air-related IQ loss in children for the purposes of this review, EPA is addressing this issue more specifically in the context of this evidence-based framework. In so doing, EPA is not determining a specific

quantitative public health policy goal in terms of an air-related IQ loss that is acceptable or unacceptable in the U.S. population *per se*, but instead is determining what magnitude of estimated air-related IQ loss should be used in conjunction with the specific air-related IQ loss evidence-based framework being applied in this review, recognizing the uncertainties and limitations in this framework. As discussed later, the estimated air-related IQ loss resulting from the application of this evidence-based framework should not be viewed as a bright line estimate of expected IQ loss in the population that would or would not occur. Nonetheless, these results provide a useful guide for the Administrator to use in making the basically qualitative public health policy judgment about the risk to public health that could reasonably be expected to result from exposure to the ambient air quality patterns that would be allowed by varying levels of the standard, in light of the averaging time, form, and indicator specified above.

In that context, it is important to recognize that the air-related IQ loss framework provides estimates for the mean of a subset of the population. It is an estimate for a subset of children that are assumed to be exposed to the level of the standard. The framework in effect focuses on the sensitive subpopulation that is the group of children living near sources and more likely to be exposed at the level of the standard. The evidence-based framework estimates a mean air-related IQ loss for this subpopulation of children; it does not estimate a mean for all U.S. children.

EPA is unable to quantify the percentile of the U.S. population of children that corresponds to the mean of this sensitive subpopulation. Nor is EPA confident in its ability to develop quantified estimates of air-related IQ loss for higher percentiles than the mean of this subpopulation. EPA expects that the mean of this subpopulation represents a high, but not quantifiable, percentile of the U.S. population of children. As a result, EPA expects that a standard based on consideration of this framework would provide the same or greater protection from estimated air-related IQ loss for a high, albeit unquantifiable, percentage of the entire population of U.S. children.

One industry association commenter noted agreement with EPA's focus on population mean (or median) for the framework, and the statement of greater confidence in estimates for air-related (as contrasted with total Pb-related) IQ loss at a central point in the distribution

than at an upper percentile. This commenter also stated the view that there is likely little difference in air-related IQ loss between the mean and the upper percentiles of the exposed population, based on their interpretation of EPA risk estimates for the location-specific urban case studies. While EPA disagrees with the commenter's view and interpretation of the risk estimates from these case studies (as seen by differences in median and 95th percentile estimates presented in section 5.3.2 of the Risk Assessment Report), EPA agrees that there is a much higher level of confidence in estimates of air-related IQ loss for the mean as compared to that for an upper percentile, consistent with the Agency's recognition of such limitations in the blood Pb estimates from the risk assessment, due to limitations in the available data (as noted in section II.C.h of the proposal).

(iii) Air-to-Blood Ratio

Regarding the air-to-blood ratio, CASAC, in their July 2008 advice to the Agency on the proposal, objected to constraining the range of ratios used with the framework to the range from 1:3 to 1:7 (Henderson, 2008a). In so doing, they noted that the Staff Paper concluded that while "there is uncertainty and variability in the absolute value of an air-to-blood relationship, the current evidence indicates a notably greater ratio [than the value of 1:2 used in 1978] * * * e.g., on the order of 1:3 to 1:10" (USEPA, 2007, p. 5-17). With regard to the range of 1:3 to 1:7 emphasized in the proposal, CASAC stated that the lower end of the range (1:3) "reflects the much higher air and blood levels encountered decades ago" while "the upper end of the range (1:7) fails to account for the higher ratios expected at lower current and future air and blood Pb levels, especially when multiple air-related lead exposure pathways are considered." With particular recognition of the analysis of declining blood Pb levels documented by NHANES that reflected declines in air Pb levels associated with declining use of leaded gasoline over the same period and from which CASAC notes a ratio on the order of 1:10 (Schwartz and Pitcher, 1989, as cited in Henderson, 2007a), CASAC recommended that EPA consider an air-to-blood ratio "closer to 1:9 to 1:10 as being most reflective of current conditions" (Henderson, 2008b).

Similar to the advice from CASAC, many commenters, including EPA's Children's Health Protection Advisory Committee, NESCAUM and Michigan Department of Environmental Quality

recommended that EPA consider ratios higher than the upper end of the range used in the proposal (1:7), such as values on the order of 1:9 or 1:10 or somewhat higher and rejected the lower ratios used in the proposal as being inappropriate for application to today's children. In support of this recommendation, commenters cite ratios resulting from the study noted by CASAC (Schwartz and Pitcher, 1989), as well as others by Hayes *et al.* (1994) and Brunekreef *et al.* (1983), and also air-to-blood ratio estimates from the exposure/risk assessment.

EPA agrees with CASAC and these commenters that an upper end air-to-blood ratio of 1:7 does not give appropriate weight to the air-to-blood ratios derived from or reported by the studies by Schwartz and Pitcher (1989) and Brunekreef *et al.* (1983)⁷⁸ and on ratios derived from the risk assessment results, which extend higher than the range identified in the proposal for consideration with the framework. Accordingly, EPA agrees that the range of air-to-blood estimates appropriate for consideration in using the air-related IQ loss evidence-based framework should extend up to ratios greater than the 1:7 ratio presented as an upper end in the proposal, such that the evidence-based framework should also consider values on the order of 1:10.

Alternatively, two industry commenters supported the range presented in the proposal of 1:3 to 1:7.⁷⁹ These two and another industry commenter asserted that higher air-to-blood ratios are not supported by the evidence. Specifically, one commenter disagrees with CASAC's interpretation of the Schwartz and Pitcher (1989) study with regard to air-to-blood ratio, stating that the study indicates a potential ratio of 1:7.8, rather than 1:9 or 1:10 as stated by CASAC, and that there is a weak association between air Pb associated with leaded gasoline usage and blood Pb, making the Schwartz and Pitcher study inappropriate to consider. EPA considers both the CASAC approach and the alternate approach presented by the commenter to generally represent conceptually sound strategies for translating the relationship between gasoline usage and blood Pb (provided in the Schwartz and Pitcher, 1989

⁷⁸ EPA agrees that the study by Hayes *et al.* (1994), cited by CASAC and commenters, presents an air-to-blood ratio greater 1:10, but notes that we are not relying on this study in our decision as it has not been reviewed as part of the Criteria Document or Staff Paper (as described in Section I.C).

⁷⁹ A ratio of 1:5 was recommended by one of these commenters (Doe Run Resources Corp.).

study) to air-to-blood Pb ratios. In addition, EPA notes that these approaches support both the commenters ratio of approximately 1:8 and the CASAC recommendation for EPA to use an estimate "closer to 1:9 to 1:10". Further, EPA disagrees with the commenter's view that the association between gasoline-related air Pb and blood Pb is weak. On the contrary, the body of evidence regarding this relationship is robust (e.g., USEPA, 1986a, sections 11.3.6 and 11.6). As stated in the 1986 Criteria Document, "there is strong evidence that changes in gasoline lead produce large changes in blood lead" (USEPA, 1986a, p. 11-187). Further, EPA notes that the analysis by Hayes *et al.* (1994), cited by the commenter as basis for their view regarding leaded gasoline, recognizes the role of leaded gasoline combustion in affecting blood Pb levels through pathways other than the inhalation pathway (e.g., via dust, soil and food pathways).⁸⁰

Additionally, two commenters stated that the "higher ratios" have been generated inappropriately, citing ratios reported by Brunekreef (1984) or those derived from NHANES data (e.g., Schwartz and Pitcher, 1989 or Hayes *et al.*, 1994) as inappropriately including blood Pb not associated with air Pb concentrations in the derivation of the air-to-blood ratio. Last, two of the three industry commenters suggested that some of the air-to-blood ratios derived from the risk assessment are overstated as a result of the methodology employed.

EPA generally disagrees with these commenters' assertions that nonair sources of blood Pb are a source of bias in studies indicating ratios above 1:7 that were identified in the proposal, and emphasized by CASAC and by other commenters, as described above. For example, in section II.B.1.c of the proposal, the proposal noted ratios of 1:8.5 (Brunekreef *et al.*, 1983; Brunekreef, 1984), as well as a ratio of approximately 1:10 (presented by CASAC in consideration of Schwartz and Pitcher, 1989). In reporting these ratios, authors of these studies described how consideration was given or what adjustments were made for other sources of blood Pb, providing strength to their conclusion that the reported air-to-blood ratio reflects air Pb contributions, with little contribution from nonair sources. In addition, the study by Hilts (2003) includes an analysis that provides control for potential confounders, including

⁸⁰ See previous footnote regarding Hayes *et al.* (1994).

alternate sources of Pb exposure, through study design (i.e., by following a similar group of children located within the same study area over a period of time). As discussed in section II.A.2.a above, the study authors report a ratio of 1:6 from this study and additional analysis of the data by EPA for the initial time period of the study resulted in a ratio of 1:7.

With regard to air-to-blood ratios derived from the risk assessment, while EPA recognizes uncertainties in these estimates, particularly those extending substantially above 1:10 (as described in the Risk Assessment Report and section II.C of the proposal), EPA disagrees with commenters' conclusions that they do not provide support for estimates on the order of 1:10.

In summary, while EPA agrees with the industry commenters that a ratio of 1:5 or 1:7.8 is supportable for use in the evidence-based framework, as noted above, EPA interprets the current evidence as providing support for use of a higher range than that described in the proposal that is inclusive at the upper end of estimates on the order of 1:10 and at the lower end on the order of 1:5. Further, EPA agrees with CASAC that the lower end of the range in the proposal, an air-to-blood ratio of 1:3, is not supported by the evidence for application to the current population of U.S. children, in light of the multiple air-related exposure pathways by which children are exposed, in addition to inhalation of ambient air, and of today's much lower air and blood Pb levels. Taking these factors into consideration, we conclude that the air-related IQ loss evidence-based framework should consider air-to-blood ratios of 1:10 at the upper end and 1:5 at the lower end.

(iv) Concentration—Response Functions

Regarding the appropriate C–R functions to consider with the evidence-based framework, CASAC, in their July 2008 advice to the Agency on the proposal notice (Henderson, 2008a), objected to EPA's consideration of C–R functions based on analyses of populations "*exhibiting much higher blood Pb levels than is appropriate for current U.S. populations*" (emphasis in original). They note that the second set of C–R functions, while including some drawn from analyses of U.S. children with mean blood Pb levels below 4 µg/dL, also includes studies with mean or median blood Pb levels ranging up to 9.7 µg/dL. Further, they emphasize that we are concerned "*with current blood Pb levels in the setting of a health-protective NAAQS, not with blood Pb levels of the past*" (emphasis in original). In conclusion, they state that

"the selection of C–R function should be based on determining which studies indicate slopes that best reflect the current, lower blood Pb levels for children in the U.S.—which, in this instance, are those studies from which *steeper* slopes are drawn" (emphasis in original) (Henderson, 2008a).

A number of commenters (including EPA's Children's Health Protection Advisory Committee, NESCAUM and some state agencies) made recommendations with regard to C–R functions that were similar to those of CASAC. These commenters recommended consideration of C–R functions with slopes appreciably steeper than the median value representing the second set of functions in the proposal, giving greater weight to steeper slopes drawn from analyses involving children with lower blood Pb levels, closer to those of children in the U.S. today. Some of these commenters (e.g., NESCAUM) additionally suggested alternate approaches to identify a slope estimate relevant to today's blood Pb levels, considering lower blood Pb level studies across both sets of functions presented in the proposal, and to avoid placing inappropriate weight on a single highest value.

Based on the evidence described in detail in the Criteria Document and briefly summarized in section II.A.2.c above, EPA agrees with CASAC and these commenters that, given the nonlinearity of the blood Pb-IQ loss relationship (steeper slope at lower blood Pb levels), the C–R functions appropriate to use with the air-related IQ loss framework are those drawn from analyses of children with blood Pb levels closest to those of children in the U.S. today. As a result of this nonlinear relationship, a given increase in blood lead levels (e.g., 1 µg/dl of Pb) is expected to cause a greater incremental increase in adverse neurocognitive effects for a population of children with lower blood Pb levels than would be expected to occur in a population of children with higher blood Pb levels. Thus, estimates of C–R functions drawn from analyses of children with blood Pb levels that are more comparable to blood Pb levels in today's U.S. children are likely to better represent the relationship between health effects and blood Pb levels that would apply for children in the U.S. now and in the future, as compared to estimates derived from analyses of children with higher blood lead levels. As discussed in section II.A.2.a.ii above, blood Pb levels in U.S. children have declined dramatically over the past thirty years. The geometric mean blood Pb level for U.S. children aged five years and below,

reported for NHANES in 2003–04 (the most recent years for which such an estimate is available), is 1.8 µg/dL and the 5th and 95th percentiles are 0.7 µg/dL and 5.1 µg/dL, respectively (Axelrad, 2008a, 2008b). The mean blood Pb levels in all of the analyses from which C–R functions were drawn and described in the proposal (presented in Table 1 of section II.A.2.c above) are higher than this U.S. mean and some are substantially higher.

In consideration of the advice from CASAC and comments from the public, we have further considered the analyses presented in Table 1 of section II.A.2.c above from which quantitative relationships between IQ loss and blood Pb levels are described in the proposal (section II.B.2.b) for the purpose of focusing on those analyses that are based on blood Pb levels that best reflect today's population of children in the U.S. Given the evidence of nonlinearity and of steeper slopes at lower blood Pb levels (summarized in section II.A.2.c above), a focus on children with appreciably higher blood Pb levels could not be expected to identify a slope estimate that would be reasonably representative for today's population of children. More specifically, in applying the evidence-based framework, we are focused on a subpopulation of U.S. children, those living near air sources and more likely to be exposed at the level of the standard. While the air-related Pb in the blood of this subpopulation is expected to be greater than that for the general population given their greater air-related Pb exposure, we do not have information on the mean total blood Pb level (or, more specifically, the nonair component) for this subpopulation. However, even if we were to assume, as an extreme hypothetical example, that the mean for the general population of U.S. children included zero contribution from air-related sources, and added that to our estimate of air-related Pb for this subpopulation, the result would still be below the lowest mean blood Pb level among the set of quantitative C–R analyses.⁸¹ Thus, our goal in considering these quantitative analyses was to identify C–R analyses with mean blood Pb levels closest to those of today's U.S. children, including the at-risk subpopulation.⁸²

⁸¹ Using the ratio of 1:7 identified above as central within the reasonable range of air-to-blood ratios, the estimate of air-related blood Pb associated with a standard level of 0.15 µg/m³ would be approximately 1 µg/dL. Adding this to the mean total blood Pb level for the U.S. population would yield a mean total blood Pb estimate of 2.8 µg/dL.

⁸² As noted above, we also recognize that blood Pb levels are expected to further decline in response

Among the analyses presented in the proposal (Table 1), we note that six study groups from four different studies have blood Pb levels appreciably closer to the mean blood Pb levels in today's young children. Mean blood Pb levels for these study groups range from 2.9 to 4.3 µg/dL, while mean blood Pb levels for the other three study groups considered in the proposal range from 7.4 up to 9.7 µg/dL. Further, among the six slopes from analyses with blood Pb

levels closest to today's blood Pb levels, four come from two studies, with these two studies each providing two analyses of differing blood Pb levels. Focusing on the single analysis from each of the four studies that has a mean blood Pb level closest to today's mean for U.S. children yields four slopes ranging from -1.56 to -2.94, with a median of -1.75 IQ points per µg/dL (Table 3). Consistent with the evidence for nonlinearity in the C-R relationship, the slopes for the C-

R functions from these four analyses are steeper than the slopes for the other higher blood Pb level analyses. In considering the C-R functions from these four analyses with the air-related IQ loss framework in section II.C.3.c below, we have placed greater weight on the median of the group, giving less weight to the minimum or maximum values, recognizing the uncertainty in determining the C-R relationship.

TABLE 3—SUMMARY OF QUANTITATIVE RELATIONSHIPS OF IQ AND BLOOD Pb FOR ANALYSES WITH BLOOD Pb LEVELS CLOSEST TO THOSE OF CHILDREN IN THE U.S. TODAY

Blood Pb levels (µg/dL)		Study/analysis	Average linear slope ^A (IQ points per µg/dL)
Geometric mean	Range (min-max)		
2.9	0.8-4.9	Tellez-Rojo et al. 2006, <5 subgroup	-1.71
3.24	0.9-7.4	Lanphear et al. 2005 ^B , <7.5 peak subgroup	-2.94
3.32	0.5-8.4	Canfield et al. 2003 ^B , <10 peak subgroup	-1.79
3.8	1-9.3	Bellinger and Needleman 2003 ^B , <10 peak subgroup	-1.56
Median value			-1.75

^A Average linear slope estimates here are for relationship between IQ and concurrent blood Pb levels except for Bellinger & Needleman for which study reports relationship for 10-year-old IQ with 24-month blood Pb levels.

^B The Lanphear et al. (2005) pooled International study includes blood Pb data from the Rochester and Boston cohorts, although for different ages (6 and 5 years, respectively) than the ages analyzed in Canfield et al. (2003) and Bellinger and Needleman (2003).

Some commenters representing a business or industry association recommended that EPA rely on the median estimate from the second set of C-R functions presented in the proposal. As their basis for this view, these commenters made several points. For example, they stated that the extent and magnitude of nonlinearity in the IQ-blood Pb C-R relationship is "highly uncertain," and as part of their rationale for this statement they cited studies by Jusko et al. (2007) and Surkan et al. (2007) as not providing support for a nonlinear C-R function. Other statements made by these commenters in support of their view are that the maximum slope in the first set is an "outlier," that the second set reflects a greater number of studies and subjects than the first set, and that simply being closer to the blood Pb levels of today's children does not provide a better estimate than the median of the second set, with some noting that the second set is inclusive of some analyses with blood Pb levels similar to those in first set.

EPA disagrees with these commenters' view that a focus on analyses of children with blood Pb levels closer to today's children is not an important criterion for selecting a C-R function for use with the IQ loss framework. On the contrary, as stated

above, EPA agrees with CASAC that this is an essential criterion for this analysis. While EPA recognizes uncertainty in the quantitative characterization of the nonlinearity in the blood Pb-IQ loss relationship, the weight of the current evidence (described in detail in the Criteria Document) supports our conclusion that the blood Pb-IQ loss relationship is nonlinear, with steeper slopes at lower blood Pb levels. While EPA agrees there are a greater number of studies and subjects in the second set, the nonlinearity of the relationship at issue means that a focus on C-R functions from the studies in that set involving children with appreciably higher blood Pb levels could not be expected to identify a slope estimate that would be reasonably representative for today's population of children. In reviewing the available studies with this important criterion in mind, as described above, we have identified four different studies from which C-R functions can be drawn, and in considering these functions in the context of the air-related IQ loss framework, have focused on the median estimate for the group, consequently avoiding focus on a single estimate that may be unduly influenced by one single analysis.

With regard to the "new" studies cited by commenters above, EPA notes that we are not relying on them in this review for the reasons stated above in section I.C. After provisional consideration of these studies cited by commenters (discussed further in the Response to Comments document), EPA has determined that the more recent cited studies provide only limited information with regard to the shape of the C-R curve and, in light of other recent provisionally considered studies and those studies reviewed in the Criteria Document, do not materially change EPA's conclusion regarding nonlinearity that is well founded in the evidence described in the Criteria Document.

(v) Role of Risk Assessment

Some commenters recommended that the Administrator place greater weight on the risk estimates derived in the quantitative risk assessment, with some (e.g., the Association of Battery Recyclers) concluding that these estimates supported a level for the standard above the proposed range and some (e.g., NRDC and Missouri Coalition for the Environment) concluding that they supported a level at the lower end or below the proposed range. For the reasons identified in the

to this and other public health protection actions, including those described above in section I.D.

proposal and noted in section II.C.3.c below, the Administrator has placed primary weight on the air-related IQ loss evidence-based framework in his decision with regard to level, and less weight on risk estimates from the quantitative risk assessment. At the same time, as stated in section II.C.3.c below, he finds those estimates to be roughly consistent with and generally supportive of the estimates from the evidence-based framework.

c. Conclusions on Level

Having carefully considered the public comments on the appropriate level of the Pb standard, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of Pb reached in the Criteria Document and Staff Paper, briefly summarized above in sections II.A.1 and II.A.2 and discussed more fully in sections II.A and II.B of the proposal, remain valid. In considering the level at which the primary Pb standard should be set, as in reaching a final decision on the need for revision of the current standard, the Administrator considers the entire body of evidence and information, in an integrated fashion, giving appropriate weight to each part of that body of evidence and information. In that context the Administrator continues to place primary consideration on the body of scientific evidence available in this review on the health effects associated with Pb exposure. In so doing, the Administrator primarily focuses on the air-related IQ loss evidence-based framework summarized in section II.C.3.a above and described in the proposal, recognizing that it provides useful guidance for making the public health policy judgment on the degree of protection from risk to public health that is sufficient but not more than necessary.

As described in section II.E.3.d of the proposal and recognized in section II.C.3.a above, the air-related IQ loss framework is used to inform the selection of a standard level that would protect against air-related IQ loss (and related effects) of a magnitude judged by the Administrator to be of concern in subpopulations of children exposed to the level of the standard, taking into consideration uncertainties inherent in such estimates. This framework calls for identifying a target degree of protection in terms of an air-related IQ loss for such subpopulations of children (discussed further below), as well as two other parameters also relevant to this framework—a C–R function for population IQ response associated with blood Pb level and an air-to-blood ratio.

With regard to estimates for air-to-blood ratio, the Administrator has further considered the evidence regarding air-to-blood relationships described in section II.A.2.a.iii above in light of advice from CASAC and comments from the public as described in section II.C.2.b above. Accordingly, he recognizes that the evidence includes support for ratios greater than 1:7 (the upper end of the range focused on in the proposal), including estimates ranging from 1:8 to 1:10. He also recognizes that the estimates developed from the quantitative exposure and risk assessments also include values greater than 1:7, including values ranging up to 1:10 and some higher. Additionally, as noted in section II.A.2.a.iii above, the evidence as a whole also indicates that variation in the value of the ratios appears to relate to the extent to which the range of air-related pathways are included and the magnitude of the air and blood Pb levels assessed, such that higher ratios appear to be associated with more complete assessments of air-related pathways and lower air and blood Pb levels. Taking all of these considerations into account, the Administrator concludes that the reasonable range of air-to-blood estimates to use in the air-related IQ loss framework includes ratios of 1:5 up to ratios on the order of 1:10. He does not consider lower ratios to be representative of the full range of air-related pathways and the ratios expected at today's air and blood Pb levels. The Administrator also concludes that it is appropriate to focus on 1:7 as a generally central value within this range.

With regard to C–R functions, the Administrator has further considered the evidence regarding quantitative relationships between IQ loss and blood Pb levels described in section II.A.2.c above, in light of advice from CASAC and comments from the public as described in section II.C.3.b above. He recognizes the evidence of nonlinearity and of steeper slopes at lower blood Pb levels (summarized in section II.A.2.c above), and as a result, he believes it is appropriate to focus on those analyses that are based on blood Pb levels that most closely reflect today's population of children in the U.S., recognizing that the evidence does not include analyses involving mean blood Pb levels as low as the mean blood Pb level for today's children. He notes that, as described in section II.C.3.b above, a review of the evidence with this focus in mind has identified four analyses that have a mean blood Pb level closest to today's mean for U.S. children and that yield

four slopes ranging from -1.56 to -2.94 , with a median of -1.75 IQ points per $\mu\text{g}/\text{dL}$ (Table 3). The Administrator concludes that it is appropriate to consider this set of C–R functions for use in the air-related IQ loss evidence based framework, as this set of C–R functions best represents the evidence pertinent to children in the U.S. today. In addition, the Administrator determines that it is appropriate to give more weight to the central estimate for this set of functions, which is the median of the set of functions, and not to rely on any one function.

As noted in the proposal, in considering this evidence-based framework, the Administrator recognizes that there are currently no commonly accepted guidelines or criteria within the public health community that would provide a clear basis for reaching a judgment as to the appropriate degree of public health protection that should be afforded to protect against risk of neurocognitive effects in sensitive populations, such as IQ loss in children. With regard to making a public health policy judgment as to the appropriate protection against risk of air-related IQ loss and related effects, the Administrator believes that ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur. The Administrator recognizes, however, that in the case of setting a NAAQS, he is required to make a judgment as to what degree of protection is requisite to protect public health with an adequate margin of safety.

The Administrator generally agrees with CASAC and the commenters who emphasize that the NAAQS should prevent air-related IQ loss of a significant magnitude in all but a small percentile of the population. However, as discussed above in section II.C.3.b, it is important to note that in selecting a target degree of public health protection that should be afforded to at-risk populations of children in terms of air-related IQ loss as estimated by the evidence-based framework being applied in this review, the Administrator is not determining a specific quantitative public health policy goal for air-related IQ loss that would be acceptable or unacceptable for the entire population of children in the United States. Instead, he is determining what magnitude of estimated air-related IQ loss should be used in conjunction with this specific framework, in light of the uncertainties in the framework and the limitations in using the framework.

In that context, the air-related IQ loss framework provides estimates for the mean air-related IQ loss of a subset of the population of U.S. children, and there are uncertainties associated with those estimates. It provides estimates for that subset of children likely to be exposed to the level of the standard, which is generally expected to be the subpopulation of children living near sources who are likely to be most highly exposed. In providing estimates of the mean air-related IQ loss for this subpopulation of children, the framework does not provide estimates of the mean air-related IQ loss for all U.S. children. The Administrator recognizes, as discussed above, that EPA is unable to quantify the percentile of the U.S. population of children that corresponds to the mean of this sensitive subpopulation, nor can EPA confidently develop quantified estimates for upper percentiles for this subpopulation. EPA expects that the mean of this subpopulation represents a high, but not quantifiable, percentile of the U.S. population of children. As a result, the Administrator expects that a standard based on consideration of this framework would provide the same or greater protection from estimated air-related IQ loss for a high, albeit unquantifiable, percentage of the entire population of U.S. children.⁸³

In addition, EPA expects that the selection of a maximum, not to be exceeded, form in conjunction with a rolling 3-month averaging time over a three-year span, discussed in section II.C.2. above, will have the effect that the at-risk subpopulation of children will be exposed below the level of the standard most of the time. In light of this and the significant uncertainty in the relationship between time period of ambient level, exposure, and occurrence of a health effect, the choice of an air-related IQ loss to focus on in applying the framework should not be seen as a decision that a specific level of air-related IQ loss will occur in fact in areas where the revised standard is just met

or that such a loss has been determined as acceptable if it were to occur. Instead, the choice of such an air-related IQ loss is one of the judgments that need to be made in using the evidence-based framework to provide useful guidance in making the public health policy judgment on the degree of protection from risk to public health that is sufficient but not more than necessary, taking into consideration the patterns of air quality that would likely occur upon just meeting the standard as revised in this rulemaking.

In considering the appropriate air-related IQ loss to accompany application of the framework, the Administrator has considered the advice of CASAC and public comments on this issue, discussed above in section II.C.3.b. The Administrator recognizes that comments on the proposal have highlighted the ambiguity in using an air-related IQ loss for the framework that is phrased in terms of a range. For example, if a range of 1–2 points IQ loss is selected, it is unclear whether the intent is to limit points of air-related IQ loss to below 1, below 2, or below some level in between. For clarity, it is more useful to use a specific level as compared to a range. In addition, recognizing the uncertainties inherent in evaluating the health impact of an IQ loss across a population, as well as the uncertainties in the inputs to the framework, the Administrator believes it is appropriate to use a whole number for the air-related IQ loss level.

In consideration of comments from CASAC and the public and in recognition of the uncertainties in the health effects evidence and related information, as well as the role of a selected air-related IQ loss in the application of the framework, the Administrator concludes that an air-related IQ loss of 2 points should be used in conjunction with the evidence-based framework in selecting an appropriate level for the standard. Given the uncertainties in the inputs to the framework, the uncertainties in the

relationship between ambient levels, exposure period, and occurrence of health effects, and the focus of the framework on the sensitive subpopulation of more highly exposed children, a standard level selected using this air-related IQ loss, in combination with the selected averaging time and form, would significantly reduce and limit for a high percentage of U.S. children the risk of experiencing an air-related IQ loss of that magnitude.

With this specific air-related IQ loss in mind, the Administrator considered the application of this framework to a broad range of standard levels, using estimates for the two key parameters—air-to-blood ratio and C–R function—that are appropriate for use within the framework, as shown in Table 4 below. In so doing, the Administrator recognized that, relying on the median of the four C–R functions from analyses with blood Pb levels closest to those of today’s children, a standard level in the lower half of the proposed range (0.10–0.20 µg/m³) would limit the estimated mean IQ loss from air-related Pb to below 2 points, depending on the choice of air-to-blood ratio within the range from 1:5 to 1:10.

As noted above, however, the Administrator does not believe it is appropriate to consider only a single air-to-blood ratio. Using the air-to-blood ratio of 1:7, a generally central estimate within the well supported range of estimates, the estimates of air-related IQ loss are below a 2-point IQ loss for standard levels of 0.15 µg/m³ and lower. At a level of 0.15 µg/m³, the Administrator recognizes that use of a 1:10 ratio produces an estimate greater than 2 IQ points and use of a 1:5 ratio produces a lower IQ loss estimate. Given the uncertainties and limitations in the air-related IQ loss framework, the Administrator views it as appropriate to place primary weight on the results from this central estimate rather than estimates derived using air-to-blood-ratios either higher or lower than this ratio.

TABLE 4—ESTIMATES OF AIR-RELATED MEAN IQ LOSS FOR THE SUBPOPULATION OF CHILDREN EXPOSED AT THE LEVEL OF THE STANDARD

Potential level for standard (µg/m ³)	Air-related mean IQ loss (points) for the subpopulation of children exposed at level of the standard		
	IQ loss estimate is based on median slope of 4 C–R functions with blood Pb levels closer to those of today’s U.S. children (range shown for estimates based on lowest and highest of 4 slopes)		
	Air-to-blood ratio		
	1:10	1:7	1:5
0.50	>5*	>5*	4.4 (3.9–7.4)

⁸³ Further, in determining what level of estimated IQ loss should be used for evaluating the results

obtained from this specific evidence-based framework, the Administrator is not determining

that such an IQ loss is appropriate for use in other contexts.

TABLE 4—ESTIMATES OF AIR-RELATED MEAN IQ LOSS FOR THE SUBPOPULATION OF CHILDREN EXPOSED AT THE LEVEL OF THE STANDARD—Continued

Potential level for standard (µg/m ³)	Air-related mean IQ loss (points) for the subpopulation of children exposed at level of the standard		
	IQ loss estimate is based on median slope of 4 C-R functions with blood Pb levels closer to those of today's U.S. children (range shown for estimates based on lowest and highest of 4 slopes)		
	Air-to-blood ratio		
	1:10	1:7	1:5
0.40		4.9 (4.4–8.2)	3.5 (3.1–5.9)
0.30	5.3 (4.7–8.8)	3.7 (3.3–6.2)	2.6 (2.3–4.4)
0.25	4.4 (3.9–7.4)	3.1 (2.7–5.1)	2.2 (2.0–3.7)
0.20	3.5 (3.1–5.9)	2.5 (2.2–4.1)	1.8 (1.6–2.9)
0.15	2.6 (2.3–4.4)	1.8 (1.6–3.1)	1.3 (1.2–2.2)
0.10	1.8 (1.6–2.9)	1.2 (1.1–2.1)	0.9 (0.8–1.5)
0.05	0.9 (0.8–1.5)	0.6 (0.5–1.0)	0.4 (0.4–0.7)
0.02	0.4 (0.3–0.6)	0.2 (0.2–0.4)	0.2 (0.2–0.3)

* For these combinations of standard levels and air-to-blood ratios, the appropriateness of the C-R function applied in this table becomes increasingly uncertain such that no greater precision than “>5” for the IQ loss estimate is warranted.

The Administrator has also considered the results of the exposure and risk assessments conducted for this review to provide some further perspective on the potential magnitude of risk of air-related IQ loss. The Administrator finds that these quantitative assessments provide a useful perspective on the risk from air-related Pb. However, in light of the important uncertainties and limitations associated with these assessments, as summarized in section II.A.3 above and discussed in sections II.C and II.E.3.b of the proposal, for purposes of evaluating potential standard levels, the Administrator places less weight on the risk estimates than on the evidence-based assessment. Nonetheless, the Administrator finds that the risk estimates are roughly consistent with and generally supportive of the evidence-based air-related IQ loss estimates summarized above.⁸⁴

In the Administrator’s view, the above considerations, taken together, provide no evidence-or risk-based bright line that indicates a single appropriate level. Instead, there is a collection of scientific evidence and other information, including information about the uncertainties inherent in many relevant factors, which needs to be considered together in making the public health policy judgment to select the

appropriate standard level from a range of reasonable values. In addition, the results of the evidence-based framework are seen as a useful guide in determining whether the risks to public health from exposure to ambient levels of Pb in the air, in the context of a specified averaging time and form, provide a degree of protection from risk with an adequate margin of safety that is sufficient but not more than necessary.

Based on consideration of the entire body of evidence and information available at this time, as well as the recommendations of CASAC and public comments, the Administrator has decided that a level for the primary Pb standard of 0.15 µg/m³, in combination with the specified choice of indicator, averaging time, and form, is requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety. The Administrator notes that this level is within the range recommended by CASAC, the Staff Paper, and by the vast majority of commenters. The Administrator concludes that a standard with a level of 0.15 µg/m³ will reduce the risk of a variety of health effects associated with exposure to Pb, including effects indicated in the epidemiological studies at low blood Pb levels, particularly including neurological effects in children, and the potential for cardiovascular and renal effects in adults.

The Administrator notes that the evidence-based framework indicates that for standard levels above 0.15 µg/m³, the estimated mean air-related IQ loss in the subpopulation of children exposed at the level of the standard would range in almost all cases from above 2 points to 5 points or more with the range of air-to-blood ratios

considered. He concludes, in light of his consideration of all of the evidence, including the framework discussed above, that the protection from air-related Pb effects at the higher blood Pb levels that would be allowed by standards above 0.15 µg/m³ would not be sufficient to protect public health with an adequate margin of safety.

In addition, the Administrator notes that for standard levels below 0.15 µg/m³, the estimated mean IQ loss from air-related Pb in the subpopulation of children exposed at the level of the standard would generally be somewhat to well below 2 IQ points regardless of which air-to-blood ratio within the range of ratios considered was used. The Administrator concludes in light of all of the evidence, including the evidence-based framework, that the degree of public health protection that standards below 0.15 µg/m³ would likely afford would be greater than what is necessary to protect public health with an adequate margin of safety.

The Administrator also recognizes that several commenters expressed concern that the proposal did not adequately address the need for the standard to be set with an adequate margin of safety. As noted above, in section I, the requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in

⁸⁴ For example, in considering a standard level of 0.2 µg/m³, we note that the risk assessment provides estimates falling within the range of 1.2 to 3.2 points IQ loss for the general urban case study and <3.7 for the primary Pb smelter subarea. These estimates are inclusive of the range of estimates for the 0.20 standard level presented in Table 4 based on the median C-R slope applied in the air-related IQ loss framework. As noted in section II.A.3.a above, these case studies, based on the nature of the population exposures represented by them, relate more closely to the air-related IQ loss evidence-based framework than other case studies assessed.

selecting a primary standard that includes an adequate margin of safety, the Administrator is seeking not only to prevent pollutant levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

Nothing in the Clean Air Act, however, requires the Administrator to identify a primary standard that would be protective against demonstrated harms, and then identify an additional "margin of safety" which results in further lowering of the standard. Rather, the Administrator's past practice has been to take margin of safety considerations into account in making decisions about setting the primary standard, including in determining its level, averaging time, form and indicator, recognizing that protection with an adequate margin of safety needs to be sufficient but not more than necessary.

Consistent with past practice, the Administrator has taken the need to provide for an adequate margin of safety into account as an integral part of his decision-making on the appropriate level, averaging time, form, and indicator of the standard. As discussed above, the consideration of health effects caused by different ambient air concentrations of Pb is extremely complex and necessarily involves judgments about uncertainties with regard to the relationships between air concentrations, exposures, and health effects. In light of these uncertainties, the Administrator has taken into account the need for an adequate margin of safety in making decisions on each of the elements of the standards. Consideration of the need for an adequate margin of safety is reflected in the following elements: selection of TSP as the indicator and the rejection of the use of PM₁₀ scaling factors; selection of a maximum, not to be exceeded form, in conjunction with a 3-month averaging time that employs a rolling average, with the requirement that each month in the 3-month period be weighted equally (rather than being averaged by individual data) and that a 3-year span be used for comparison to the standard; and, the use of a range of inputs for the evidence-based framework, that includes a focus on higher air-to-blood ratios than the lowest ratio considered to be supportable, and steeper rather than shallower C-R functions, and the consideration of these inputs in selection of 0.15 µg/m³ as the level of the standard. The Administrator concludes based on his review of all of the evidence (including the evidence-

based framework) that when taken as a whole the standard selected today, including the indicator, averaging time, form, and level, will be sufficient but not more than necessary to protect public health, including the health of sensitive subpopulations, with an adequate margin of safety.

Thus, after carefully taking the above comments and considerations into account, and fully considering the scientific and policy views of the CASAC, the Administrator has decided to revise the level of the primary Pb standard to 0.15 µg/m³. In the Administrator's judgment, based on the currently available evidence, a standard set at this level and using the specified indicator, averaging time, and form would be requisite to protect public health with an adequate margin of safety. The Administrator judges that such a standard would protect, with an adequate margin of safety, the health of children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurobehavioral and neurocognitive effects, in children. A standard set at this level provides a very significant increase in protection compared to the current standard. The Administrator believes that a standard set at 0.15 µg/m³ would be sufficient to protect public health with an adequate margin of safety, and believes that a lower standard would be more than what is necessary to provide this degree of protection. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

D. Final Decision on the Primary Lead Standard

For the reasons discussed above, and taking into account information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and the public comments, the Administrator is revising the various elements of the standard to provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects in children, including neurocognitive and neurobehavioral effects. Specifically, the Administrator has decided to revise the level of the primary standard to a

level of 0.15 µg/m³, in conjunction with retaining the current indicator of Pb-TSP. The Administrator has also decided to revise the form and averaging time of the standard to a maximum (not to be exceeded) rolling 3-month average evaluated over a 3-year period.

Corresponding revisions to data handling conventions, including allowance for the use of Pb-PM₁₀ data in certain circumstances, and the treatment of exceptional events are specified in revisions to Appendix R, as discussed in section IV below. Corresponding revisions to aspects of the ambient air monitoring and reporting requirements for Pb are discussed in section V below, including sampling and analysis methods (e.g., a new Federal reference method for monitoring Pb in PM₁₀, quality assurance requirements), network design, sampling schedule, data reporting, and other miscellaneous requirements.

III. Secondary Lead Standard

A. Introduction

The NAAQS provisions of the Act require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that secondary standards be set to eliminate all risk of adverse welfare effects, but rather at a level requisite to protect public welfare from those effects that are judged by the Administrator to be adverse.

This section presents the rationale for the Administrator's final decision to revise the existing secondary NAAQS. In considering the currently available evidence on Pb-related welfare effects, there is much information linking Pb to potentially adverse effects on organisms and ecosystems. However, given the evaluation of this information in the Criteria Document and Staff Paper which highlighted the substantial limitations in the evidence, especially the lack of evidence linking various effects to specific levels of ambient Pb, the Administrator concludes that the available evidence supports revising the secondary standard but does not provide a sufficient basis for establishing a secondary standard for Pb that is different from the primary standard.

1. Overview of Welfare Effects Evidence

A secondary NAAQS addresses welfare effects and "effects on welfare" include, but are not limited to, effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being. CAA section 302(h). A qualitative assessment of welfare effects evidence related to ambient Pb is summarized in this section, drawing from the Criteria Document, Chapter 6 of the Staff Paper and from the Proposed Rule. The presentation here summarizes several key aspects of the welfare evidence for Pb. Lead is persistent in the environment and accumulates in soils, aquatic systems (including sediments), and some biological tissues of plants, animals and other organisms, thereby providing long-term, multi-pathway exposures to organisms and ecosystems. Additionally, EPA recognizes that there have been a number of uses of Pb, especially as an ingredient in automobile fuel but also in other products such as paint, lead-acid batteries, and some pesticides, which have significantly contributed to widespread increases in Pb concentrations in the environment, a portion of which remains today (e.g., CD, Chapters 2 and 3).

Ecosystems near smelters, mines and other industrial sources of Pb have demonstrated a wide variety of adverse effects including decreases in species diversity, loss of vegetation, changes to community composition, decreased growth of vegetation, and increased number of invasive species. These sources may have multiple pathways for discharging Pb to ecosystems, and apportioning effects between air-related pathways and other pathways (e.g., discharges to water) in such cases is difficult. Likewise, apportioning these effects between Pb and other stressors is complicated because these point sources also emit a wide variety of other heavy metals and sulfur dioxide which may cause toxic effects. There are no field studies which have investigated effects of Pb additions alone but some studies near large point sources of Pb have found significantly reduced species composition and altered community structures. While these effects are significant, they are spatially limited: The majority of contamination occurs within 20 to 50 km of the emission source (CD, section AX7.1.4.2).

By far, the majority of air-related Pb found in terrestrial ecosystems was

deposited in the past during the use of Pb additives in gasoline. Many sites receiving Pb predominantly through such long-range transport of gasoline-derived small particles have accumulated large amounts of Pb in soils (CD, p. AX7-98). There is little evidence that terrestrial sites exposed as a result of this long range transport of Pb have experienced significant effects on ecosystem structure or function (CD, section AX7.1.4.2 and p. AX7-98). Strong complexation of Pb by soil organic matter may explain why few ecological effects have been observed (CD, p. AX7-98). Studies have shown decreasing levels of Pb in vegetation which seems to correlate with decreases in atmospheric deposition of Pb resulting from the removal of Pb additives to gasoline (CD, section AX 7.1.4.2).

Terrestrial ecosystems remain primarily sinks for Pb but amounts retained in various soil layers vary based on forest type, climate, and litter cycling (CD, section 7.1). Once in the soil, the migration and distribution of Pb is controlled by a multitude of factors including pH, precipitation, litter composition, and other factors which govern the rate at which Pb is bound to organic materials in the soil (CD, section 2.3.5).

Like most metals the solubility of Pb is increased at lower pH. However, the reduction of pH may in turn decrease the solubility of dissolved organic material (DOM). Given the close association between Pb mobility and complexation with DOM, a reduced pH does not necessarily lead to increased movement of Pb through terrestrial systems and into surface waters. In areas with moderately acidic soil (i.e., pH of 4.5 to 5.5) and abundant DOM, there is no appreciable increase in the movement of Pb into surface waters compared to those areas with neutral soils (i.e., pH of approximately 7.0). This appears to support the theory that the movement of Pb in soils is limited by the solubilization and transport of DOM. In sandy soils without abundant DOM, moderate acidification appears likely to increase outputs of Pb to surface waters (CD, section AX 7.1.4.1).

Lead exists in the environment in various forms which vary widely in their ability to cause adverse effects on ecosystems and organisms. Current levels of Pb in soil also vary widely depending on the source of Pb but in all ecosystems Pb concentrations exceed natural background levels. The deposition of gasoline-derived Pb into forest soils has produced a legacy of slow moving Pb that remains bound to organic materials despite the removal of

Pb from most fuels and the resulting dramatic reductions in overall deposition rates. For areas influenced by point sources of air Pb, concentrations of Pb in soil may exceed by many orders of magnitude the concentrations which are considered harmful to laboratory organisms. Adverse effects associated with Pb include neurological, physiological and behavioral effects which may influence ecosystem structure and functioning. Ecological soil screening levels (Eco-SSLs) have been developed for Superfund site characterizations to indicate concentrations of Pb in soils below which no adverse effects are expected to plants, soil invertebrates, birds and mammals. Values like these may be used to identify areas in which there is the potential for adverse effects to any or all of these receptors based on current concentrations of Pb in soils.

Atmospheric Pb enters aquatic ecosystems primarily through the erosion and runoff of soils containing Pb and deposition (wet and dry). While overall deposition rates of atmospheric Pb have decreased dramatically since the removal of Pb additives from gasoline, Pb continues to accumulate and may be re-exposed in sediments and water bodies throughout the United States (CD, section 2.3.6).

Several physical and chemical factors govern the fate and bioavailability of Pb in aquatic systems. A significant portion of Pb remains bound to suspended particulate matter in the water column and eventually settles into the substrate. Species, pH, salinity, temperature, turbulence and other factors govern the bioavailability of Pb in surface waters (CD, section 7.2.2).

Lead exists in the aquatic environment in various forms and under various chemical and physical parameters which determine the ability of Pb to cause adverse effects either from dissolved Pb in the water column or Pb in sediment. Current levels of Pb in water and sediment also vary widely depending on the source of Pb. Conditions exist in which adverse effects to organisms and thereby ecosystems may be anticipated given experimental results. It is unlikely that dissolved Pb in surface water constitutes a threat to ecosystems that are not directly influenced by point sources. For Pb in sediment, the evidence is less clear. It is likely that some areas with long term historical deposition of Pb to sediment from a variety of sources as well as areas influenced by point sources have the potential for adverse effects to aquatic communities. The long residence time of Pb in sediment and its ability to be

resuspended by turbulence make Pb likely to be a factor for the foreseeable future. Criteria have been developed to indicate concentrations of Pb in water and sediment below which no adverse effects are expected to aquatic organisms. These values may be used to identify areas in which there is the potential for adverse effects to receptors based on current concentrations of Pb in water and sediment.

2. Overview of Screening Level Ecological Risk Assessment

This section presents a brief summary of the screening-level ecological risk assessment conducted by EPA for this review. The assessment is described in detail in *Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas, Pilot Phase* (ICF, 2006). Various limitations have precluded performance of a full-scale ecological risk assessment. The discussion here is focused on the screening level assessment performed in the pilot phase (ICF, 2006) and takes into consideration CASAC recommendations with regard to interpretation of this assessment (Henderson, 2007a, b). The following summary focuses on key features of the approach used in the assessment and presents only a brief summary of the results of the assessment.

A screening level risk assessment was performed to estimate the potential for ecological risks associated with exposures to Pb emitted into ambient air. A case study approach was used which included areas surrounding a primary Pb smelter and a secondary Pb smelter, as well as a location near a nonurban roadway. Soil, surface water, and/or sediment concentrations were estimated for each of the three initial case studies from available monitoring data or modeling analysis, and then compared to ecological screening benchmarks to assess the potential for ecological impacts from Pb that was emitted into the air. A national-scale screening assessment was also used to evaluate surface water and sediment monitoring locations across the United States for the potential for ecological impacts associated with atmospheric deposition of Pb. An additional case study was identified to look at gasoline derived Pb effects on an ecologically vulnerable ecosystem but various limitations precluded any analyses.

The ecological screening values used in this assessment to estimate the potential for ecological risk were developed from the Eco-SSLs methodology, EPA's recommended ambient water quality criteria, and sediment screening values developed by

MacDonald and others (2000, 2003). Soil screening values were derived for this assessment using the Eco-SSL methodology with the toxicity reference values for Pb (USEPA, 2005d, 2005e) and consideration of the inputs on diet composition, food intake rates, incidental soil ingestion, and contaminant uptake by prey (details are presented in section 7.1.3.1 and Appendix L, of ICF, 2006). Hardness specific surface water screening values were calculated for each site based on EPA's recommended ambient water quality criteria for Pb (USEPA, 1984). For sediment screening values, the assessment relied on sediment "threshold effect concentrations" and "probable effect concentrations" developed by MacDonald et al. (2000). The methodology for these sediment criteria is described fully in section 7.1.3.3 and Appendix M of the pilot phase Risk Assessment Report (ICF, 2006).

A Hazard Quotient (HQ) was calculated for various receptors to determine the potential for risk to that receptor. The HQ is calculated as the ratio of the media concentration to the ecotoxicity screening value, and represented by the following equation: $HQ = (\text{estimated Pb media concentration}) \div (\text{ecotoxicity screening value})$

For each case study, HQ values were calculated for each location where either modeled or measured media concentrations were available. Separate soil HQ values were calculated for each ecological receptor group for which an ecotoxicity screening value has been developed (i.e., birds, mammals, soil invertebrates, and plants). HQ values less than 1.0 suggest that Pb concentrations in a specific medium are unlikely to pose significant risks to ecological receptors. HQ values greater than 1.0 indicate that the expected exposure exceeds the ecotoxicity screening value and that there is a potential for adverse effects.

There are several uncertainties that apply across case studies noted below:

- The ecological risk screen is limited to specific case study locations and other locations for which Pb data were available. Efforts were made to ensure that the Pb exposures assessed were attributable to airborne Pb and not dominated by nonair sources. However, there is uncertainty as to whether other sources might have actually contributed to the Pb exposure estimates.

- A limitation to using the selected ecotoxicity screening values is that they might not be sufficient to identify risks to some threatened or endangered species or unusually sensitive aquatic ecosystems (e.g., CD, p. AX7-110).

- The methods and database from which the surface water screening values (i.e., the AWQC for Pb) were derived is somewhat dated. New data and approaches (e.g., use of pH as indicator of bioavailability) may now be available to estimate the aquatic toxicity of Pb (CD, sections X7.2.1.2 and AX7.2.1.3).

- No adjustments were made for sediment-specific characteristics that might affect the bioavailability of Pb in sediments in the derivation of the sediment quality criteria used for this ecological risk screen (CD, sections 7.2.1 and AX7.2.1.4; Appendix M, ICF, 2006). Similarly, characteristics of soils for the case study locations were not evaluated for measures of bioavailability.

- Although the screening value for birds used in this analysis is based on reasonable estimates for diet composition and assimilation efficiency parameters, it was based on a conservative estimate of the relative bioavailability of Pb in soil and natural diets compared with water soluble Pb added to an experimental pellet diet (Appendix L, ICF, 2006).

The following is a brief summary of key observations related to the results of the screening-level ecological risk assessment. A complete discussion of the results is provided in Chapter 6 of the Staff Paper and the complete presentation of the assessment and results is presented in the pilot phase Risk Assessment Report (ICF, 2006).

For the case studies, the concentrations of Pb in soil and sediments in various locations exceeded screening values for these media indicating potential for adverse effects to terrestrial organisms (plants, birds and mammals) and to sediment dwelling organisms. While it was not possible to dissect the contributions of air Pb emissions from other sources, it is likely that, at least for the primary smelter, that the air contribution is significant. For the other case studies, the contributions of current air emissions to the Pb burden, is less clear.

The national-scale screen of surface water data initially identified 15 areas for which water column levels of dissolved Pb were greater than hardness adjusted chronic criteria for the protection of aquatic life indicating a potential for adverse effect if concentrations were persistent over chronic periods. Acute criteria were not exceeded at any of these locations. The extent to which air emissions of Pb have contributed to these surface water Pb concentrations is unclear. In the national-scale screen of sediment data associated with the 15 surface water sites described above, threshold effect

concentration-based HQs at nine of these sites exceeded 1.0. Additionally, HQs based on probable effect concentrations exceeded 1.0 at five of the sites, indicating probable adverse effects to sediment dwelling organisms. Thus, sediment Pb concentrations at some sites are high enough that there is a likelihood that they would cause adverse effects to sediment dwelling organisms. However, the contribution of air emissions to these concentrations is unknown.

B. Conclusions on the Secondary Lead Standard

1. Basis for the Proposed Decision

The current standard was set in 1978 to be identical to the primary standard (1.5 $\mu\text{g Pb}/\text{m}^3$, as a maximum arithmetic mean averaged over a calendar quarter), the basis for which is summarized in section II.C.1. At the time the standard was set, the Agency concluded that the primary air quality standard would adequately protect against known and anticipated adverse effects on public welfare, as the Agency stated that it did not have evidence that a more restrictive secondary standard was justified. In the rationale for this conclusion, the Agency stated that the available evidence cited in the 1977 Criteria Document indicated that "animals do not appear to be more susceptible to adverse effects from lead than man, nor do adverse effects in animals occur at lower levels of exposure than comparable effects in humans" (43 FR 46256). The Agency recognized that Pb may be deposited on the leaves of plants and present a hazard to grazing animals. With regard to plants, the Agency stated that Pb is absorbed but not accumulated to any great extent by plants from soil, and that although some plants may be susceptible to Pb, it is generally in a form that is largely unavailable to them. Further the Agency stated that there was no evidence indicating that ambient levels of Pb result in significant damage to manmade materials and Pb effects on visibility and climate are minimal.

The secondary standard was subsequently considered during the 1980s in development of the 1986 Criteria Document (USEPA, 1986a) and the 1990 Staff Paper (USEPA, 1990b). In summarizing OAQPS staff conclusions and recommendations at that time, the 1990 Staff Paper stated that a qualitative assessment of available field studies and animal toxicological data suggested that "domestic animals and wildlife are as susceptible to the effects of lead as laboratory animals used to investigate human lead toxicity risks." Further, the 1990 Staff Paper highlighted concerns

over potential ecosystem effects of Pb due to its persistence, but concluded that pending development of a stronger database that more accurately quantifies ecological effects of different Pb concentrations, consideration should be given to retaining a secondary standard at or below the level of the then-current secondary standard of 1.5 $\mu\text{g}/\text{m}^3$.

Given the full body of current evidence, despite wide variations in Pb concentrations in soils throughout the country, Pb concentrations are in excess of concentrations expected from geologic or other non-anthropogenic forces. There are several difficulties in quantifying the role of recent air emissions of Pb in the environment: Some Pb deposited before the standard was enacted is still present in soils and sediments; historic Pb from gasoline continues to move slowly through systems as does current Pb derived from both air and nonair sources. Additionally, the evidence of adversity in natural systems is limited due in no small part to the difficulty in determining the effects of confounding factors such as multiple metals or factors influencing bioavailability in field studies.

The evidence summarized above, in the Proposed Rule, in section 4.2 of the Staff Paper, and described in detail in the Criteria Document, informs our understanding of Pb in the environment today and evidence of environmental Pb exposures of potential concern. For areas influenced by point sources of air Pb that meet the current standard, concentrations of Pb in soil may exceed by many orders of magnitude the concentrations which are considered harmful to laboratory organisms (CD, sections 3.2 and AX7.1.2.3). In addition, conditions exist in which Pb associated adverse effects to aquatic organisms and thereby ecosystems may be anticipated given experimental results. While the evidence does not indicate that dissolved Pb in surface water constitutes a threat to those ecosystems that are not directly influenced by point sources, the evidence regarding Pb in sediment is less clear (CD, sections AX7.2.2.2 and AX7.2.4). It is likely that some areas with long term historical deposition of Pb to sediment from a variety of sources as well as areas influenced by point sources have the potential for adverse effects to aquatic communities. The Staff Paper concluded, based on laboratory studies and current media concentrations in a wide range of areas, that it seems likely that adverse effects are occurring, particularly near point sources, under the current standard. The long residence time of Pb in sediment and its ability to

be resuspended by turbulence make Pb contamination likely to be a factor for the foreseeable future. Based on this information, the Staff Paper concluded that the evidence suggests that the environmental levels of Pb occurring under the current standard, set nearly thirty years ago, may pose risk of adverse environmental effect.

In addition to the evidence-based considerations described in the previous section, the screening level ecological risk assessment is informative, taking into account key limitations and uncertainties associated with the analyses. As discussed in the previous section, as a result of its persistence, Pb emitted in the past remains today in aquatic and terrestrial ecosystems of the United States. Consideration of the environmental risks associated with the current standard is complicated by the environmental burden associated with air Pb concentrations that exceeded the current standard, predominantly in the past. Concentrations of Pb in soil and sediments associated with the case studies exceeded screening values for those media, indicating potential for adverse effect in terrestrial organisms (plants, birds, and mammals) and in sediment dwelling organisms. While the contribution to these Pb concentrations from air as compared to nonair sources has not been quantified, air emissions from the primary smelting facility at least are substantial (Appendix D, USEPA 2007b; ICF 2006).

The national-scale screens, which are not focused on particular point source locations, indicate the ubiquitous nature of Pb in aquatic systems of the United States today. Further, the magnitude of surface water Pb concentrations in several aquatic systems exceeded screening values and sediment Pb concentrations at some sites in the national-scale screen were high enough that the likelihood that they would cause adverse effects to sediment dwelling organisms may be considered "probable". A complicating factor in interpreting the findings for the national-scale screening assessments is the lack of clear apportionment of Pb contributions from air as compared to nonair sources, such as industrial and municipal discharges. While the contribution of air emissions to the elevated concentrations has not been quantified, documentation of historical trends in the sediments of many water bodies has illustrated the sizeable contribution that airborne Pb can have on aquatic systems (e.g., Staff Paper, section 2.8.1). This documentation also indicates the greatly reduced contribution in many systems as compared to decades ago (presumably

reflecting the phase-out of Pb-additives from gasoline used by cars and trucks). However, the timeframe for removal of Pb from surface sediments into deeper sediment varies across systems, such that Pb remains available to biological organisms in some systems for much longer than in others (Staff Paper, section 2.8; CD, pp. AX7–141 to AX7–145).

The case study locations included in the screening assessment, with the exception of the primary Pb smelter site, are currently meeting the current Pb standard, yet Pb occurs in soil and aquatic sediment in some locations at concentrations indicative of a potential for harm to some terrestrial and sediment dwelling organisms. While the role of airborne Pb in determining these Pb concentrations is unclear, the historical evidence indicates that airborne Pb can create such concentrations in sediments and soil.

Based on its review of the Staff Paper, CASAC advised the Administrator that *“The Lead Panel unanimously affirms its earlier judgments that, as with the primary (public-health based) Lead NAAQS, the secondary (public-welfare based) standard for lead also needs to be substantially lowered * * ** Therefore at a minimum, the level of the secondary Lead NAAQS should be at least as low as the level of the recommended primary lead standard.” (Henderson, 2008a). CASAC also recognized that EPA lacked data to provide a clear quantitative basis for setting a secondary standard that differed from the primary standard. (Henderson 2007a, 2008a).

In considering the adequacy of the current standard in providing protection from Pb-related adverse effects on public welfare, the Administrator considered in the proposal the body of available evidence (briefly summarized above in section III.). The proposal indicated that depending on the interpretation, the available data and evidence, primarily qualitative, suggests that there was the potential for adverse environmental impacts under the current standard. Given the limited data on Pb effects in ecosystems, it is necessary to look at evidence of Pb effects on organisms and extrapolate to ecosystem effects. Therefore, taking into account the available evidence and current media concentrations in a wide range of areas, the Administrator concluded in the proposal that there is potential for adverse effects occurring under the current standard, although there are insufficient data to provide a quantitative basis for setting a secondary standard different than the primary. While the role of current airborne

emissions is difficult to apportion, deposition of Pb from air sources is occurring and this ambient Pb is likely to be persistent in the environment similarly to that of historically deposited Pb which has persisted, although location specific dynamics of Pb in soil result in differences in the timeframe during which Pb is retained in surface soils or sediments where it may be available to ecological receptors (USEPA, 2007b, section 2.3.3).

Based on these considerations, and taking into account the observations, analyses, and recommendations discussed above, the Administrator proposed to revise the current secondary Pb standard by making it identical in all respects to the proposed primary Pb standard (described in section II.D above).

2. Comments on the Proposed Secondary Standard

EPA notes that CASAC, in their July 2008 letter, did not provide comments on the discussion and proposal regarding the secondary standard. Commenters who expressed an opinion on the proposed revision to the secondary standard, including a number of national organizations, individual States, Tribal associations, and local organizations, and combined comments from various environmental groups supported the position that the secondary Pb standard should be revised to the level of the primary standard. Some commenters recommended that the secondary standard be no less stringent than the primary, one commenter recommended that the standard be no more stringent than the primary, and some commenters recommended that the secondary standard be identical to the primary. One commenter concurred with the Agency’s finding, consistent with CASAC’s prior advice, that the current scientific knowledge was lacking and that further research was necessary to quantitatively inform an appropriate secondary standard. For the reasons discussed above and in the proposal, we agree with commenters that the secondary standard should be at this time set equal to the primary in indicator, level, form and averaging time and that more research is needed to further inform the development of a secondary Pb standard.

3. Administrator’s Conclusions

In considering the adequacy of the current secondary standard in providing requisite protection from Pb-related adverse effects on public welfare, the Administrator has considered the body of available evidence (briefly

summarized above and in the proposal). The screening-level risk assessment, while limited and accompanied by various uncertainties, suggests occurrences of environmental Pb concentrations existing under the current standard that could have adverse environmental effects in terrestrial organisms (plants, birds and mammals) and in sediment dwelling organisms. Environmental Pb levels today are associated with atmospheric Pb concentrations and deposition that have combined with a large reservoir of historically deposited Pb in environmental media.

In considering this evidence, as well as the views of CASAC, summarized above, the Staff Paper and associated support documents, and views of public commenters on the adequacy of the current standard, the Administrator concurs with CASAC’s recommendation that the secondary standard should be substantially revised and concludes that given the current state of evidence, the current secondary standard for Pb is not requisite to protect public welfare from known or anticipated adverse effects.

C. Final Decision on the Secondary Lead Standard

The secondary standard is defined in terms of four basic elements: Indicator, averaging time, level and form, which serve to define the standard and must be considered collectively in evaluating the welfare protection afforded by the standards. With regard to the pollutant indicator for use in a secondary NAAQS, EPA notes that Pb is a persistent pollutant to which ecological receptors are exposed via multiple pathways. While the evidence indicates that the environmental mobility and ecological toxicity of Pb are affected by various characteristics of its chemical form, and the media in which it occurs, information is insufficient to identify an indicator other than total Pb that would provide protection against adverse environmental effect in all ecosystems nationally. Thus, the same rationale for retaining Pb-TSP for the indicator apply here as for the primary standard.

Lead is a cumulative pollutant with environmental effects that can last many decades. There is a general lack of data that would indicate the appropriate level of Pb in environmental media that may be associated with adverse effects. The EPA notes the influence of airborne Pb on Pb in aquatic systems and of changes in airborne Pb on aquatic systems, as demonstrated by historical patterns in sediment cores from lakes and Pb measurements (section 2.8.1; CD, section AX7.2.2; Yohn *et al.*, 2004; Boyle *et al.*, 2005), as well as the

comments of the CASAC Pb panel that a significant change to current air concentrations (e.g., via a significant change to the standard) is likely to have significant beneficial effects on the magnitude of Pb exposures in the environment and Pb toxicity impacts on natural and managed terrestrial and aquatic ecosystems in various regions of the U.S., the Great Lakes and also U.S. territorial waters of the Atlantic Ocean (Henderson, 2007a, Appendix E). The Administrator concurs with CASAC's conclusion that the level of the secondary standard should be set at least as low as the level of the primary standard and that the Agency lacks the relevant data to provide a clear, quantitative basis for setting a secondary Pb NAAQS that differs from the primary in indicator, averaging time, level, or form. Based on these considerations, and taking into account the observations, analyses, and recommendations discussed above, the Administrator is revising the current secondary Pb standard by making it identical in all respects to the primary Pb standard.

IV. Appendix R—Interpretation of the NAAQS for Lead

EPA proposed to add Appendix R, Interpretation of the National Ambient Air Quality Standards for Pb, to 40 CFR part 50 in order to provide data handling procedures for the proposed Pb standard. The proposed Appendix R detailed the computations necessary for determining when the proposed Pb NAAQS would be met. The proposed appendix also addressed data reporting; sampling frequency and data completeness considerations; the use of scaled low-volume Pb-PM₁₀ data as a surrogate for Pb-TSP data (or vice versa), including associated scaling instructions; and rounding conventions. The purpose of a data interpretation guideline in general is to provide the practical details on how to make a comparison between multi-day, possibly multi-monitor, and (in the unique instance of the proposed Pb NAAQS) possibly multi-parameter (i.e., Pb-TSP and/or low-volume Pb-PM₁₀) ambient air concentration data to the level of the NAAQS, so that determinations of compliance and violation are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all. When data are insufficient, for example because of failure to collect valid ambient data on enough days in enough months (because of operator error or events beyond the control of the operator), no

determination of current compliance or violation is possible.

In the proposal, proposed rule text was provided only for the example of a Pb NAAQS based on a Pb-TSP indicator, a monthly averaging time, and a second maximum form. The preamble discussed how the rule text would be different to accommodate a Pb-PM₁₀ indicator and/or a quarterly averaging time with a not-to-be-exceeded form.

A. Ambient Data Requirements

1. Proposed Provisions

Section 3 of the proposed Appendix R, Requirements for Data Used for Comparisons with the Pb NAAQS and Data Reporting Considerations, specified that all valid FRM/FEM Pb-TSP data and all valid FRM/FEM Pb-PM₁₀ data submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting specified monitoring requirements in 40 CFR part 58 related to quality assurance, monitoring methods, and monitor siting shall be used in design value calculations.⁸⁵ Because 40 CFR 58 requirements were revised in 2006 and were proposed for further revision in this rulemaking, and because the FRM/FEM criteria for Pb-PM₁₀ are being established for the first time in this rulemaking, EPA wanted to provide clarity about whether data collected before the effective dates of the 2006 revisions and of this final rule could be used for comparisons to the NAAQS. The proposal therefore provided that Pb-TSP and Pb-PM₁₀ data representing sample collection periods prior to January 1, 2009 (i.e., "pre-rule" data) would also be considered valid for NAAQS comparisons and related attainment/nonattainment determinations if the sampling and analysis methods that were utilized to collect those data were consistent with the provisions of 40 CFR part 58 that were in effect at the time of original sampling or that are in effect at the time of the attainment/nonattainment determination, and if such data are submitted to AQS prior to September 1, 2009.

This section of the proposed rule also required that in the future Pb data be reported in terms of local temperature and pressure conditions, but provided that Pb data collected prior to January 1, 2009 and reported to AQS in terms of standard temperature and pressure conditions would be compared directly

to the level of the NAAQS without re-adjustment to local conditions, unless the monitoring agency voluntarily re-submitted them with such adjustment.

Finally, this section provided for the taking of make-up samples within seven days after a scheduled sampling day fails to produce valid data. It also specified that all data, including scheduled samples, make-up samples, and any extra samples (i.e., non-scheduled samples that are not eligible to be considered make-up samples because they either were taken too long after the missed sample or another non-scheduled sample is already being used as the make-up sample) would be used in calculating the monthly average concentration.

2. Comments on Ambient Data Requirements

One commenter argued that Pb concentrations should continue, as in the past, to be reported in terms of standard temperature and pressure conditions and that only those values should be compared to the level of the NAAQS. In support of this view, this commenter claimed generally that ambient air Pb concentrations used in deriving relationships between air Pb concentrations and blood Pb levels were in terms of standard temperature and pressure. Another commenter expressed a similar but less specific concern about consistency between the conditions for reporting concentrations and the logic used by the Administrator to set the level of the NAAQS. For reasons described in the Response to Comments document, EPA rejects these arguments.

Another commenter supported the requirement for Pb concentrations to be submitted in terms of local conditions and the option of monitoring agencies to resubmit older data in those terms, but wanted EPA to restrain monitoring agencies which do resubmit data from withdrawing the data submitted earlier in terms of standard conditions. EPA agrees that the previously submitted data should not be withdrawn, but we will instruct states to this effect through guidance rather than by regulation, since nowhere now do the air monitoring or data interpretation regulations address the possibility of data withdrawal.

As proposed, 40 CFR 50.3 is amended to say that Pb-TSP concentrations are to be reported in terms of local conditions of temperature and pressure. The corresponding requirement for Pb-PM₁₀ data is contained in the FRM method specification in Appendix Q. Appendix R retains a statement that this is the manner in which both types of data are submitted.

⁸⁵ As explained below, under the proposal sufficiently complete Pb-TSP data would take precedence over Pb-PM₁₀ data, so not all Pb-PM₁₀ data would necessarily be actually used in the design value calculations.

3. Conclusions on Ambient Data Requirements

The final provisions of Appendix R regarding what ambient data are to be used for comparisons to the NAAQS are as proposed. Sections IV.C and IV.D of this preamble also address certain related issues involving what ambient data are to be used in making comparisons to the NAAQS.

B. Averaging Time and Procedure

1. Proposal on Averaging Time and Procedure

EPA proposed in the alternative two averaging times for the revised NAAQS: A monthly period and a calendar quarter. In both approaches, the averaging time would be based on non-overlapping periods, the 12 individual calendar months in the case of a monthly averaging time and the 4 conventional calendar quarters (January–March, etc.) in the case of calendar quarter. In the case of a monthly averaging time all valid 24-hour Pb concentration data from the month would be arithmetically averaged to calculate the average concentration, and the average would be considered valid depending on the completeness of the data relative to the monitoring schedule, see section IV.C. Similarly, in the case of a quarterly average, all valid 24-hour data would be averaged to calculate the quarterly average concentration.

2. Comments on Averaging Time and Procedure

There were many public comments on the selection of the averaging time, addressed in section II.C.2. For the reasons discussed in that section, the final rule establishes the averaging time as a rolling 3-month period. Also, the final rule contains a 2-step procedure for calculating the 3-month average concentration, in which the average concentration for individual calendar months are calculated from all available valid 24-hour data in each month, and then three adjacent monthly averages are summed and divided by three to form the 3-month average concentration. In this way, each month's average will be weighted the same in calculating the 3-month average even if the months have different numbers of days with valid 24-hour concentration data. As explained in section II.C.2, this reduces the possibility that any one month's concentration could be very high compared to the 3-month average, compared to the proposed 1-step approach to calculating an average over three months.

3. Conclusions on Averaging Time and Procedure

The final rule establishes the averaging time as a rolling 3-month period. The final rule contains a 2-step procedure for calculating the average concentration for a 3-month period. First, the average concentration for individual calendar months are calculated from all available valid 24-hour data in each month giving equal weight to each day with valid monitoring data. Then, the three adjacent monthly averages are summed and divided by three to form the 3-month average concentration.⁸⁶

The final text of Appendix R also includes a provision that gives the Administrator discretion to use an alternate 3-step approach to calculating the 3-month average concentration instead of the 2-step approach described above. The Administrator will have this discretion only in a situation in which the number of extra sampling days during a month within the 3-month period is greater than the number of successfully completed scheduled and make-up sample days in that month. In such a situation, including all the available valid sampling days in the calculation of a monthly average concentration (and thereby into the calculation of a 3-month average concentration) might in result in an unrepresentative value for the monthly average concentration. This provision is to protect the integrity of the monthly and 3-month average concentration values in situations in which, by intention or otherwise, extra sampling days are concentrated in a period or periods during which ambient concentrations are particularly high or low. As explained in section IV.C, the final version of Appendix R does not apply a completeness requirement to individual months, but instead applies the completeness criteria to each 3-month averaging period as a whole. As a result, it is conceivable that a month

⁸⁶ In the final Appendix R, there is a provision to calculate a "3-month" average based on only one (or two) months of data if two (or one) of the months in the 3-month period have no valid reported data at all. In this case, the sum of the available monthly averages is divided by the number of months contributing data. Because a lack of data for an entire month (or two) would mean that the completeness over a 3-month period cannot be higher than 67 percent (or 33 percent), which is less than the normal requirement for 75 percent completeness, a situation like this could result in a valid 3-month average concentration only via application of the "above NAAQS" diagnostic data substitution test described in section IV.C. With that test, if substituting historically low data for the month (or two months) of missing data still results in a 3-month average above the level of the NAAQS, then the 3-month mean computed from only two (or one) months of data is deemed valid and complete.

used to form a valid 3-month average may itself have as few as two scheduled sampling days with valid data if the other two months have valid data for all five scheduled sampling days. In such a case, even a small number of extra samples could dominate the monthly average, which would then in turn contribute to the 3-month average with a weighting of one-third. The extra sampling days, however, may systematically tend to have been higher or lower Pb concentration days.⁸⁷ For example, a monitoring agency might have deliberately increased sampling frequency during episodes of high Pb concentration in order to better understand the scope and causes of high concentrations. It is also possible for a monitoring agency to pick days for extra sampling in ways that make those days tend to have lower Pb concentrations, for example by paying attention to wind direction or source operations. If extra sampling days are systematically related to concentration, the average of all data during a month might not fairly represent the average of the daily concentrations actually occurring across all the days in the month. The potential for the monthly average to become seriously distorted increases as the number of extra sampling days increases. Therefore, the final rule does not trigger the discretion to use the alternate 3-step approach described below unless the number of extra sampling days is greater than the number of scheduled and make-up days that have valid data.

In the case of a Pb sampling schedule in which an ambient sample is scheduled to be taken every sixth day, the first step in the 3-step approach is to average all scheduled, make-up, and extra samples taken on a given scheduled sample day and on any of the five days following that sampling day. Typically, there will be up to five such 6-day averages in a month; there can be fewer 6-day averages if one or more of the 6-day periods yielded no valid data. The second step is to average these 6-day averages together to calculate the monthly average. This approach has the effect of giving equal weight to each 6-day period during a month regardless of how many samples were actually obtained during the 6 days, which mitigates the potential for the monthly average to be distorted. The third step in calculating the 3-month average would be to average the three monthly averages giving equal weight to each

⁸⁷ The scheduled sampling days, in contrast, are expected to be uncorrelated with Pb concentration, since they do not emphasize any particular day of the week.

month, as described above in the standard 2-step approach to calculating the 3-month mean.

The above discussion has been simplified for easier understanding, by not addressing all the possible situations that can arise and that are addressed explicitly or implicitly by the final rule text. The following provides additional details.

(1) The example presumes a one-in-six sampling schedule, which is the minimum required in the final rule. If the site is operating on a one-in-three schedule, the first step in the alternate approach is to average the daily concentrations over periods of three days, then those three-day averages (up to 10, typically) are averaged to get the monthly average.

(2) The first day of scheduled one-in-six sampling typically will not fall on the first day of the calendar month, and there may be make-up or extra samples on the 1 to 5 days (1 or 2 days in the case of one-in-three sampling) of the same calendar month that precede the first scheduled day of the month. These samples will stay associated with their actual calendar month as follows. Any extra and make-up samples taken within the month but before the first scheduled sampling day of the month will be associated with and averaged with the last scheduled sampling day of the month and any days in the month following the last scheduled sampling day. In a 30-day month, this approach will always associate the last scheduled day of the month with five unscheduled days within the same month just as for the other scheduled sampling days, even when it is less than five days from the start of the next month, preserving the concept of giving equal weight to equal calendar time.

(3) In February, with 28 or 29 days, under the final rule's alternate approach one of the scheduled sampling days will end up associated with fewer than five unscheduled days, but those days will nevertheless carry equal weight with the four 6-day periods. EPA recognizes this slight departure from the concept of giving equal weight to equal calendar time.

(4) In months with 31 days, there will also be a departure from the concept of equal weight to equal calendar time. Most often, one of the "6-day" periods will actually have 7 days included in it. Rarely, the last day of a 31-day month will be a scheduled sampling day, and the effect will be to give the Pb measurement from this day equal weight in the monthly average as the five 6-day averages. In such a case, the Administrator may choose not to exercise the discretion to use the

alternate 3-step approach, for example if the measurement on the last day of a 31-day month is unusually high or low.

C. Data Completeness

1. Proposed Provisions

EPA proposed that if a monthly averaging time were selected, the basic completeness requirement for a monthly average concentration to be valid would be that at least 75 percent of the scheduled sampling days have produced valid reported data. EPA also proposed that if the maximum quarterly average concentration were selected, each month in the quarter would be required to meet this completeness test. Two "diagnostic" tests involving data substitution were proposed, which in some cases would allow a reasonably confident conclusion about the existence of an exceedance or lack thereof to be made despite data completeness of less than 75 percent.

EPA also asked for comment, but did not propose any specifics for, two other tests that could allow conclusions about exceedances to be made in additional situations when data completeness was substandard. One of these would compare the average monthly concentration to an unspecified fraction of the level of the NAAQS, in effect applying a safety margin to offset the risk of error caused by the small sample size of measured concentrations. The other test would create a statistically derived confidence interval for the average monthly concentration based on the daily data and then would test whether that interval was entirely above (indicating an exceedance) or entirely below (indicating the lack of an exceedance) the level of the NAAQS. These same tests would be used under the alternative proposal of a quarterly averaging time. However, in the proposal, EPA described these completeness tests only in the context of a monthly average concentration (i.e., for the proposed second maximum monthly average form).

2. Comments on Data Completeness

No comments were received directly on the details of the proposal regarding data completeness. One commenter expressed concern that the two diagnostic tests for use when data are less than 75 percent complete could leave an indeterminate outcome even when the weight of evidence indicates an exceedance or a lack of an exceedance. EPA believes that a proposed provision of Appendix R, which is included in the final rule, allowing for case-by-case use of incomplete data with the approval of

the Administrator allows EPA to appropriately address such a situation.

3. Conclusions on Data Completeness

The final rule differs from the monthly averaging time version of the proposal in the following aspects. These changes have been made to align Appendix R with the selected maximum rolling 3-month averaging time and form of the NAAQS and the final requirement for one-in-six day sampling (discussed in section V of this preamble). Because one-in-six sampling means that typically only five samples will be scheduled each month, only a single sample could be missed (and not made up) without completeness falling below the 75 percent level. Therefore, requiring 75 percent completeness at the monthly level could easily result in one month in a 3-year period being judged incomplete, making it impossible to make a finding of attainment of the NAAQS even when the available data in that and other months strongly suggest attainment.⁸⁸ To avoid this, the final rule applies the 75 percent completeness requirement at the 3-month level by averaging the three monthly completeness values to get the 3-month completeness value. Specifically, under the final rule 3-month completeness would be calculated and tested for every 3-month period. This reduces the likelihood of an incompleteness situation for an entire 3-year evaluation period due to as few as two missed samples in a single month.

In the proposed rule, the two diagnostic tests based on data substitution were applied within an individual month that has incomplete data relative to the 75 percent requirement. In the final rule, the tests remain and data are still substituted within the individual month (i.e., if a day of concentration data is missing from January in one of the three years, the missing concentration is substituted with the highest or lowest (depending on which diagnostic test is being applied) available measured Pb concentration from other days in the three Januarys). However, the last step of the diagnostic test, comparison of the substituted average concentration to the level of the NAAQS, is done for the 3-month average concentration not the monthly average concentration since a 3-month averaging time has been selected.

⁸⁸ Incomplete data for one month of a 3-year period would not necessarily prevent a finding of a NAAQS violation, because a single 3-month average concentration above the NAAQS level in any period not affected by that month's incompleteness would constitute a violation.

EPA is not finalizing any version of either of the two incompleteness approaches on which comment was sought, described above, because they may potentially result in incorrect conclusions regarding violations or the lack thereof. Because the number of valid daily concentration values remaining after even only a few missed days of monitoring would be quite small, a missing sample on a high-concentration day might make a confidence interval derived from the available data appear smaller than the actual variability of the daily concentrations, leading to an incorrect conclusion about the probability of a NAAQS violation. EPA may continue to study these or similar approaches for application in future NAAQS reviews. Another possible application of these approaches could be to inform the Administrator's case-by-case decisions on whether to use data that are incomplete for comparison to the NAAQS, as was proposed and as the final rule allows the Administrator to do.⁸⁹

D. Scaling Factors To Relate Pb-TSP and Pb-PM₁₀

1. Proposed Provisions

EPA proposed that Pb-PM₁₀ monitoring could be conducted to meet Pb monitoring requirements at the option of the monitoring agency, but that site-specific scaling factors would have to be developed to adjust the Pb-PM₁₀ concentrations to represent estimated Pb-TSP concentrations before comparison to the level of the Pb-TSP NAAQS. One year of side-by-side measurement with both types of samplers would be required to collect paired data for developing these scaling factors, and Pb-TSP monitoring could not be discontinued at a Pb-PM₁₀ monitoring site until the factor for that site had been approved. The proposed Appendix R contained detailed requirements for the number of data pairs successfully collected during the year of testing, the degree of correlation required between the two types of measurements, and the stability of the ratio of concentration averages from month to month, and also provided the formula for calculating the scaling factor.

EPA also asked for comment on the possibility of adopting a default scaling factor, or a set of factors applicable in different situations, instead of requiring the development of site-specific factors. EPA noted in the proposal that paired

Pb-TSP and Pb-PM₁₀ data from three historical monitoring sites suggested that site-specific scaling factors for source-oriented monitoring sites may vary between 1.1 and 2.0, but that the range may also be greater. EPA asked for comment on possible default scaling factor values within a range of 1.1 to 2.0 for application to Pb-PM₁₀ data collected at source-oriented monitoring sites. EPA also noted in the proposal that it appears that site-specific factors generally have ranged from 1.0 to 1.4 for non-source-oriented monitoring sites (with the factors for three sites ranging from 1.8 to 1.9), and that the ratios may be influenced by measurement variability in both samplers as well as by actual air concentrations. EPA asked for comment on possible default scaling factor values within a range of 1.0 to 1.9 for application to Pb-PM₁₀ data collected at monitoring sites that are not source-oriented.

2. Comments on Scaling Factors

Many commenters addressed the scaling factor issues raised in the proposal, often as part of overarching comments on the interrelated issues of the choice of indicator⁹⁰, whether and for what locations the final rule should allow Pb-PM₁₀ monitoring instead of TSP-Pb monitoring, and whether and how Pb-PM₁₀ data, if collected, should be considered in determining compliance with or violation of the Pb-TSP NAAQS. Comments on the specific subject of scaling factors to relate Pb-PM₁₀ measurements to Pb-TSP concentrations are addressed here. Other comments related to the Pb-PM₁₀ versus TSP-Pb monitoring and data use aspects of the proposal are addressed in section IV.E.

Comment on scaling factors were overwhelmingly negative towards EPA's proposal to allow Pb-PM₁₀ monitoring in place of Pb-TSP monitoring at any site on the condition that the monitoring agency first develop a site-specific scaling factor. Most commenters also did not support the alternative of establishing default scaling factors. Some commenters proposed that instead of allowing Pb-PM₁₀ monitoring in place of Pb-TSP monitoring and then applying site-specific or default scaling factors to Pb-PM₁₀ concentrations before comparison to the NAAQS, Pb-PM₁₀ monitoring only be allowed at certain types of sites.

Some commenters said that it would be burdensome on state monitoring

agencies to have to develop site-specific scaling factors because two kinds of monitoring equipment would have to be deployed at each site, one set of which would become superfluous whether or not a scaling factor was successfully developed. Concerns were also expressed that the actual ratio of the two parameters could vary over time, and therefore that EPA's proposal that a scaling factor could be used indefinitely once developed on the basis of one year of paired measurements would not be protective of public health. No comments were received on the specifics of the proposal regarding the amount and type of data that would be required to be collected or the specific correlation criteria and formula for developing a site-specific scaling factor.

The final rule does not contain any provisions for the development of site-specific scaling factors, for two reasons. The proposed requirement for a year of paired measurements would require considerable initial investment of equipment, labor time, and laboratory costs by a monitoring agency for paired measurement of both Pb-PM₁₀ and Pb-TSP in hopes of obtaining the option of indefinitely monitoring only for Pb-PM₁₀ thereafter. The lack of any interest in this approach on the part of monitoring agencies is one of the reasons it is not included in the final rule. Second, given the considerations leading to retaining Pb-TSP as the indicator for the NAAQS, considerable caution should be applied on any scaling factor approach because of the uncertainty associated with the development and use of scaling factors.

Since issuing the proposal, EPA has engaged a statistical consultant to review whether the proposed criteria regarding the amount and type of data that would be required to be collected and the specific correlation criteria and formula for developing a site-specific scaling factor were practical and scientifically sound. This assessment examined both the proposed criteria which were structured around the proposed monthly averaging time and a modified approach structured around a 3-month averaging time. The consultant's report has been submitted to the public docket.⁹¹ This assessment was able to "test drive" the proposed criteria and formula only on a relatively small number of data sets containing a sufficient number of Pb-TSP and *high-volume* Pb-PM₁₀ data pairs, and as such could not be completely definitive regarding the merits of the criteria and formula when applied to *low volume*

⁸⁹ No public comment was received on this provision.

⁹⁰ Comments regarding whether Pb-TSP or Pb-PM₁₀ should be the indicator for the NAAQS and EPA's response to them are discussed in section II.C.1.

⁹¹ Scaling Factor: PM₁₀ versus TSP, Neptune and Company, Inc., Final Report, September 30, 2008.

Pb-PM₁₀ data. Also, EPA does not necessarily endorse every aspect of the assessment or its conclusions even apart from this data type disparity. However, EPA believes based on our review of the consultant's work that there are significant unresolved issues with the proposed criteria and formula with respect to their scientific adequacy and appropriateness for the intended purpose, and that these issues could result in not providing the protection intended by the Pb NAAQS.⁹² This is another reason why the site-specific scaling factor approach is not included in the final rule. One finding in the consultant's report is that among the 21 sites where sufficient paired exist to meet the proposed data requirements for development of site-specific scaling factors, the proposed criteria for month-to-month consistency of the ratios of the two types of measurement and for overall correlation between the two measurements across the year were met at only four sites, three of which appear to be non-source-oriented.⁹³ For the non-source-oriented sites and years of data for which all the proposed criteria were met, the scaling factors fell in the range of 1.2 to 1.4. This indicates that while the observation at proposal was true that there are three non-source-oriented sites with some paired data that result in ratios in the range of 1.8 to 1.9, the data from these sites would be inadequate for developing site-specific scaling factors under the criteria of the proposed rule.

The alternative approach of establishing default scaling factors was also opposed by virtually all commenters who addressed it, and no

⁹² The issues include but are not limited to the following: The available paired data sets with enough pairs of data to apply the criteria are all from sites where Pb-TSP concentrations were well below the final level of the revised NAAQS so there is uncertainty about how well they represent sites for which the accuracy of the scaling factor is critical to compliance with or violation of the NAAQS; many of the available data sets were not able to meet the proposed criteria for the correlation between parameters and for consistency of the ratio between parameter averages from month to month, meaning that no valid scaling factors could be derived following the terms of the proposed Appendix R; the proposed methods are sensitive to how measurements below the method detection limit are reported and it is not clear how this reporting was done in the available sets of paired data, and EPA did not propose any particular reporting conventions for public comment; the site-specific scaling factors in some cases varied from year to year in those few cases where more than one year had enough pairs of data; and there are indications that a linear relationship between the two parameters with a non-zero intercept may be a better representation than a scaling factor which inherently presumes a zero intercept.

⁹³ The consultant's report does not characterize the orientation of the monitoring sites, but based on other information it appears that sites 060250005, 260770905, and 261390009 are non-source oriented.

commenter supported any specific default factor or set of default factors. Many commenters asserted that no reliable default factor or factors could be developed and that all Pb measurements for comparison to the NAAQS should be Pb-TSP measurements because of the possible presence of ultra-coarse particles containing significant amounts of Pb. One commenter did not oppose the concept of default scaling factors but even that commenter said that EPA should conduct more testing before developing such factors. A number of commenters said that if scaling factors are used, they should be conservative, health protective factors to ensure that the use of Pb-PM₁₀ monitors does not result in increased lead exposures; some of these commenters pointed to the case of a particular Pb monitoring site that was reported in the preamble to the proposed rule to have a scaling factor of 2.0. Other commenters argued that the data set from the site (in East Helena, MT) suggesting such a high ratio of Pb-TSP to Pb-PM₁₀ was not representative of the current emissions profile of sources subject to emission standards adopted since that data set was collected, and that a scaling factor for future application should be lower than 2.0.

The final rule does not provide a default scaling factor or set of factors for relating the two types of Pb concentration measurements. Any default factor or factors would be subject to greater technical pitfalls than would site-specific scaling factors. EPA believes, considering the data presented at the time of the proposal, the comments, and the consultant's assessment described above, that the variability and thus the uncertainty in the relationship of the two types of Pb measurement is not conducive to developing a default scaling factor to address all situations in which it might be applied, unless it were set so large that it effectively discouraged Pb-PM₁₀ monitoring (see below). Also, while in concept multiple default scaling factors applicable to different situations should be more successful in avoiding this problem, they could never be as good as site-specific factors about which EPA has the technical reservations described above, in addition to the practical reservations expressed by all monitoring agencies which commented on the subject. For these reasons, EPA is not adopting either site specific or default scaling factors for use as described in the proposal.

However, as discussed below, the final rule does permit the use of Pb-PM₁₀ monitoring, and direct comparison of Pb-PM₁₀ concentrations to the Pb-TSP

NAAQS, in certain situations in which EPA can be confident that such monitoring and data comparisons will in fact be a protective approach, and where such monitoring may be attractive for other reasons that were described in the proposal and also noted by commenters. Several commenters supported allowing Pb-PM₁₀ monitoring to meet Pb monitoring requirements in some situations and, in only those situations, comparing Pb-PM₁₀ data directly without any scaling factor to the Pb-TSP indicator-based NAAQS. The thrust of these comments was that this approach to making use of Pb-PM₁₀ monitors and their data would be an acceptably protective approach provided that Pb-PM₁₀ monitoring and associated comparison to the NAAQS is limited to sites where there is good reason to expect that Pb-TSP concentrations are well below the level of the NAAQS and/or that based on the nature of the nearby sources the fraction of ultra-coarse Pb in Pb-TSP would be low. Some commenters recommended this approach to monitoring only if the NAAQS has been set at a particular level. Because an appropriate response to these comments involves many of the same facts and considerations that EPA has taken into account in addressing the comments explicitly about scaling factors, above, we address these comments here as part of the discussion of data interpretation, noting that section V of this preamble discusses in more detail the changes to 40 CFR 58 associated with our disposition of these comments.

EPA agrees that given the several attractions of low-volume Pb-PM₁₀ monitoring as far as accuracy and representativeness over an area, it is appropriate to allow for the use of Pb-PM₁₀ monitors instead of Pb-TSP monitors at locations where there is very little likelihood that Pb-TSP levels will exceed the NAAQS. We also believe that in general the non-source-oriented monitoring sites required in CBSAs with populations over 500,000 (see Section V) meet this condition. Our experience with paired data at apparently non-source-oriented sites, as detailed in the Staff Paper and the preamble to the proposal, augmented by the statistical consultant's report mentioned above, supports the conclusion that the ratio of Pb-TSP concentrations to Pb-PM₁₀ concentrations at non-source-oriented sites is consistently within the range of 1.0 to 1.4.⁹⁴ The corresponding range of

⁹⁴ Of 20 sites with paired data which EPA believed at the time of the proposal to not be influenced by nearby industrial sources, only 3 had

ultra-coarse Pb fraction is zero to 0.3. Also, a new EPA staff analysis, completed since proposal, of recent Pb-TSP concentrations at existing monitoring sites that appear to be non-source-oriented (including all sites with complete data from at least one Pb-TSP monitor, not just sites with paired data) shows that nearly all of them have been well below the final level of the NAAQS; in fact, nearly all have had 3-month average Pb-TSP concentrations in 2005–2007 that do not exceed 50 percent of the NAAQS.⁹⁵ Therefore there is, in the Administrator's judgment, little risk to the protective effect of the NAAQS in allowing the use of Pb-PM₁₀ monitors at such sites and in comparing the Pb-PM₁₀ measurements directly to the Pb-TSP NAAQS. The final rule allows this, with two safeguards to further ensure the protection intended by the Pb-TSP NAAQS. The first protection is a pre-condition that the available Pb-TSP monitoring data at the site during the previous three years, if any are available, do not show any 3-month average concentrations equal to or greater than 0.10 µg/m³, which is 67 percent of the final NAAQS level.⁹⁶ Thus unlike the proposed use of scaling factors, where an approved scaling factor could have been applied to any and all recorded measured levels of Pb-PM₁₀, increasing the concern over the protectiveness of this approach, here the use of Pb-PM₁₀ data does not raise similar concerns. To guard against the possibility that any of these required sites may be different in a way that contradicts the previous experience at such sites and against the possibility that source conditions around one or more of these monitoring sites may change over time, the final rule also provides that if any 3-month average

ratios of average concentrations of Pb-TSP to Pb-PM₁₀ greater than 1.4. One of these sites had only 13 data pairs. The other two sites had very low concentrations of both parameters, such that the ratio may reflect the influence of data rounding/truncation or censoring of data below the method detection limit more than actual atmospheric concentration ratios. Also, these paired data were from 2001 or earlier. (Development of Pb-PM₁₀ to Pb-TSP Scaling Factors, Mark Schmidt, 4/22/08.) Also, as noted above, the data from these sites are not adequate for the development of site-specific scaling factors if the proposed criteria for such data are applied to them.

⁹⁵ M. Schmidt and P. Lorang (October 15, 2008). Memo to Lead NAAQS Docket, Analysis of Expected Range of Pb-TSP Concentrations at Non-Source Oriented Monitoring Sites in CBSAs with Population Over 500,000.

⁹⁶ Based on the analysis described in the memo referenced in the previous footnote, EPA estimates that this provision might have the effect of prohibiting the use of Pb-PM₁₀ monitoring for at most only a few existing Pb monitoring sites which otherwise might be eligible for Pb-PM₁₀ monitoring instead of Pb-TSP monitoring.

concentration of Pb-PM₁₀ is ever observed to be equal to or greater than 0.10 µg/m³, a Pb-TSP monitor must be installed.⁹⁷ This 33 percent margin against the level of the NAAQS is protective for the long run situation, given that the available data strongly suggest that scaling factors will rarely if ever be greater than 1.4 at non-source-oriented sites. If the 3-month average Pb-PM₁₀ concentration at a site was below 0.10 µg/m³ and the scaling factor at that site was 1.4, the 3-month Pb-TSP concentration would be below the level of the NAAQS. EPA notes that some commenters suggested that this flexibility be pre-conditioned on there being site-specific affirmative evidence that Pb-TSP concentrations are less than 50 percent of the NAAQS. However, for many of the required monitoring sites of this type there will be no pre-existing Pb monitoring data and in the absence of a dominant nearby industrial source attempts to estimate Pb concentrations using air quality modeling techniques would be very uncertain. EPA believes that the evidence from the many existing non-source-oriented sites is sufficient to support allowing this flexibility without a site-specific hurdle, other than the provision tied to existing monitoring data if there are any.

EPA has also considered whether any of the required source-oriented sites should be allowed to be monitored for Pb-PM₁₀ rather than Pb-TSP, also with the Pb-PM₁₀ concentrations compared directly to the Pb-TSP NAAQS. As explained in Section V, the final requirements for monitoring near sources of Pb are based on the quantity of Pb emitted being above an emissions threshold. We are extending the allowance for the use of Pb-PM₁₀ monitors to allow Pb-PM₁₀ monitors without the use of scaling factors for source-oriented monitors where Pb concentrations are expected to be less than 0.10 µg/m³ (based on modeling or historic data) and where the ultra-course Pb fraction is expected to be low. We are also requiring, as for non-source-oriented sites, that a Pb-TSP monitor be required at a source-oriented site if at some point in the future the Pb-PM₁₀ monitor shows that Pb-PM₁₀ concentrations are equal to or greater than 0.10 µg/m³.⁹⁸ A state may also operate non-required Pb monitors at any

⁹⁷ When the Pb-TSP monitor is installed, the monitoring agency would have the option of discontinuing the Pb-PM₁₀ monitor, and we expect that most agencies would do so for cost reasons.

⁹⁸ If three years of Pb-TSP monitoring results in no 3-month average Pb concentration equal to or greater than 0.10 µg/m³, as might occur after the source improves its control of Pb emissions, the site would again be eligible for Pb-PM₁₀ monitoring.

other locations of its choosing, and these may be of any type.

3. Conclusions on Scaling Factors

The final version of Appendix R eliminates all reference to scaling factors. As explained in detail in section V, the final rule allows Pb-PM₁₀ monitoring as a surrogate for Pb-TSP monitoring under certain specified conditions, with continuation of such monitoring being contingent on measured 3-month average Pb-PM₁₀ concentrations remaining without application of any scaling factor staying less than 0.10 µg/m³. Section IV.E discusses how Pb-PM₁₀ monitoring data will be used as a surrogate for Pb-TSP in comparisons to the Pb-TSP NAAQS to determine compliance with or violation of the NAAQS.

E. Use of Pb-TSP and Pb-PM₁₀ Data

1. Proposed Provisions

The proposed text of Appendix R provided that complete Pb-TSP data would be given precedence over both incomplete and complete (scaled) Pb-PM₁₀ data, when both were collected in the same month at the same site, and prohibited the mixing of the two types of data in calculating the average Pb concentration for a single month. Pb-TSP data would be used in preference to Pb-PM₁₀ data to form a monthly average Pb concentration whenever the Pb-TSP data meets the test for completeness and valid monthly average, i.e., whenever 75 percent of scheduled samples have valid data or one or the other of the two diagnostic tests in the case of less than 75 percent completeness results in a valid monthly average. If the Pb-TSP data were not complete enough to allow development of a monthly average, the available scaled Pb-PM₁₀ data from the site for that month would be used provided they were complete enough. Scaled Pb-PM₁₀ data could be used to show both compliance and violation of the NAAQS.

2. Comments on Use of Pb-TSP and Pb-PM₁₀ Data

No comments were received specifically on the proposed provisions of Appendix R addressing the precedence between Pb-TSP and Pb-PM₁₀ data. However, the elimination of scaling factors from the final rule and the inclusion of flexibility for Pb-PM₁₀ monitoring only in limited situations, done by EPA in the final rule in response to comments summarized above, have required EPA to reconsider the proposed provisions on the use of

Pb-PM₁₀ data and to make changes in the final version of Appendix R.

First, EPA has considered whether a comparison of Pb-PM₁₀ monitoring data to the NAAQS should be able to result in a conclusion that the NAAQS has been violated if the comparison shows that a 3-month average Pb-PM₁₀ concentration is above the level of the Pb-TSP NAAQS. This situation could occur at a site that is required by the final rule's Pb monitoring requirement which is allowed to use Pb-PM₁₀ monitoring in place of Pb-TSP monitoring, although EPA believes it is unlikely given the preconditions in the final rule regarding which required sites may use Pb-PM₁₀ monitoring. It might also occur at a non-required site, where the rule does not attempt to restrict the monitoring agency's flexibility to use Pb-PM₁₀ monitoring and thus a monitoring agency might choose not to adhere to the same preconditions. Given that a Pb-PM₁₀ monitor will generally capture somewhat less or at most the same quantity of Pb as would a Pb-TSP monitor on a given day, EPA believes that if a 3-month average of Pb-PM₁₀ concentrations is based on data that meets the 75 percent completeness test, including the associated diagnostic data substitution tests described in IV.B, and is above the level of the NAAQS, that situation should be considered to be a NAAQS violation.

This should be the case even if a Pb-TSP monitor at the same site has recorded a complete, valid 3-month average Pb-TSP concentration below the NAAQS for the same 3-month period. As just stated, a Pb-PM₁₀ monitor will generally capture somewhat less or at most the same quantity of Pb as would a Pb-TSP monitor on a given day. While it is conceivable that a malfunction of a Pb-PM₁₀ monitor, an operator error, or simple variability could cause a single measured Pb-PM₁₀ concentration to be higher than a valid same-day collocated Pb-TSP concentration measurement, EPA expects based on experience that this will be rare, particularly because 40 CFR part 58 appendix A and EPA quality assurance guidance contain required and recommended procedures to avoid equipment malfunctions and operator errors and to invalidate any data affected by them before submission to EPA's air quality data base. Also, since 3-month averages will be based on multiple measurements, a significant effect on 3-month average concentrations from such factors is an even more remote possibility. EPA believes that the only situation at all likely to arise in which a complete 3-month average of Pb-PM₁₀ indicates a NAAQS violation while a complete 3-

month average of Pb-TSP for the same period does not would be when the Pb-PM₁₀ average includes more days of monitoring than the Pb-TSP average, and those additional days tend towards high concentrations. This can occur if the Pb-PM₁₀ measurements are being taken on a more frequent schedule, if they are missing fewer days of scheduled data than for the Pb-TSP measurements (counting make-up samples), or if more extra samples are taken for Pb-PM₁₀ than for Pb-TSP. Regardless of which cause or causes are responsible, EPA believes that the Pb-PM₁₀ average based on more days of sampling would generally be the more robust indication of ambient concentrations, and the site should be considered to have violated the NAAQS.

Next, EPA has considered whether a comparison of Pb-PM₁₀ monitoring data to the NAAQS should be able to result in a conclusion that the NAAQS has been met if the comparison shows that all the 3-month average Pb-PM₁₀ concentrations over a 3-year period are below the level of the Pb-TSP NAAQS and there is no Pb-TSP data showing a violation, or should such a comparison only lead to the more limited conclusion that there has not been a demonstrated NAAQS violation.⁹⁹ In considering this issue, EPA notes that while the final rule allows the use of Pb-PM₁₀ monitoring in place of Pb-TSP monitoring only at required non-source-oriented monitoring sites that by their nature are expected to have a low fraction of ultra-coarse Pb, even a low fraction is not a zero fraction. Also, the expectation of a low ultra-coarse fraction may turn out to be incorrect due to unexpected causes. Also, monitoring agencies may also deploy Pb-PM₁₀ monitors at non-required sites which may have higher or unknown fractions of ultra-coarse Pb. Appendix R must anticipate the availability of data from such sites, as EPA believes that such data should not be ignored and that states should know in advance how it will be used if collected. Because Pb-PM₁₀ data may include data from sites with non-zero ultra-coarse fractions and may include data from sites with high or unknown ultra-coarse fractions, EPA believes it would undermine the protectiveness of the NAAQS to always allow any Pb-PM₁₀ data from any monitoring site to demonstrate compliance with the NAAQS. Some site applicability restriction and/or compliance margin when using Pb-PM₁₀

⁹⁹ Such a comparison based on actual Pb-TSP data would of course be able to support a compliance conclusion, because Pb-TSP is the actual indicator for the NAAQS.

data to show compliance would be needed to avoid undermining the protectiveness of the NAAQS. The technical issues to be overcome in designing site applicability restrictions and/or compliance margins would be the same as the issues that arise when considering default scaling factors, described above.

EPA is also mindful that the distinction between a finding of compliance with the NAAQS and not making a finding of violation is much more theoretical than practical. The distinction is not important to the initial stages of the implementation process for a revised NAAQS, because (1) by the time of the initial designations very few Pb-PM₁₀ monitoring sites will have three years of data so a finding of compliance would not be possible anyway¹⁰⁰, and (2) there is no practical difference in planning or implementation requirements between areas that have been found to be in compliance with the NAAQS and areas for which it can only be said that they have not been found to be in violation of the NAAQS. However, later, for an area initially designated nonattainment, an affirmative finding that the area is complying with the NAAQS is required in order for the area to be redesignated attainment (also referred to as maintenance) after emission controls are implemented. In the latter situation, however, a Pb-TSP monitor should be operating at any site that has initially shown a violation based on either Pb-TSP or Pb-PM₁₀, since Pb-TSP monitoring must begin at any site where Pb-PM₁₀ concentrations have exceeded even 50 percent of the NAAQS. This makes it moot whether Pb-PM₁₀ data alone can be used to redesignate a nonattainment area to attainment after emission controls are implemented. In light of the technical issues and the lack of any substantive consequences, the final version of Appendix R does not allow Pb-PM₁₀ data to be used to show affirmative compliance with the NAAQS.

The above discussion addresses the compliance versus violation consequences of comparing Pb-PM₁₀ and Pb-TSP data to the Pb-TSP NAAQS. EPA has also considered the issue of how design values should be determined when there is only Pb-PM₁₀ data or there is a mixture of Pb-PM₁₀ data and Pb-TSP data for a single monitoring site over a given period. In

¹⁰⁰ Only a handful of low-volume Pb-PM₁₀ monitoring sites are now operational none of which indicate NAAQS violations. In addition, any sites which begin operation in response to the final monitoring requirements cannot collect three years of data by the time designations must be completed.

addition to conveying the compliance or noncompliance status of a monitoring site, design values are also used as an informative indicator of pollutant levels more generally. For the revised Pb NAAQS, the design value in simple terms is the highest valid 3-month average concentration at a monitoring site over whatever period of three years is being reported.¹⁰¹ It is necessary to be specific in Appendix R about whether and when Pb-PM₁₀ data can be used in the calculation of the design value. In the proposal, the simple principle applied was that complete Pb-TSP data for a month or quarter always would have precedence over scaled Pb-PM₁₀ data, but that in the absence of complete Pb-TSP data, scaled Pb-PM₁₀ data would be used regardless of the resulting value of the design value. For the same reason described above that Pb-PM₁₀ data will not be allowed to support a finding of compliance with the NAAQS, it would be inappropriate to use such data to develop a design value whose value is below the level of the NAAQS.

Therefore, the final version of Appendix R provides that the only situation in which Pb-PM₁₀ data will be used to calculate the design value is when doing so results in a higher design value than using only Pb-TSP data and that design value is above the level of the NAAQS.

3. Conclusions on Use of Pb-TSP and Pb-PM₁₀ Data

The final version of Appendix R specifies that the NAAQS is violated whenever Pb-PM₁₀ data or Pb-TSP data result in a 3-month average concentration above the NAAQS level, but that compliance with the NAAQS can only be demonstrated using Pb-TSP data. Pb-PM₁₀ data will be used in the calculation of a design value only when doing so results in a higher design value than using only Pb-TSP data and that design value is above the level of the NAAQS.

F. Data Reporting and Rounding

1. Proposed Provisions

EPA proposed that individual daily concentrations of Pb be reported to the nearest thousandth $\mu\text{g}/\text{m}^3$ (0.xxx) with additional digits truncated, and that monthly averages calculated from the daily averages would be rounded to the nearest hundredth $\mu\text{g}/\text{m}^3$ (0.xx). Decimals 0.xx5 and greater would be

¹⁰¹ It is also possible for a period of less than three years to have a valid design value, but only if the procedures in Appendix R when applied to that shorter period result in a design value greater than the level of the NAAQS. It is possible to establish a violation of the NAAQS on a monitoring period as short as three months but three years are needed to establish compliance with the NAAQS.

rounded up, and any decimal lower than 0.xx5 would be rounded down. E.g., a monthly average of 0.104925 would round to 0.10 and a monthly average of 0.10500 would round to 0.11. Because the proposed NAAQS level would be stated to two decimal places, no additional rounding beyond what is specified for monthly averages would be required before a design value selected from among rounded monthly averages would be compared to the level of the NAAQS.

2. Comments on Data Reporting and Rounding

No comments were received on this aspect of the proposal.

3. Conclusions on Data Reporting and Rounding

The final version of Appendix R differs from that proposed because the proposed version addressed a single month as the averaging time for the NAAQS and the final NAAQS is based on a 3-month average concentration. In the preamble to the proposal, EPA did not specifically address whether and how, in the case of the NAAQS being based on a 3-month averaging time, calculated monthly averages would be rounded before being used to calculate the 3-month average. The final version of Appendix R specifies that all digits of the monthly average shall be retained for the purpose of calculating the 3-month average, with the 3-month average then rounded to the nearest hundredth $\mu\text{g}/\text{m}^3$, i.e., 3-month average decimals 0.xx5 and greater would be rounded up and any decimal lower than 0.xx5 would be rounded down. Because individual monthly averages are never compared to the level of the NAAQS there is no need to specify a rounding convention for them, and retaining all digits until the final comparison of the 3-month average to the NAAQS allows a more precise determination of compliance compared to rounding at both the monthly and 3-month levels.

G. Other Aspects of Data Interpretation

One implication of the selection of a rolling 3-month period as the averaging time of the NAAQS is that there will be two 3-month periods that span each pair of adjacent calendar years: November-January and December-February. EPA has considered whether, for any three-calendar-year period, the 3-month averaging periods including one or both of the two months of the year prior to those three years and/or the averaging periods including one or both of the two months following those three years will be included in determining whether a monitoring site has met or violated the

NAAQS. This issue was not discussed in the proposal, because the monthly average and calendar quarterly average options discussed in the proposal do not raise this issue. The final version of Appendix R provides that the 3-month averages which include either of the two months prior to a three-calendar-year period will be associated with that 3-year period, and that the 3-month averages which include either of the two months after the three-calendar-year period will not be associated with it. The latter two months would be within the next 3-year period and their data would affect compliance during that next 3-year period. Thus, for example, the thirty-six 3-month averages that will be considered in determining compliance with the NAAQS for the 3-year "2010–2012" evaluation period will be based on data from November and December of 2009, and all of 2010, 2011, and 2012. Data from November 2009 will be used as part of the calculation of one 3-month average, and data from December 2009 will be used as part of the calculation of two 3-month averages. Data from November and December of 2012 will be used but only for 3-month averages which are made up solely of months in 2012. Thus, for the 2010–2012 period, November 2009 through January 2010 is the first 3-month period and October through December 2012 is the last 3-month period.

This approach has been selected for practical reasons, because the once-per-year deadline for certifying data submitted to AQS means that data from January and February of the year after a three-calendar-year period will most often still be preliminary and uncertified as to completeness and accuracy for 12 months beyond when data from the three-calendar-year period itself (and the two previous months) are final and ready to be used for compliance determinations.

Generally, a violation will have occurred if any of the 36 three-month average concentrations of either Pb-TSP or Pb-PM₁₀ exceeds the level of the NAAQS,¹⁰² and a finding of compliance will require that all 36 3-month averages of Pb-TSP be at or below the level of the NAAQS. The final Appendix R addresses the special situation of a new monitoring site which has started sampling by January 15 of a certain year. After the first three years of data collection, only 34 3-month average concentrations will be available. In this

¹⁰² A violation will exist as soon as any 3-month average exceeds the level of the NAAQS. It is not required that three years of data collection be completed before a site can be found in violation. This is consistent with the proposal.

situation, Appendix R provides that a finding of compliance will be made if all 34 available 3-month average concentrations of Pb-TSP are at or below the level of the NAAQS.

As discussed in Section V on monitoring requirements, EPA proposed and is finalizing a change to the Pb monitoring requirements to no longer allow monitoring agencies to combine several daily Pb-TSP filters for chemical analysis, at required Pb monitoring sites.¹⁰³ The proposed Appendix R presumed this change and did not address how data from such "composite" samples would be used in comparisons to the NAAQS. However, on further reflection EPA believes that whatever composite sample data have been collected and submitted to AQS before the prohibition on using the composite sample approach takes effect should be considered for purposes of initial designations under the revised NAAQS, if those data fall within the period on which designations will be based. The final version of Appendix R therefore includes specific provisions addressing how to account for composite sample data in determining data completeness and in calculating a monthly and 3-month average concentration value. These provisions will also govern the use of any composite sample data that are collected at non-required monitoring sites, indefinitely. The only noteworthy issue EPA had to consider in developing these provisions was what to do when the submitted data for a monitoring site includes both a composite sample Pb value and one or more individual daily sample Pb values. Because it is impossible to tell the exact days represented by a composite sample, Appendix R specifies that either the composite sample or the available daily data (if complete daily data were collected) will be used depending on which has the lower pollutant occurrence code,¹⁰⁴ but they will not be

¹⁰³ The FRM specification in the new Appendix Q for Pb-PM₁₀ monitoring excludes the possibility of composite sampling for Pb-PM₁₀, so this in an issue that applies only to Pb-TSP.

¹⁰⁴ The pollutant occurrence code is a numerical code (1, 2, 3, etc.) used to distinguish the data from two or more monitors for the same parameter at a single monitoring site. For example, if a monitoring agency has been using both composite analysis for filters from one sampler and individual sample analysis for filters from a collocated sampler, data from these would be distinguished using this code. Choosing which set of data to use based on which has the lower code value is an approach chosen for its simplicity, to avoid specifying what would have to be a complicated set of procedures to determine which set of data or combination of the two sets actually is the more robust for determining whether the NAAQS is met.

combined because that might give double weight to some days.

V. Ambient Monitoring Related to Revised Lead Standards

We are finalizing several changes to the ambient air monitoring and reporting requirements for Pb to account for the revised NAAQS and to update the Pb monitoring network. Ambient Pb monitoring data are used for comparison to the Pb NAAQS, for analysis of trends and accountability in areas with sources that have implemented controls, in the assessment of control strategies, for evaluating spatial variation of Pb concentrations across an area, and as an input to health studies used to inform reviews of the NAAQS. Ambient data are collected and reported by state, local, and tribal monitoring agencies ("monitoring agencies") according to the monitoring requirements contained in 40 CFR parts 50, 53, and 58. This section summarizes the proposed changes to the monitoring requirements in the May 20, 2008 notice of proposed rulemaking, the major comments received on the proposed changes, and the final changes to the Pb monitoring regulations being promulgated with this action. This section is divided into discussions of the monitoring requirements for the sampling and analysis methods (including quality assurance requirements), network design, sampling schedule, data reporting, and other miscellaneous requirements.

A. Sampling and Analysis Methods

We are finalizing changes to the sampling and analysis methods for the Pb monitoring network. Specifically, we are continuing to use the current Pb-TSP Federal Reference Method (FRM, 40 CFR part 50 Appendix G), but are finalizing a new Federal Reference Method (FRM) for monitoring Pb in PM₁₀ (Pb-PM₁₀) for the limited situations where it will be permitted, lowering the Pb concentration range required during Pb-TSP and Pb-PM₁₀ candidate Federal Equivalent Method (FEM) comparability testing, and finalizing changes to the quality assurance requirements for Pb monitoring. The following paragraphs provide background, rationale, and details for the final changes to the sampling and analysis methods.

1. Pb-TSP Method

No substantive changes are being made to the Pb-TSP method. The current FRM for Pb sampling and analysis is based on the use of a high-volume TSP FRM sampler to collect the particulate matter sample and the use of

atomic absorption (AA) spectrometry for the analysis of Pb in a nitric acid extract of the filter sample (40 CFR 50 Appendix G). There are 21 FEMs currently approved for Pb-TSP.¹⁰⁵ All 21 FEMs are based on the use of high-volume TSP samplers and a variety of approved equivalent analysis methods.¹⁰⁶

a. Proposed Changes

We stated in the NPR that if the final standard is based on Pb-TSP, we believed it would be appropriate to continue use of the current high-volume FRM for measuring Pb-TSP. We proposed to make several minor changes in 40 CFR 50 Appendix G to correct reference citations. However, we did not propose any substantive changes to Appendix G.

In addition, we stated in the NPR that we believe that low-volume Pb-TSP samplers might be superior to high-volume TSP samplers. We pointed out that presently, a low-volume TSP sampler cannot obtain FRM status, because the FRM is specified in design terms that preclude designation of a low-volume sampler as a FRM. We also suggested that a low-volume Pb-TSP monitoring system (including an analytical method for Pb) could be designated as a FEM Pb-TSP monitor, if side-by-side testing were performed as prescribed by 40 CFR 53.33. We proposed amendments to 40 CFR 53.33 (described below in section V.A.3) to make such testing more practical and to clarify that both high-volume and low-volume TSP methods could use this route to FEM status. We also held a consultation with the CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee on approaches for the development of a low-volume TSP sampler FRM or FEM.

b. Comments on Pb-TSP Method

This section addresses comments we received on our proposal to continue the use of the Pb-TSP FRM as the monitoring method for the Pb NAAQS, and comments on the use of low-volume TSP samplers as either a FEM or FRM for Pb-TSP. We also received comments on a number of related topics that are not discussed in this section. We received comments on the use of Pb-PM₁₀ as the Pb indicator, and those comments are addressed in Section II.C.1 of this preamble. We received comments on the use of scaled Pb-PM₁₀,

¹⁰⁵ For a list of currently approved FRM/FEMs for Pb-TSP refer to: <http://www.epa.gov/ttn/amtic/criteria.html>.

¹⁰⁶ The 21 distinct approved FEMs represent less than 21 fundamentally different analysis methods, as some differ only in minor aspects.

or other ways to supplement Pb-TSP monitoring data with Pb-PM₁₀ data, and those comments are addressed in Section IV.D, and in Section V.B of this preamble.

We received a number of comments on our proposal to continue the use of high-volume TSP samplers as the sampling method for Pb. In their comments on the proposed rule, CASAC reiterated their concerns over the measurement uncertainty due to effects of wind speed and wind direction on sampling efficiency.¹⁰⁷ These concerns were discussed in detail in our proposed rule, and as such are not reiterated here. However, CASAC stated that if the final level of the NAAQS were to be set at 0.10 µg/m³ or above, then the high-volume Pb-TSP sampler should be used. Some public commenters also stated similar concerns with the performance of the Pb-TSP sampler.

A large number of other commenters stated that the high-volume TSP sampler should continue to be the sampler for determining compliance with the Pb NAAQS. They expressed concerns that PM₁₀ samplers would not capture ultra-coarse particles (i.e., particulate matter with an aerodynamic diameter greater than 10 µm), and could greatly underestimate Pb concentrations in the ambient air, especially near Pb sources.

Despite some limitations with sampler performance and consistent with CASAC advice for methods at the level of the NAAQS we have chosen, we believe the high-volume sampler is the most appropriate currently available sampler for the measurement of Pb-TSP in ambient air. Ultra-coarse particulate matter (larger than PM₁₀) can contribute to a significant portion of the total Pb concentration in ambient air, especially near Pb sources (Schmidt, 2008) where Pb-TSP concentrations may be as much as twice as high as Pb-PM₁₀. Furthermore, we believe the precision and bias of the high-volume TSP sampler are acceptable and similar to those for other PM samplers (Camalier and Rice, 2007).

We received several comments supporting the need for the development of a low-volume Pb-TSP sampler. However, in our consultation with CASAC's AAMM Subcommittee, we were cautioned against finalizing a new low-volume Pb-TSP FRM without an adequate characterization of the

sampler's performance over a wide range of particle sizes.¹⁰⁸ We agree with the interest for a low-volume Pb-TSP sampler and the desire for such a sampler to be adequately characterized prior to being promulgated as a new FRM. Accordingly, we plan to further investigate the possibility of developing a low-volume FRM in the future.

c. Decisions on Pb-TSP Method

We are maintaining the current FRM and FEMs for Pb-TSP as the sampling and analysis methods for monitoring for the Pb NAAQS. As proposed, we are making minor editorial changes to 40 CFR 50 Appendix G (the FRM for Pb-TSP) to correct some reference citations. We are not making any other substantive changes to Appendix G.

2. Pb-PM₁₀ Method

We are finalizing a new FRM for Pb-PM₁₀ monitoring based on the use of the low-volume PM_{10C} FRM (40 CFR part 50, Appendix O) sampler coupled with energy dispersive x-ray fluorescence (XRF) as the analysis method. This section describes the proposed Pb-PM₁₀ FRM, the comments we received, and the final Pb-PM₁₀ FRM requirements being promulgated with this action.

a. Proposed FRM for Pb-PM₁₀ Monitoring

We proposed a new Pb-PM₁₀ FRM based on the use of the already promulgated PM_{10C} FRM coupled with XRF as the analysis method. We proposed to use the low-volume PM_{10C} sampler for the FRM for Pb-PM₁₀ rather than the existing PM₁₀ FRM specified by Appendix J, for several reasons. The low-volume PM_{10C} FRM sampler meets more demanding performance criteria (Appendix L) than are required for the PM₁₀ samplers described in Appendix J. PM_{10C} samplers can be equipped with sequential sampling capabilities (i.e., the ability to collect more than one sample between operator visits). The low-volume PM_{10C} sampler can also precisely maintain a constant sample flow rate corrected to actual conditions by actively sensing changes in temperature and pressure and regulating sampling flow rate. Use of a low-volume sampler for the Pb-PM₁₀ FRM would also provide network efficiencies and operational consistencies with the samplers that are in widespread use for the PM_{2.5} FRM network, and that are seeing growing use in the PM₁₀ and

PM_{10-2.5} networks. Finally, the use of a low-volume sampler is consistent with the comments and recommendations from CASAC and members of CASAC's AAMM Subcommittee (Henderson 2007a, Henderson 2008a, Russell 2008b).

We proposed XRF as the FRM analysis method because we believe that it has several advantages which make it a desirable analysis method. XRF does not require sample preparation or extraction with acids prior to analysis. It is a non-destructive method; therefore, the sample is not destroyed during analysis and can be archived for future re-analysis if needed. XRF analysis is a cost-effective approach that could be used to simultaneously analyze for many additional metals (e.g., arsenic, antimony, and iron) which may be useful in source apportionment. XRF is also the method used for the urban PM_{2.5} Chemical Speciation Network (required under Appendix D to 40 CFR part 58) and for the Interagency Monitoring of Protected Visual Environments (IMPROVE) rural visibility monitoring program in Class I visibility areas, and is being considered by EPA for a role in PM_{10-2.5} coarse speciation monitoring. Based on data from the PM_{2.5} speciation monitoring program, the XRF analysis method when coupled with the low-volume PM_{10C} sampler, is expected to have an adequate method detection limit (MDL, the lowest quantity of a substance that can be distinguished from the absence of that substance) and meet the measurement uncertainty goals for precision and bias as determined through the data quality objective (DQO) analysis (Papp, 2008), as explained later in this preamble.

b. Comments on the proposed Pb-PM₁₀ FRM

We received a number of comments on the proposed FRM for Pb-PM₁₀. In addition, the CASAC AAMM Subcommittee provided a peer review of the proposed Pb-PM₁₀ FRM. The following paragraphs describe the comments received and our responses.

The CASAC AAMM Subcommittee agreed with our proposed use of the PM_{10C} sampler. Other comments on our proposed use of the low-volume PM_{10C} sampler for the Pb-PM₁₀ FRM were in support of the PM_{10C} as an appropriate sampler for the FRM. We are promulgating the Pb-PM₁₀ FRM based on the use of the low-volume PM_{10C} sampler.

We also received comments on our proposed use of XRF as the analysis method for the Pb-PM₁₀ FRM, including comments from CASAC's AAMM

¹⁰⁷ Sampling efficiency refers to the percentage of total Pb (or PM) that is collected by the sampler. For the TSP sampler, research shows that the sampling efficiency varies for particulates greater than PM₁₀ as a function of wind speed and wind direction.

¹⁰⁸ Proper characterization of a new Pb-TSP FRM sampler would require extensive wind-tunnel testing and field testing. Wind tunnel testing would be complicated by the difficulty in quantifiably generating and delivering precise amounts of ultra-coarse PM in a wind-tunnel setting.

Subcommittee during the peer review of the proposed FRM. Several commenters agreed with our proposed use of XRF as the analysis method, citing several of the advantages we identified in the preamble to the proposed rule.

However, several other commenters suggested that Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) would be a more appropriate analysis method for the FRM.

The AAMM Subcommittee and other commenters raised concerns with the potential for measurement bias due to non-uniform filter loadings. They noted that the analysis beam of the XRF analyzer does not cover the entire filter collection area; therefore, it is possible for the measurement to be biased if the Pb particles deposit more (or less) on the edge of the filter as compared to the center of the filter. To address these concerns, EPA's Office of Research and Development (ORD) conducted qualitative and quantitative tests of filter deposits generated in the laboratory under controlled conditions. Although test results confirmed prior reports of formation of a deposition band at the circumference of the PM_{10C} filters, this band comprises only 5 percent of the filter's deposition area. Quantitative analysis of collected calibration aerosols in the 0.035 micrometer to 12.5 micrometer size range revealed that use of either a centrally located 10 mm or 20 mm spot size can accurately represent the filter's mean mass concentration within approximately 2 percent. Similar results were obtained using a PM_{2.5} FRM sampler and a "total particulate sampler" (a PM_{2.5} sampler with the internal separator removed). Based on these results, it can be concluded that any non-uniformity of particle deposition on PM_{10C} filters will represent a small fraction of the overall uncertainty in ambient Pb concentration measurement. As such, we believe the concerns associated with non-uniform filter loading are sufficiently addressed to allow XRF as an appropriate analysis method for the FRM.

The AAMM Subcommittee and other commenters suggested ICP-MS as an alternative to the XRF analysis method. Advantages identified with ICP-MS included the analysis of the entire filter deposit and a higher sensitivity (i.e., lower MDL). We agree that the ICP-MS analysis method is also an appropriate method for the analysis of Pb. However, ICP-MS (and other analysis methods requiring the extraction of Pb prior to analysis) also has potential bias due to uncertainty in the percentage of total Pb that is extracted. While this bias can be minimized by use of very strong acids (i.e., hydrogen fluoride), many

laboratories wish to avoid these strong acids due to the damage they can do to the analyzer and due to safety concerns. In addition, ICP-MS is a destructive method and samples cannot be saved for further analysis. We agree that the ICP-MS method is more sensitive than the XRF method. However, the XRF method detection limit provides sufficient sensitivity for use in determining compliance with the Pb NAAQS being promulgated today. As pointed out in our preamble to the proposed rule, we estimated the method detection limit for XRF and ICP-MS coupled with low-volume sampling to be 0.001 µg/m³ and 0.00006 µg/m³, respectively. No commenters disagreed with these estimates.

Several states requested approval for alternative analysis methods because their laboratories are already equipped to perform those analysis methods. Our decision to use XRF as the FRM analysis method does not prevent monitoring agencies from using alternative analysis methods. However, before these alternative analysis methods can be used they must be approved as FEMs for the measurement of Pb-PM₁₀. Monitoring agencies can seek FEM approval for alternative analysis methods by following the FEM requirements (40 CFR Part 53.33). In addition, we plan to approve (after conducting the necessary testing and developing the necessary applications ourselves) FEMs for ICP-MS and Graphite Furnace Atomic Absorption (GFAA) to support monitoring agencies that prefer to use these analysis methods.

We also received comments on the specific details of the proposed XRF analysis method. The AAMM Subcommittee and one other commenter raised concerns about the lack of a thin-film XRF National Institute of Standards and Technology (NIST)-traceable Pb standard. NIST currently offers Standard Reference Material (SRM) 2783, "Air Particulate on Filter Media", that is a polycarbonate filter that contains a certified concentration for Pb equivalent to 0.013 ± 0.002 µg/m³. Calibration materials for XRF are not destroyed during analysis; therefore, the SRM should be stable over time and can be reused multiple times if properly handled and protected.

The AAMM Subcommittee raised concerns regarding lot-specific laboratory blanks, field blanks, and possible contamination of filters. The commenters suggested that the laboratory blanks (the results of Pb analysis of "clean" filters that have not been used in a sampler) that are used for XRF background measurement and

correction be lot-specific. The addition of lot-specific laboratory blanks will help minimize contamination that may be due to new filter lots and the analytical system. A few commenters suggested the addition of field blanks in order to minimize the Pb contamination of filters in the field. Field blanks are filter blanks that are sent to the field and are placed into the sampler for the sampling duration without ambient air flow. We agree with the suggestions to make laboratory blanks lot-specific and to add the collection of field blanks. A comment to add annual MDL determinations and filter-lot specific MDL determinations was received. We agree that the addition of annual MDL estimates and lot-specific MDL determinations is an improvement to the proposed FRM text. In addition, several editorial comments were received that related to modifying existing statements to add clarity and help to ensure consistency across laboratories. We are making changes to the XRF analysis method to address these editorial comments.

We received one comment related to the need for data quality objectives (DQOs). We agree with the commenter on the need for DQOs for the Pb-PM₁₀ FRM. Since the time of proposal, we have completed the DQO analysis to evaluate the acceptable measurement uncertainty for precision and bias. The DQO report is in the docket. As part of that process, the recommended goals for precision were defined as an upper 90 percent confidence limit for the coefficient of variation of 20 percent and the goals for bias were defined as an upper 95 percent confidence limit for the absolute bias of 15 percent. We have reflected this in our final regulation.

c. Decision on Pb-PM₁₀ FRM

We are finalizing the FRM for Pb-PM₁₀ as proposed with the exception of the following amendments and additions. Changes to the XRF analysis method are being made to address comments received during the public comment period and peer review of the proposed Pb-PM₁₀ FRM. These changes include a revision to the Pb-PM₁₀ FRM text to include reference to the SRM 2783 NIST-traceable calibration standard. The FRM text was modified to add a section that requires the collection of field blanks, and clarify that the laboratory blanks used for background measurement and correction shall be lot-specific. We added the requirements for annual MDL estimates and lot-specific MDL determinations. Several minor changes were made to address editorial comments received that related to modifying existing statements to add

clarity and help to ensure consistency across laboratories. Examples of these changes include the addition of other commercial XRF instrumentation vendors; clarification of the maximum filter loading for Pb analysis which is based on the maximum mass loading ($200 \mu\text{g}/\text{m}^3$) for a $\text{PM}_{10\text{C}}$ sampler; inclusion of additional references for spectral processing methods; and clarification that the FRM applies specifically to Pb. A reference was included for additional guidance if multi-elemental analysis is performed. To ensure consistency in reporting uncertainties for Pb by XRF across laboratories, an equation to calculate uncertainties was added and follows the same procedure used for XRF in the $\text{PM}_{2.5}$ speciation program. Based on the DQO process, the FRM precision and bias requirements were modified to reflect the measurement uncertainty goals of 20 percent and 15 percent, respectively.

3. FEM Requirements

We are finalizing changes to the FEM requirements for Pb. These requirements will apply for both Pb-TSP and Pb- PM_{10} methods. This section discusses the proposed changes to the FEM requirements, comments received on the proposed changes, and the final FEM requirements being promulgated with this action.

a. Proposed FEM Requirements

The current FEM requirements state that the ambient Pb concentration range at which the FEM comparability testing must be conducted to be valid is 0.5 to $4.0 \mu\text{g}/\text{m}^3$. Currently there are few locations in the United States where FEM testing can be conducted with assurance that the ambient concentrations during the time of the testing would exceed $0.5 \mu\text{g}/\text{m}^3$. In addition, the Agency proposed to lower the Pb NAAQS level to between 0.10 and $0.30 \mu\text{g}/\text{m}^3$. Consistent with this proposed revision, we also proposed to revise the Pb concentration requirements for candidate FEM testing to a range of 30 percent of the revised level to 250 percent of the revised level in $\mu\text{g}/\text{m}^3$. The requirements were changed from actual concentration values to percentages of the NAAQS level to allow the FEM requirements to remain appropriate if subsequent changes to NAAQS levels occur during future NAAQS reviews.

The current FEM does not have a requirement for a maximum MDL. In order to ensure that candidate analytical methods have adequate sensitivity or MDLs, we proposed adding a requirement for testing of a candidate

FEM. The applicant must demonstrate that the MDL of the method is less than 1 percent of the level of Pb NAAQS.

We proposed to modify the FEM requirements for audit samples. Audit samples are the known concentration or reference samples provided by EPA and used to verify the accuracy with which a laboratory conducts the FRM analytical procedure before it may be compared to the candidate FEM. The current requirements are that audit samples be analyzed at levels that are equal to 100, 300, and $750 \mu\text{g}$ per spiked filter strip (equivalent to 0.5 , 1.5 , and $3.75 \mu\text{g}/\text{m}^3$ of sampled air). We proposed to revise the levels of the audit concentrations to percentages (30 percent, 100 percent and 250 percent) of the level of the Pb NAAQS to provide for reduced audit concentrations that are more appropriate for a reduced level of the revised NAAQS.

The existing FEM requirements are based on the high-volume TSP sampler, and as such, refer to $\frac{3}{4}$ -inch x 8-inch glass fiber strips. In order to also accommodate the use of low-volume sample filters, we proposed to add references to 46.2 mm filters where appropriate. For FEM candidates that differ only from the FRM with respect to the analysis method for Pb, pairs of these filters will be collected by a pair of FRM samplers.

b. Comments

We received few comments on the proposed amendments to the FEM requirements for Pb. One commenter suggested that the proposed MDL requirement, 1 percent of the NAAQS, was overly stringent, and that an MDL of 5 percent would be sufficient. Another commenter suggested that an MDL at 10 percent would be more achievable. After reviewing these comments, we have reconsidered the requirement for the MDL to be 1 percent of the NAAQS or less and now believe that the requirement may be unduly restrictive. The MDL represents an estimate of the lowest Pb concentration that can be reliably distinguished from a blank. The concept of the "limit of quantitation" (LOQ), the level at which we can reasonably tell the difference between two different values, is often used to determine the concentration at which we have confidence in the accuracy of the measurement. The LOQ is usually estimated at 5 to 10 times the MDL. At a MDL of 5 percent (i.e., $0.0075 \mu\text{g}/\text{m}^3$), the maximum LOQ would still be less than one half of the NAAQS (i.e., $0.075 \mu\text{g}/\text{m}^3$). We believe this is adequate for the purposes of determination of compliance with the NAAQS. The three most commonly

used Pb- PM_{10} analysis methods (XRF, ICP-MS, and GFAA) all have estimated method detection limits below 5 percent of the revised Pb NAAQS. We note, however, that for areas where concentrations may frequently be well below the NAAQS such as at non-source-oriented sites it may be desirable to use a FEM with a more sensitive analysis method (such as ICP-MS) to assure fewer non-detect measurements and to provide better accuracy at concentrations well below the NAAQS.

We received two comments supporting the development and consideration of the use of continuous Pb monitors. We agree that the FEM testing requirements should include language regarding FEM testing and approval of continuous or semi-continuous monitors.

c. Decisions on FEM Requirements

We are finalizing the FEM requirements for Pb as proposed except for the addition of certain language including FEM testing and approval of continuous or semi-continuous monitors.

4. Quality Assurance Requirements

We are finalizing changes to the quality assurance (QA) requirements for Pb. These requirements will apply for both Pb-TSP and Pb- PM_{10} measurements. This section discusses the proposed changes to the QA requirements, comments received on the proposed changes, and the final QA requirements being promulgated with this action.

a. Proposed Changes

We proposed modifications to the quality assurance (QA) requirements for Pb in 40 CFR part 58 Appendix A paragraph 3.3.4 in order to accommodate Pb- PM_{10} monitoring. In addition, we proposed to consolidate several existing requirements for PM samplers (TSP and PM_{10} samplers) into paragraph 3.3.4 to clarify that these requirements also apply to Pb-TSP and Pb- PM_{10} samplers. The following paragraphs detail the QA requirements we proposed to amend.

The collocation requirement for all TSP samplers (15 percent of a primary quality assurance originations sites at a 1 in 12 day sampling frequency, paragraph 3.3.1) applies to TSP samplers used for Pb-TSP monitoring. These requirements are the same for PM_{10} (paragraph 3.3.1); thus, no changes are needed to accommodate low-volume Pb- PM_{10} samplers. However, to clarify that this requirement applies to Pb- PM_{10} monitoring, in addition to mass measurements for PM_{10} , we proposed to

add a reference to this requirement in paragraph 3.3.4. The current requirement for selecting the collocated site requires that the site be selected from the sites having annual mean concentrations among the highest 25 percent of the annual mean concentration for all sites in the network.

The sampler flow rate verifications requirement (paragraph 3.3.2) for low-volume PM₁₀ and for TSP are at different intervals. To clarify that this requirement also applies to Pb monitoring (in addition to sample collection for TSP and PM₁₀ mass measurements) we proposed to add a reference to this requirement in paragraph 3.3.4.

Paragraph 3.3.4.1 has an error in the text that suggests an annual flow rate audit for Pb, but then includes reference in the text to semi-annual audits. The correct flow rate audit frequency is semi-annual. We proposed to correct this error. We also proposed to change the references to the Pb FRM to include the proposed Pb-PM₁₀ FRM.

Paragraph 3.3.4.2 discusses the audit procedures for the Pb analysis method. This section assumes the use of a high-volume TSP sampler, and we proposed edits to account for the proposed Pb-PM₁₀ FRM.

We proposed to require one audit at one site within each primary quality assurance organization (PQAO) once per year. We also proposed that, for each quarter, one filter of a collocated sample filter pair from one site within each PQAO be sent to an independent laboratory for analysis, for a total of 5 audits per year. The independent measurement on one filter from each pair would be compared to the monitoring agency's routine laboratory's measurement on the other filter of the pair, to allow estimation of any bias in the routine laboratory's measurements.

b. Comments

We received one comment on the proposed QA requirements specifically addressing the overall sampling and analysis bias. The commenter was concerned that the proposal to implement one independent performance evaluation audit (similar to the PM_{2.5} Performance Evaluation Program (PEP)) and then augment that sample with four samples from collocated precision site would be inadequate. The commenter suggested that in order for the audit program to be successful it would require the same independent laboratory be used by all monitoring agencies across the country.

We believe it is important to have a measurement of the bias of the overall

method for Pb (including both sampling and analysis aspects). We proposed five audits per PQAO per year (one independent audit and four collocated samples all analyzed at an independent lab). This proposal was based on data evaluations of PM_{2.5} bias information, and the assumption that no PQAO would have more than 5 Pb sites.

However, we now recognize that some PQAO are likely to have more than 5 sites, and as part of our consideration of this comment, we are revising the audit requirements to require 1 additional audit per PQAO and an additional 2 collocated sample filters for PQAO's with more than 5 sites. This sampling frequency would parallel the PM_{2.5} performance evaluation. Based on our review of PM_{2.5} bias information, five audits per year for PQAOs with five or fewer monitoring sites provide an adequate assessment of bias over a 3-year period. We believe we can provide an adequate three-year estimate of bias with this approach since it will yield the same number of audit results as the PM_{2.5} PEP program. In addition, the statistic used to assess bias for PM_{10-2.5} and the gaseous pollutants (section 4.1.3) will be used for the Pb bias assessment and will be referenced in section 4.4.2. This will eliminate the need to assess bias by combining data from the flow rate audits and Pb audit strips as discussed in sections 4.4.2 through 4.4.5, so this assessment will be removed. The use of the flow rate audits and Pb audit strips will be able to be assessed separately using statistics already available in Appendix A. Sections 4.2.2 and 4.2.3 for flow rate information and section 4.1.3 will be used for the Pb strip assessment.

Like the PM_{2.5} PEP program, we are planning to implement an audit program for monitoring agencies requesting federal implementation of the audits, but allow monitoring agencies to implement their own audit program. We plan to utilize one laboratory for the analysis of the Pb audit samples for those monitoring organization requesting federal implementation of these audits.

However, we expect some states will elect to implement their own audits. Independent laboratory services will be offered to monitoring organizations that are self-implementing this performance evaluation program, however, they may use other independent labs. Based on the current PM_{2.5} PEP program, we expect the majority of monitoring agencies will elect to make use of the federally implemented audit program.

We also received comments on our proposed precision and bias goals from individual members of the CASAC

AAMM Subcommittee as part of the consultation on March 25, 2008. The AAMM Subcommittee members indicated that we should base the precision and bias goals on the findings of the ongoing DQO analysis identified in our proposal. We have completed the DQO analysis as described in the proposed rule, and a copy of the report is in the docket for this rule. Based on the findings from the DQO analysis, we are finalizing a goal for precision and bias of 20 percent and 15 percent, respectively. These values allow for slightly higher uncertainty than the proposed values and reflect the finding that the existing high-volume samplers may not routinely be capable of meeting the proposed precision and bias goals.

c. Decisions on Quality Assurance Requirements

We are finalizing amendments to the QA requirements for Pb measurements as proposed with the following differences. Based on the DQO analysis, the goal for acceptable measurement uncertainty will be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 20 percent and as an upper 95 percent confidence limit for the absolute bias of 15 percent. The evaluation of precision will also be limited to those data greater than or equal to 0.02 µg/m³. These goals are included in section 2.3.1 of 40 CFR Part 58 Appendix A. We are requiring 1 PEP audit per year per PQAO with 5 or fewer sites, and 2 PEP audits per year per PQAO with more than 5 sites. Due to the addition of the Pb performance evaluation, a reference to the statistical assessment of bias used for PM_{10-2.5} and the gaseous pollutants (section 4.1.3) has been included in section 4.4.2 and the requirement for the bias calculation using the Pb strips in combination with the flow rate audits, as discussed in sections 4.4.2 through 4.4.5, has been removed and sections 4.2.2 and 4.2.3 have been used to assess flow rate information and section 4.1.3 has been used for the Pb strip laboratory bias assessment.

B. Network Design

As a result of this Pb NAAQS review and the tightening of the standards, EPA recognizes that the current network design requirements are inadequate to assess compliance with the revised NAAQS. Accordingly, we are promulgating new network design requirements for the Pb NAAQS surveillance network. The following sections provide background, rationale, and details for the final changes to the Pb network design requirements.

1. Proposed Changes

We proposed to modify the existing network design requirements for the Pb surveillance monitoring network to achieve better understanding of ambient Pb air concentrations near Pb emission sources and to provide better information on exposure to Pb in large urban areas. We proposed that monitoring be presumptively required at sites near sources that have Pb emissions (as identified in the latest National Emissions Inventory (NEI) or by other scientifically justifiable methods and data) that exceed a Pb "emission threshold". This monitoring requirement would apply not only to existing industrial sources of Pb, but also to fugitive sources of Pb (e.g., mine tailing piles, closed industrial facilities) and airports where leaded aviation gasoline is used. In this context, the "emission threshold" was intended to be the lowest amount of Pb emissions per year for a source that may reasonably be expected to result in ambient air concentrations at a nearby monitoring site in excess of the proposed Pb NAAQS (as discussed later, based on reasonable worst case scenarios). We conducted an analysis to estimate the appropriate emission threshold (Cavender 2008a) which is available in the docket for this rulemaking. Using the results from this analysis, we proposed that the emission threshold be set in the range of 200 kg–600 kg per year total Pb emissions (including point, area, and fugitive emissions and including Pb in all sizes of PM), corresponding to the proposed range of levels for the Pb NAAQS, with the final selection of the threshold to be dependent on the final level for the NAAQS.

We recognized that a number of factors influence the actual impact a source of Pb has on ambient Pb concentrations (e.g., local meteorology, emission release characteristics, and terrain). Accordingly, we also proposed to allow monitoring agencies to petition the EPA Regional Administrator to waive the requirement to monitor near a source that emits less than 1000 kilograms per year where it can be shown that ambient air concentrations at that site are not expected to exceed 50 percent of the NAAQS during a three-year period (through modeling, historical monitoring data, or other means). We proposed that for facilities identified as emitting more than 1000 kilograms per year in the NEI, a waiver would only be provided for those sites at which it could be demonstrated that actual emissions are less than the emission threshold.

We proposed that source-oriented monitors be located at locations of maximum impact classified primarily as microscale monitors representative of small hot-spot areas adjacent or nearly adjacent to facility fence-lines. We also indicated that source-oriented monitors may be located at locations of maximum impact but which are representative of larger areas and classified as middle scale. Additionally we sought comments on the appropriateness of requiring monitors near Pb sources.

We also proposed a small network of non-source-oriented monitors in urban areas in addition to the source-oriented monitors discussed above, in order to gather additional information on the general population exposure to Pb in ambient air. While it is expected that these non-source-oriented monitors will show lower concentrations than source-oriented monitors, data from these non-source-oriented monitors will be helpful in better characterizing population exposures to ambient air-related Pb and may assist in determining nonattainment boundaries. We proposed to require one non-source-oriented monitor in each Core Based Statistical Area (CBSA, as defined by the Office of Management and Budget¹⁰⁹) with a population of 1,000,000 people or more as determined in the most recent census estimates. Based on the most current census estimates, 52 CBSAs would be required to have non-source-oriented population monitors (see <http://www.census.gov/popest/metro/index.html> for the latest census estimates.)

We noted in our proposal that monitoring agencies would need to install new Pb monitoring sites as a result of the proposed revisions to the Pb monitoring requirements. We estimated that the size of the required Pb network would range between approximately 160 and 500 sites, depending on the level of the final standard. If the size of the final network is on the order of 500 sites, we proposed to allow monitoring agencies to stagger the installation of newly required sites over two years, with at least half the newly required Pb monitoring sites being installed and operating by January 1, 2010 and the remaining newly required monitoring sites installed and operating by January 1, 2011. As proposed, monitors near the highest Pb emitting sources would need to be installed in the first year, with monitors near the lower Pb emitting sources and non-source-oriented monitors being

¹⁰⁹ For the complete definition of CBSA refer to: <http://www.census.gov/population/www/estimates/aboutmetro.html>.

installed in the second year. We also proposed to allow monitoring agencies one year following the release of updates to the NEI or an update to the census to add new monitors if these updates would trigger new monitoring requirements.

We also proposed to allow States to use Pb-PM₁₀ monitors to meet the network design requirements if our proposed use of scaled Pb-PM₁₀ data was adopted in the final rule.

2. Comments on Network Design

We received several comments on the proposed network design requirements. These comments and our responses are broken down into the following categories: source-oriented monitoring, non-source-oriented monitoring, roadway monitoring, the use of Pb-PM₁₀ samplers, and the required timeline for installing newly required monitors.

a. Source-oriented monitoring

We received several comments supporting the need for monitoring near Pb sources. Alternatively, one commenter suggested that near source monitoring is not necessary because "the EPA and the State already know where and what the problems are" and "EPA should * * * develop control standards to deal with the problem * * *" We note individual sources do not violate a NAAQS but that under the CAA a primary method to achieve control of emissions at sources contributing to an exceedance of the NAAQS is the State Implementation Plan (SIP). We expect the highest concentrations of Pb to be near sources of Pb due to its dispersion characteristic. Monitoring data are important evidence used to designate areas as non-attainment of the NAAQS. Thus, monitoring near Pb sources is needed to properly designate areas that violate or contribute to air quality in a nearby area that does not meet the Pb NAAQS.

We received a comment that the methods used in developing the emission thresholds estimated ambient impacts over different averaging periods, and that the emission thresholds should be recalculated for all methods using the final averaging period. We recognized this issue in our memorandum documenting the analysis (Cavender, 2008a), and we have recalculated the estimate of the lowest Pb emission rate that under reasonable worst-case conditions could lead to Pb concentrations exceeding the NAAQS, based on the final level and form of the standard (Cavender, 2008b).

We also received comments on the approach used in developing the

proposed emission thresholds that would trigger consideration of the placement of a monitoring site near a Pb source. Commenters expressed concerns that the approach overestimated the potential impact of Pb sources, and would result in either unnecessary burden on monitoring agencies or worse yet, monitoring agencies would install and operate monitors at sources that had little to no potential to exceed the NAAQS. Several commenters suggested various alternative levels, including a threshold of 1 ton or higher, basing their recommendations on concerns such as the reliability of data in the NEI. Other commenters suggested that EPA was in the best position to determine which sources had the potential to exceed the NAAQS.

We note that the approach used in developing the emission threshold in the proposal was intended to represent a reasonable worst case scenario. As such, we recognize that many Pb sources which emit at or above the proposed emission threshold will have Pb impacts that are below the Pb NAAQS. To account for this, we proposed to allow monitoring agencies to request monitoring waivers if they could demonstrate that facilities would not contribute to a Pb impact of greater than 50 percent of the NAAQS. However, upon further consideration, we agree that by basing the threshold on these worse case conditions we will be placing an unnecessary burden on monitoring agencies to evaluate or monitor around sources that may not have a significant potential to exceed the NAAQS. As a result, we are finalizing changes to our approach for requiring source-oriented monitors. We are including a requirement that monitoring agencies conduct monitoring taking into account sources that are expected to exceed or shown to have contributed to a maximum concentration that exceeded the NAAQS, the potential for population exposure, and logistics. In addition, specifically we are requiring monitoring agencies to conduct monitoring at sources which emit Pb at a rate of 1.0 or more tons per year. This emissions rate corresponds to two times the estimate of the lowest Pb emission rate that under reasonable worst-case conditions could lead to Pb concentrations exceeding the NAAQS. This recognizes the thresholds used in the proposal represented reasonable worst case scenarios, and that a more appropriate approach to balance the factors important in designing a network is to use a higher threshold that is more likely to clearly identify sources that

would contribute to exceedences of the NAAQS. In addition, the State, and the Agency working together will identify what additional sources should be taken into account because they are expected to or have been shown to contribute to maximum concentrations that contribute to exceedences.

To account for the other sources that may contribute to a maximum Pb concentration in ambient air in excess of the NAAQS, we are retaining the authority granted to the EPA Regional Administrator in the existing monitoring requirements to require monitoring "where the likelihood of Pb air quality violations is significant or where the emissions density, topography, or population locations are complex and varied." We believe that these final monitoring requirements are adequate to ensure that monitoring will be conducted respecting facilities that have the potential to exceed the NAAQS without placing undue burden on monitoring agencies.

We received several comments supporting the need for monitoring waivers, and one comment that did not support waivers. Those in favor of the waivers pointed out that, as discussed above, many Pb sources will result in much lower Pb impacts than the "worst case" Pb source. They argued that the states need flexibility in meeting the source-oriented monitoring requirements, and agreed that it is appropriate to focus on sites near those Pb sources with the greater potential to result in Pb concentrations that exceed the Pb NAAQS. The commenter who cautioned against the allowance of monitoring waivers expressed concerns that modeling results are not exact and this uncertainty could result in waivers being granted when actual Pb concentrations could exceed the NAAQS. We took the uncertainty of modeled results into account when proposing to limit waivers to situations where the modeled data indicated maximum concentrations would be 50 percent of the NAAQS, rather than at 100 percent of the NAAQS, and we believe this provides a sufficiently protective approach to account for uncertainty in modeling and other assessments estimating a Pb source's expected impacts.

We received comments questioning the need to restrict the provision of waivers to sites near sources emitting less than 1000 kg/yr. We agree it is possible for sources greater than 1000 kg/yr to have an impact less than 50 percent of the NAAQS under certain conditions. We also acknowledge the need for flexibility in implementing the Pb NAAQS monitoring network. As

such, we have reconsidered our proposed restriction limiting waivers to those for sources emitting less than 1000 kg/yr, and we are not finalizing a restriction on the size of sources near sites eligible for a waiver from the source-oriented monitoring requirement.

We received comments on relying on the National Emission Inventory (NEI) to identify Pb sources with emissions greater than the emission threshold. In general, several commenters said better data should be used to identify Pb sources emitting above the proposed emission threshold. Several commenters expressed concerns with the accuracy of the NEI, and recommended allowing states to use "the best available information" on emissions from Pb sources. Some commenters pointed to differences in Pb emissions data reported in the Toxics Release Inventory and the NEI as evidence that the NEI was inaccurate. One commenter said current practices to reduce toxic emissions are not reflected in the NEI and wanted the opportunity to update the information. Commenters said EPA should correct the errors in the NEI or allow states to submit revised local data that more accurately reflect Pb emissions before emissions inventory data are used to determine which sources exceed the threshold.

We agree that the most current Pb emissions information should be used when making final decisions about which sources exceed the emission threshold. This may include datasets that could include sources not contained in the NEI. We acknowledge that many of the NEI emission estimates likely would be improved with more site specific data (e.g., emissions test data). We have added the phrase "or other scientifically justifiable methods and data" to the monitoring requirements to clarify that NEI emissions estimates are not the only emission estimates that can be used to estimate emissions.

We received comments that the proposed source-oriented monitoring requirements did not address situations where multiple sources contribute to Pb concentrations at one location. Our proposed waiver requirements do take into account the impacts from multiple sources. The proposed language stated that waivers could only be granted for source-oriented sites that did not "contribute to a maximum Pb concentration in ambient air in excess of 50 percent of the NAAQS". We recognize that exceedences of the standard may be caused by emissions from a number of smaller sources none of which would cause a violation in

isolation, but we expect it is unlikely that violations would occur when all of the sources in an area are below the emissions threshold due to the rapid decrease in Pb concentrations with distance from a Pb source. However, the purposes of the monitoring network would be undermined if multiple sources in a single area were able to receive waivers, with the result that no monitor was required even though Pb concentrations in the area were in excess of 50 percent of the standard. Accordingly, EPA expects that Regional Administrators, in deciding whether to grant waivers, will take into account whether other waivers have been granted or sought for sources in the same area, and whether the cumulative emissions of the sources in the area warrant at least one monitor being sited.

Several monitoring agencies expressed concern about the need for flexibility in implementing the source-oriented monitoring requirements. We believe that the proposed rule provides significant flexibility to monitoring agencies for the implementation of the monitoring requirements. One area where we believe it is appropriate to provide additional flexibility is for situations where multiple sources above the emission threshold contribute to a single maximum impact. A strict reading of the proposed source-oriented monitoring requirement could be that monitoring agencies would be required to monitor each Pb source separately. This was not intended, and our existing monitoring guidance is clear that a single monitor can be used to monitor multiple sources where the maximum impact is influenced by multiple sources. Nonetheless, we believe it is appropriate to clarify this point in the rule language. As such, we are adding a clause to the source-oriented monitoring requirement that specifies that a single monitor can be used to monitor multiple Pb sources where they contribute to a single maximum impact.

We received two comments that source-oriented monitors should be located at the location of maximum estimated Pb concentration without consideration for the potential for population exposure, and six comments that source-oriented monitors should be located in an area where population exposure occurs. In their comments on the proposed rule, one commenter argued that monitors “should be located in or around only those Pb point sources with a nearby population base” because “air Pb concentrations have regulatory importance largely in those areas where significant groups of children are exposed for considerable time periods.” The commenter argued that as an

example “a rural road going by a lead mining facility is an unlikely place that children will spend considerable amounts of time” and as such “placing a monitoring site on such a road would have de minimis, if any, value.” Another commenter suggested that “monitors should be located near playgrounds, sports fields, long-established highways, and the like.”

Siting of required monitors at the expected maximum concentration in ambient air is consistent with how all NAAQS pollutants are monitored.¹¹⁰ In considering the siting criteria for the required Pb source-oriented monitors, we recognize that Pb is a persistent, multimedia pollutant, such that deposited Pb from current emissions can contribute to human exposures over extended amounts of time. Also, Pb deposited in one area can be transported to another area by “tracking” from vehicle and foot traffic. In addition, unlike the case for other criteria pollutants, ingestion of deposited Pb is a major Pb exposure pathway. Given these complexities, it is appropriate to allow siting agencies to also consider the potential for population exposure in siting monitors near sources.

In our proposed rule, we recognized that there are reasons for not requiring monitoring at the location of expected maximum concentration such as logistical limitations (i.e., the location of expected maximum concentration occurs in the middle of a lake). In consideration of public comments on this issue and due to the complexities of Pb, we believe it is appropriate, in the final rule, to also allow states to consider the potential for population exposure as a factor (in addition to other factors such as logistical considerations) when siting required source-oriented monitors. Thus, we are including the potential for population exposure as a factor that monitoring agencies can consider when siting a maximum concentration source-oriented monitoring site required under part 58.

b. Non-source-oriented monitoring

We received a number of comments on our proposed non-source-oriented monitoring requirement. One state and several tribes commented that the proposed population limit would result in no required non-source-oriented monitors in low population states and tribal lands. One commenter expressed concerns that the population limit was

too high, and would result in environmental justice concerns since many poor communities would not be monitored.

As stated in the proposed rule, it is unlikely that exceedences of the Pb NAAQS will occur at sites distant from Pb sources. As such, our non-source-oriented monitoring requirements satisfy monitoring objectives in addition to ensuring compliance with the Pb NAAQS. For the most part, these monitoring sites should be sited to represent neighborhood scale exposures. We are requiring non-source-oriented Pb monitors to provide additional information that will be useful in better characterizing air-related Pb exposures in neighborhoods. Sources affecting neighborhoods may include re-entrained dust from roadways, closed industrial sources which previously were significant sources of Pb, hazardous waste sites, construction and demolition projects, or other fugitive sources of Pb. Non-source sites will also support the next Pb NAAQS review by providing additional information on the spatial variations in Pb concentrations between areas that are affected by sources to a significant degree and those that are not.

We believe it is most appropriate to focus the non-source monitoring requirements in large urban areas since high population locations are most used in health and epidemiological studies. We proposed to require one non-source-oriented monitor in each CBSA with a population of 1,000,000 or more based on the latest available census figures. That proposed requirement would have resulted in approximately 50 CBSAs required to have non-source Pb monitors. EPA notes the comments that the proposed population limit of 1,000,000 was too high, and may result in the lack of non-source-oriented monitors in smaller urban communities. Accordingly, we have decreased the population limit for requiring non-source monitors to CBSAs with a population of 500,000 people or more, thereby increasing the number of required non-source Pb monitors from approximately 50 to approximately 100 (based on 2007 population estimates from the Census Bureau).

We also note that these requirements are minimum monitoring requirements, and that state and tribal monitoring agencies may operate additional non-source-oriented monitors beyond the minimum number of required monitors. Data that meet the quality assurance requirements that are collected from non-required FRM or FEM monitors will also be used to determine compliance with the Pb NAAQS. Additionally, as

¹¹⁰ Required PM_{2.5} sites have additional criteria where monitoring sites are to represent community-wide air quality [40 CFR part 58, appendix D paragraph 4.7.1(b)] with at least one required site in a population-oriented area of expected maximum concentration.

described previously, source-oriented monitoring would be required in rural and small communities if a Pb source emitting 1 ton per year or more is present.

c. Roadway Monitoring

The majority of commenters agreed with our finding that the available data on Pb concentrations near roadways do not indicate the potential for exceedances of the proposed range of Pb NAAQS levels and requirements for monitors near roadways were not needed to ensure compliance with the NAAQS. However, one commenter argued that our finding that activity on roadways would not likely contribute to air Pb concentrations in exceedance of the proposed levels for the standard was based on data from monitors that did not represent the maximum impact from roadways.

While some of the monitors used in our analysis of air Pb impacts from activity on roadways may not represent the site of maximum impact, we believe they are representative of locations where roadway monitoring might be conducted. As we indicated in our proposal, these monitors indicate that Pb concentrations are slightly elevated near roadways, but do not occur at levels approaching the Pb NAAQS being finalized today. Nonetheless, we agree that more information on Pb concentrations near roadways would be valuable, and we encourage monitoring agencies to consider placing Pb monitors near population centers heavily impacted by roadways in some of the CBSAs required to install and operate non-source-oriented monitors to provide information for use in future NAAQS reviews. In addition, the EPA has research initiatives investigating Pb concentrations near roadways that will provide additional information that can be used in future NAAQS reviews.

d. Use of Pb-PM₁₀ Monitors

Comments were received on the use of Pb-PM₁₀ monitoring in lieu of required Pb-TSP under certain circumstances. Several commenters suggested an approach for the use of Pb-PM₁₀ monitors as an alternative to the proposed use of scaling factors. Commenters suggested that Pb-PM₁₀ monitoring would only be allowed in certain instances. Specifically, Pb-PM₁₀ monitoring would be allowed where estimated Pb concentrations were predicted to be less than 50 percent of the NAAQS and where Pb in ultra-coarse particulate was expected to be low. These commenters also suggested that if at some point in the future the monitor were to show that Pb-PM₁₀

concentrations exceeded 50 percent of the NAAQS, the monitoring agency would be required to replace the Pb-PM₁₀ monitor with a Pb-TSP monitor.

We support this suggested approach, noting that it allows for the use of Pb-PM₁₀ in areas where we do not expect Pb concentrations to exceed the Pb NAAQS without the burden and uncertainty associated with the development and use of site-specific scaling factors. As noted in section II.C.1, use of Pb-PM₁₀ monitors in these locations offers the advantages of increased monitor precision and decreased spatial variation of Pb-PM₁₀ concentrations, without raising the same concerns over a lack of protection against health risks from all particulate Pb emitted to the ambient air that support retention of Pb-TSP as the indicator.

However, we feel the combined requirements for allowing use of Pb-PM₁₀ monitors only in areas where the concentration is expected to be less than 50% of the NAAQS and where Pb in ultra-coarse particles is expected to be low may be too restrictive, especially in light of the fact that a monitoring agency may request a waiver from monitoring altogether if the expected concentration is less than 50% of the NAAQS. We believe it is appropriate to allow Pb-PM₁₀ in lieu of Pb-TSP where the maximum 3-month arithmetic mean Pb concentration is expected to be less than 0.10 µg/m³ (i.e., two thirds of the NAAQS) and where sources are not expected to emit ultra-coarse Pb. By limiting the use of Pb-PM₁₀ monitoring to locations where the Pb concentrations are less than 0.10 µg/m³ on a 3-month arithmetic mean and where ultra-coarse Pb is expected to be low, we believe that the Pb-TSP concentrations will also be less than 100% of the NAAQS. Examples of locations where Pb-PM₁₀ monitoring may be more representative of Pb-TSP levels than others are urban areas away from Pb sources (i.e., non-source-oriented monitoring locations), near airports, combustion sources, and other Pb sources which are expected to only emit Pb in the fine PM size fraction. Locations where it would not be appropriate to monitor using Pb-PM₁₀ samplers include near smelters, roadways, and sources with significant fugitive dust emissions.

We are revising the proposed allowance for the use of Pb-PM₁₀ monitors to allow Pb-PM₁₀ monitors without the use of scaling factors for non-source-oriented monitors (unless existing data indicates maximum 3-month arithmetic mean Pb concentration has exceeded 0.10 µg/m³ in the last three years) and for source-

oriented monitors where maximum 3-month arithmetic mean Pb concentration is expected to be less than 0.10 µg/m³ (based on modeling or historic data) and where ultra-coarse Pb is expected to be low. We are also requiring that a Pb-TSP monitor be required at the site if at some point in the future the Pb-PM₁₀ monitor shows that the maximum 3-month arithmetic mean Pb-PM₁₀ concentration was equal to or greater than 0.10 µg/m³. Section IV.E of this preamble discusses how data from Pb-PM₁₀ monitors will be used in comparison to the Pb NAAQS.

e. Required Timeline for Monitor Installation and Operation

We received several comments from monitoring agencies regarding the proposed timeline for monitor installation. Commenters supported the need for a staggered network deployment, especially if a large number of new monitors would be required. Two commenters argued that even the proposed two-year deployment would not provide enough time for monitoring agencies to site and install the number of monitors needed.

Based on the network design requirements being finalized with this action, we estimate that approximately 135 facilities emit Pb at levels over the "emissions threshold" of 1 ton per year and would result in required monitoring. We are also requiring urban areas with populations over 500,000 to site non-source-oriented monitors, thus another 101 monitors are required. Together the required source-oriented and non-source-oriented monitors are expected to total 236 monitors. Some of the existing 133 lead monitoring stations will be useful to support the required network, but other stations may need to move. We are estimating that approximately 90 of the existing stations are in locations that are of benefit to other monitoring objectives, even when well below the NAAQS (e.g., long-term trends or for use in a health study) and are not part of the minimum network requirements being finalized in today's action. Once the network is fully operational the 236 required stations plus an additional 90 stations in existing locations that are not required results in an expected network of 326 lead monitoring stations to adequately support characterization of lead across the country.

We believe it would be unrealistic to require monitoring agencies to site and install the required 240 new monitoring stations within one year, even if some of these are already in the right locations. However, we do believe it is reasonable to require monitoring

agencies to site and install half of these stations in one year with the remaining stations deployed in the following year. Accordingly, and as discussed further below, we are finalizing a two-year monitor deployment schedule for required monitoring.

3. Decisions on Network Design Requirements

We are finalizing new network design requirements for the Pb NAAQS monitoring network that differ from those proposed in the following aspects. The differences from the proposal reflect our consideration of the comments on the proposed network design requirements and consideration of the level, form, and averaging time for the final NAAQS being promulgated today.

We are adding a requirement that monitoring agencies conduct ambient air Pb monitoring taking into account Pb sources which are expected to or have been shown to contribute to a maximum Pb concentration in ambient air in excess of the NAAQS, the potential for population exposure, and logistics. At a minimum, there must be one source-oriented SLAMS site located to measure the maximum Pb concentration in ambient air resulting from each Pb source which emits 1.0 or more tons per year based on either the most recent NEI or other scientifically justifiable methods and data (such as improved emissions factors or site-specific data). We are maintaining the existing authority for the EPA Regional Administrator to require additional monitoring where the likelihood of Pb air quality violations is significant or where the emissions density, topography, or population locations are complex and varied. In addition, we are adding a clause to the source-oriented monitoring requirement to clarify that a single monitor may be used to monitor multiple Pb sources when the sources contribute to a single maximum Pb concentration.

In addition, monitoring agencies may consider the potential for population exposure when siting source-oriented monitors. While this change does not restrict monitoring agencies from monitoring at any location meeting the definition of ambient air, this provision allows monitoring agencies to consider the potential for population exposure when siting the required source-oriented monitors at the maximum Pb concentration.

We are removing the proposed restriction that waivers may only be granted for sites near sources emitting less than 1000 kg/yr. The EPA Regional Administrator may approve waivers for

the source-oriented monitoring requirement for any site where the monitoring agency demonstrates that the emissions from the source will not contribute to a Pb-TSP concentration greater than 50 percent of the final NAAQS (based on historic data, monitoring data, or other means).

We are requiring one non-source-oriented monitor in every CBSA with a population of 500,000 people or more. In addition, we are requiring these monitors be placed in neighborhoods within urban areas impacted by re-entrained dust from roadways, closed industrial sources which previously were significant sources of Pb, hazardous waste sites, construction and demolition projects, or other fugitive dust sources of Pb.

Monitoring agencies may use Pb-PM₁₀ monitors to meet the non-source-oriented monitoring requirements tied to CBSA population provided that historical monitoring does not indicate Pb-TSP or Pb-PM₁₀ concentrations greater than an arithmetic 3-month mean of 0.10 µg/m³, and to meet the source-oriented monitoring requirements where Pb concentrations are expected (based on historic data, monitoring data, or other means) to be less than 0.10 µg/m³ on an arithmetic 3-month mean, and ultra-coarse Pb is expected to be low. However, monitoring agencies are required to begin monitoring for Pb-TSP within six months of a measured Pb-PM₁₀ arithmetic 3-month mean concentration of 0.10 µg/m³ or more. For example, if a Pb-PM₁₀ monitoring site measures an arithmetic 3-month mean concentration of 0.10 µg/m³ or more for the period March–May 2011, the responsible monitoring agency would be required to install and begin operation of a Pb-TSP monitor at the site no later than December 1, 2011.

We are allowing monitoring agencies to stagger installation of any newly required monitors over a two-year period. Each monitoring agency is required to install and operate the required source-oriented monitors by January 1, 2010. The non-source-oriented monitors are required to be installed and operated by January 1, 2011. The annual monitoring plan due July 1, 2009 must describe the planned monitoring that will begin by January 1, 2010, and the plan due July 1, 2010 must describe the planned monitoring that will begin by January 1, 2011.

C. Sampling Frequency

We proposed to maintain the 1-in-6 day sampling frequency if the final averaging time for the NAAQS standard was based on a quarterly average. We

did not receive any comments on our proposed sampling frequency for a NAAQS based on a quarterly average. While the final NAAQS is based on a moving 3-month average rather than a quarterly average, the statistical and practical monitoring considerations are the same. As such, we are maintaining the current 1-in-6 day minimum sampling frequency as proposed (i.e., monitoring agencies will be required to collect at least one 24-hour Pb sample every six days).

D. Monitoring for the Secondary Standard

We did not propose any specific additional monitoring requirements for the secondary standard because based on the available data, we do not expect exceedances of either the primary or the secondary NAAQS away from the point sources that will be addressed by the monitoring requirements already described. We also noted that the Pb-PM_{2.5} data collected as part of the Interagency Monitoring of Protected Visual Environments (IMPROVE) program provide useful information on Pb concentrations in rural areas that can be used to track trends in ambient air Pb concentrations in rural areas including important ecosystems. We received one comment supporting our proposed reliance on the IMPROVE network Pb-PM_{2.5} data. We did not receive any other comments on additional monitoring needs to support the secondary Pb NAAQS. Thus, we are not finalizing any additional requirements for Pb monitoring specifically for the secondary Pb NAAQS.

E. Other Monitoring Regulation Changes

We are finalizing two other proposed changes to the monitoring requirements for Pb, and making one editorial revision for ease of reference. We are changing the reporting requirements to require the reporting of average pressure and temperature for each Pb sample collected. We are also removing Pb from the list of criteria pollutants where data from special purpose monitors can be excluded from consideration for designations. The proposed changes, comments received, and final amendments are described in the following paragraphs.

1. Reporting of Average Pressure and Temperature

We proposed revisions to 40 CFR 58.16(a) to add a requirement that the monitoring agency report the average pressure and temperature during the time of sampling for both Pb-TSP monitoring and Pb-PM₁₀ monitoring. We did not receive any comments on this

proposed requirement. As such, we are finalizing this requirement as proposed. Monitoring agencies may use site specific meteorological measurements generated by on-site equipment (meteorological instruments, or sampler generated), a representative nearby monitoring station, or measurements from the nearest airport reporting ambient pressure and temperature.

2. Special Purpose Monitoring

We proposed to revise 40 CFR 58.20(e) by removing the specific reference to Pb in the rule language. We proposed to make this change because the form of the proposed Pb NAAQS would allow a non-attainment finding to be based on as little as 3-months of data which would have to be considered during mandatory designations. We did not receive any comments on this proposed revision to the special purpose monitoring requirements. As such, we are finalizing the revision to 40 CFR Section 58.20(e) as proposed.

VI. Implementation Considerations

This section of the final rule discusses the specific CAA requirements related to implementation of the revised Pb NAAQS based on the structure outlined in the CAA, existing rules, existing guidance, and in some cases revised guidance.

The CAA assigns important roles to EPA, states, and tribal governments in implementing NAAQS. States have the primary responsibility for developing and implementing State Implementation Plans (SIPs) that contain state measures necessary to achieve the air quality standards in each area. EPA provides assistance to states and tribes by providing technical tools, assistance, and guidance, including information on the potential control measures.

A SIP is the compilation of regulations and control programs that a state uses to carry out its responsibilities under the CAA, including the attainment, maintenance, and enforcement of the NAAQS. States use the SIP development process to identify the emissions sources that contribute to the nonattainment problem in a particular area, and to select the emissions reduction measures most appropriate for the particular area in question. Under the CAA, SIPs must ensure that areas reach attainment as expeditiously as practicable, but by no later than the statutory attainment date that is set for the area.

The EPA's analysis of the available Pb monitoring data suggests that a large percentage of recent Pb ambient air concentrations in excess of 0.15 $\mu\text{g}/\text{m}^3$ have occurred in locations with active

industrial sources of lead emissions. Accordingly, we anticipate that many areas may be able to attain the revised NAAQS by implementing air pollution control measures on lead emitting industrial sources only. These controls could include measures such as particulate matter fabric filter control devices and industrial fugitive dust control measures applied in plant buildings and on plant grounds. However, it may become necessary in some areas to also implement controls on non-industrial, or former industrial, type sources. Based on these considerations, EPA believes that the regulations and guidance currently being used to implement the pre-existing Pb NAAQS are still appropriate to implement the revised Pb NAAQS with modifications in some cases.

The regulations and guidance which address the implementation of the pre-existing NAAQS for Pb are mainly provided in the following documents: (1) "State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990", 57 FR 13549, April 16, 1992, (2) "State Implementation Plans for Lead Nonattainment Areas; Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990", 58 FR 67748, December 22, 1993, and (3) regulations listed at 40 CFR 51.117. These documents address requirements such as designating areas, setting nonattainment area boundaries, promulgating area classifications, nonattainment area SIP requirements such as Reasonably Available Control Measures (RACM), Reasonably Available Control Technology (RACT), New Source Review (NSR), Prevention of Significant Deterioration (PSD), and emissions inventory requirements. The EPA believes that the existing guidance and regulations are sufficient to implement the revised Pb NAAQS at this time. As discussed below, EPA is finalizing some changes to the existing guidance and regulations, and EPA will, as appropriate, review, and revise or update these policies, guidance, and regulations to ensure effective implementation of the Pb NAAQS.

Several commenters submitted comments stating that the usual agency practice for revising the NAAQS has been to first promulgate a rule setting the health and welfare based standards, and then to promulgate a rule that addresses the numerous implementation issues relating to the NAAQS. These commenters stated that the lead NAAQS proposal, however, combines these two rulemakings into one compressed rule.

Commenters stated that they theoretically believe that this two-in-one rule approach could benefit states and localities by preventing the types of delays that have been encountered with the implementation of other pollutants. The commenters, however, stated that they believe that the lead NAAQS implementation provisions in the proposed rule are insufficient to give state and local agencies adequate guidance to implement the revised standard. Commenters further stated that they believe that EPA should particularly update lead control strategy and emissions inventory guidance documents to account for the change to the level of the standard.

As stated in the proposed rule, EPA believes that the regulations and guidance currently being used to implement the pre-existing Pb NAAQS are generally still appropriate to address the issues required to begin implementing the revised Pb NAAQS. As discussed in the proposal, EPA is revising the emission inventory requirements of 40 CFR 51.117(e)(1). In some areas, as discussed below, EPA is providing additional guidance in response to comments. The EPA believes that these policies, guidance and regulations should be used by states, local, and Tribal governments as a basis for implementing the revised Pb NAAQS. Also, as stated in the proposed rule, EPA will as appropriate, further review and revise or update these policies, guidance, and regulations in the future to ensure that states, local, and Tribal governments have the appropriate information necessary to fully implement the revised Pb NAAQS in a timely manner.

As discussed below, the EPA is generally finalizing the guidance concerning the implementation of the revised Pb NAAQS consistent with the proposed rule.

A. Designations for the Lead NAAQS

1. Proposal

As discussed in the proposed rule, after EPA establishes or revises a primary and/or secondary NAAQS, the CAA requires EPA and the states to begin taking steps to ensure that the new or revised NAAQS are met. The first step is to identify areas of the country that do not meet the new or revised NAAQS. The CAA defines EPA's authority to designate areas that do not meet a new or revised NAAQS. Section 107(d)(1) provides that "By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised NAAQS for any pollutant under

section 109, the Governor of each state shall * * * submit to the Administrator a list of all areas (or portions thereof) in the state” that designates those areas as nonattainment, attainment, or unclassifiable. Section 107(d)(1)(B)(i) further provides, “Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended by up to one year in the event the Administrator has insufficient information to promulgate the designations.” The term “promulgation” has been interpreted by the courts to mean the signature and dissemination of a rule.¹¹¹ By no later than 120 days prior to promulgating final designations, EPA is required to notify states or Tribes of any intended modifications to their boundaries as EPA may deem necessary. States and Tribes then have an opportunity to comment on EPA’s tentative decision. It should be noted that, whether or not a state or a Tribe provides a recommendation, EPA must promulgate the designation that it deems appropriate.

In the proposal, EPA indicated that Governors and tribal leaders would be required to submit their initial designation recommendations to EPA no later than September 2009, and the initial designation of areas for the new Pb NAAQS would occur no later than September 2010, although that date may be extended by up to one year under the CAA (or no later than September 2011) if EPA has insufficient information to promulgate the designations. These dates were based on the court-ordered schedule in effect at the time of proposal, which required a final rule to be signed no later than September 15, 2008. The court-ordered schedule was subsequently amended to require a notice of final rulemaking to be signed no later than October 15, 2008.

In the proposed rule, EPA also discussed issues related to possible schedules for designations, and EPA took comment on issues related to the anticipated designation schedule. The proposal identified two “key considerations” in establishing a schedule for designations: “(1) The advantages of promulgating all designations at the same time; and (2) the availability of a monitoring network and sufficient monitoring data to identify areas that may be violating the NAAQS” (73 FR 29267). The EPA then

stated its view that “there are important advantages to promulgating designations for all areas at the same time” and expressed its intention to do so.

The proposal also discussed EPA’s belief that the existing Pb monitoring network is not adequate to evaluate attainment of the revised Pb NAAQS at locations consistent with EPA’s proposed new monitoring network siting criteria and data collection requirements. These new requirements would result in a more strategically targeted network that would begin operation by January 1, 2010. The proposal pointed out that taking the additional year provided under section 107(d)(1)(B)(i) of the CAA (which would allow up to 3 years to promulgate initial designations following the promulgation of a new or revised NAAQS) would allow the first year of data from the new monitoring network to be available. The proposal also stated that, due to the updated monitoring network design requirements, this additional data would be of significant benefit for designating areas for the new NAAQS.

Accordingly, the proposal identified an initial designation schedule under which states (and Tribes) would be required to submit designation recommendations to EPA no later than one year following promulgation of the new NAAQS. States would be able to consider ambient data collected with the existing network FRM and FEM samplers through the end of calendar year 2008 when formulating their recommendations. The proposal further indicated that if, as EPA anticipated, EPA needed an additional year to make designations due to insufficient information, EPA would have access to Pb air quality monitoring data from calendar year 2010, which state monitoring officials have certified as being complete and accurate, since the deadline for such certification is May 1, 2011. Under this schedule, EPA would be able to consider data from calendar years 2008–2010 in formulating its proposed revisions, if any, to the designations recommended by states and Tribes. States and Tribes would then have an opportunity to comment on EPA’s proposed modifications, if any, prior to the promulgation of designations by Fall 2011. The EPA solicited comment on whether EPA has the authority to determine in this final rule that three years would be necessary to make designations. The EPA also solicited comment on making designations within two years from promulgation of a revised NAAQS.

2. Comments and Responses

Several commenters suggested that EPA should require that states with current nonattainment or maintenance areas submit designation recommendations for those counties or Metropolitan Statistical Areas (MSAs) with nonattainment or maintenance areas within 120 days of promulgation of the rule.

Section 107(d)(1)(A) provides that States shall submit recommendations for areas to be designated attainment, nonattainment, and unclassifiable “[b]y such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109.” EPA’s consistent practice in revising NAAQS has been to allow states a year to prepare their lists of designations, and the proposal likewise indicated EPA’s intent to allow a year for states to prepare their recommendations. It is often true that when a standard is made more stringent there will be existing nonattainment and maintenance areas that may be expected to be nonattainment for the new standard as well. Furthermore, EPA notes that the most recent three years of available monitoring data for East Helena, MT, one of the two current nonattainment areas, showed no violations of the current standard, although the monitors were shut down in December 2001 following the shutdown of the large stationary source of lead emissions there. The EPA also notes that preparing designation recommendations is a complex task, and the magnitude of the reduction in the Pb NAAQS, and the long interval since the last revision to the standard is likely to add to the difficulty for states.

Thus, while EPA considers the increased stringency of the standard to be relevant to the question of when states should submit designation recommendations, EPA does not believe that under the current circumstances it would be reasonable to require states to submit a list of areas to be designated attainment, nonattainment, or unclassifiable sooner than one year following promulgation year.

Therefore, pursuant to section 107(d)(1)(A), states shall, and Tribes may, provide area designation recommendations to EPA no later than October 15, 2009.¹¹² In some areas, EPA

¹¹² Under the CAA and the Tribal Authority Rule (TAR), eligible Indian Tribes may develop and submit Tribal Implementation Plans (TIPs) for EPA approval, to administer requirements under the CAA on their reservations and in nonreservation

¹¹¹ *American Petroleum Institute v. Costle*, 609 F.2d 20 (D.C. Cir. 1979).

anticipates that state and Tribal officials will be able to base their recommendations on existing monitoring data, and can therefore identify an area as "attainment" or "nonattainment." EPA also anticipates that there will be other areas where state and Tribal officials will not have sufficient information to make such a determination. State and Tribal officials are advised to identify such areas as "unclassifiable." For these areas EPA may wait until sufficient ambient air quality data from the newly deployed Pb monitoring network are available to take final action on the state and Tribal recommendations.

Several commenters stated that EPA should promulgate designations for the revised Pb NAAQS within the 2 year period provided in the CAA. Commenters further stated that they do not understand why EPA needs to take an additional year beyond the two years provided under the CAA to do the designations. In addition, the commenters stated that they believe EPA does not have the authority to take the additional year (i.e., the 3rd year provided under section 107(d)(1)(B)(i) of the CAA) to do designations for the Pb NAAQS because sufficient monitoring data is available to do the designations within 2 years of promulgation of the NAAQS.

Other commenters stated that they agree with EPA that, given that the current monitoring network for the Pb NAAQS is insufficient to base designations on for the new NAAQS, EPA should not promulgate designations until there is sufficient data from the new monitoring network.

Section 107(d)(1)(B)(i) provides that the Administrator shall promulgate the designations of all areas as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of the new or revised national ambient air quality standard. Such period may be extended by up to one year in the event the Administrator has insufficient information to promulgate the designations.

After considering the comments, and recognizing that in some locations there may be monitoring data sufficient to determine whether or not the area is attaining the standard, EPA now

areas under their jurisdiction. However, Tribes are not required to develop TIPs or otherwise implement relevant programs under the CAA. In cases where a Tribal air quality agency has implemented an air quality monitoring network which is affected by Pb emissions, the criteria and procedures identified in this rule may be applied for regulatory purposes. Certain Tribes may implement all relevant components of an air quality program for purposes of meeting the various requirements of this rule.

believes that the benefits of identifying nonattainment areas as soon as possible, in some areas as discussed shortly below, outweigh the potential administrative benefits of designating all areas at the same time.

At the same time, EPA continues to believe that the current monitoring network is inadequate for making designations in many, if not most, areas of the country, and agrees with those commenters who stated that it would be preferable to wait until additional monitoring data was available for those areas than to proceed to designate areas based only on data from the current insufficient monitoring network. The EPA notes that any delay in designations beyond two years would be based on the lack of monitoring data (and the expectation that additional monitoring data would be available if designations were delayed) and would not be based on staffing and other non-data resource issues.

Accordingly, EPA believes that the most appropriate approach to designations for the Pb NAAQS is for EPA to complete final designations as expeditiously as possible, and to recognize that "as expeditiously as possible" may result in making nonattainment designations at different times for different areas. In some areas, EPA expects that it will be possible to do designations within two years based on currently available monitoring data. In other areas, EPA expects that taking the additional year will prove necessary in order to collect the necessary monitoring data before making designations.

3. Final

After considering the comments and for the reasons discussed above, EPA no longer plans to make all designations, and particularly all nonattainment designations, at the same time. The EPA intends to make designations as expeditiously as possible in areas where monitoring data is currently sufficient, or will be sufficient in the immediate future, to accurately characterize the areas as either not attaining or attaining the new Pb NAAQS. In some cases this will be possible as expeditiously as practicable, but no later than two years following promulgation of the final rule. In other cases this will not be possible until additional data are collected from the newly deployed monitoring network, and may take up to three years.

B. Lead Nonattainment Area Boundaries

1. Proposal

The process for initially designating areas following the promulgation of a

new or revised NAAQS is prescribed in section 107(d)(1) of the CAA. This section of the CAA provides each state Governor an opportunity to recommend initial designations of attainment, nonattainment, or unclassifiable for each area in the state. Section 107(d)(1) of the CAA also directs the state to provide the appropriate boundaries to EPA for each area of the state, and provides that EPA may make modifications to the boundaries submitted by the state as it deems necessary. A lead nonattainment area must consist of that area that does not meet (or contributes to ambient air quality in a nearby area that does not meet) the Pb NAAQS. Thus, a key factor in setting boundaries for nonattainment areas is determining the geographic extent of nearby source areas contributing to the nonattainment problem. For each monitor or group of monitors that exceed a standard, nonattainment boundaries must be set that include a sufficiently large enough area to include both the area judged to be violating the standard as well as the source areas that are determined to be contributing to these violations.

Historically, Pb NAAQS violations have been the result of lead emissions from large stationary sources and mobile sources that burn lead-based fuels. In some locations, a limited number of area sources have also been determined to have contributed to violations. Since lead has been successfully phased out of motor vehicle gasoline, these sources are no longer a significant source of ambient lead concentrations. At the revised standard level, EPA expects stationary sources to be the primary contributor to violations of the NAAQS. However, it is possible that fugitive dust emissions from area sources containing deposited lead will also contribute to violations of the revised Pb NAAQS. The location and dispersion characteristics of these sources of ambient lead concentrations are important factors in determining nonattainment area boundaries.

In the proposed rule, EPA proposed to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard. This presumption was also EPA's recommendation for defining the nonattainment boundaries for the 1978 Pb NAAQS, and is described in the 1992 General Preamble (57 FR 13549). In the proposed rule, EPA also requested comment on an option to presumptively define the nonattainment boundary using the OMB-defined Metropolitan Statistical Area (MSA) associated with

the violating monitor(s). This presumption was used historically, by the CAA requirement, for the 1-hr ozone and CO NAAQS nonattainment boundaries, and was also recommended by EPA as the appropriate presumption for the 1997 8-hour ozone and PM_{2.5} NAAQS nonattainment boundaries. In the proposed rule we stated that under either option, the state and EPA may conduct additional area-specific analyses that could lead EPA to depart from the presumptive boundary. The factors relevant to such an analysis are described below.

For the proposed Pb NAAQS, EPA recommended that nonattainment area boundaries that deviate from presumptive county boundaries should be supported by an assessment of several factors, which are discussed below. The factors for determining nonattainment area boundaries for the Pb NAAQS under this recommendation closely resemble the factors identified in recent EPA guidance for the 1997 8-hour ozone NAAQS, the 1997 PM_{2.5} NAAQS, and the 2006 PM_{2.5} NAAQS nonattainment area boundaries. For this particular option of the proposal, EPA would consider the following factors in assessing whether to exclude portions of a county and whether to include additional nearby areas outside the county as part of the designated nonattainment area:

- Emissions in areas potentially included versus excluded from the nonattainment area.
- Air quality in potentially included versus excluded areas.
- Population density and degree of urbanization including commercial development in included versus excluded areas.
- Expected growth (including extent, pattern and rate of growth).
- Meteorology (weather/transport patterns).
- Geography/topography (mountain ranges or other air basin boundaries).
- Jurisdictional boundaries (e.g., counties, air districts, reservations, etc.).
- Level of control of emission sources.

The proposal indicated that analyses of these factors may suggest nonattainment area boundaries that are either larger or smaller than the county boundary. A demonstration supporting the designation of boundaries that are less than the full county would be required to show both that violation(s) are not occurring in the excluded portions of the county and that the excluded portions are not source areas that contribute to the observed violations. Recommendations to designate a nonattainment area larger

than the county should also be based on an analysis of these factors. The proposal stated that EPA would consider these factors as well in evaluating state and Tribal recommendations and assessing whether any modifications are appropriate.

Under previous Pb implementation guidance, EPA advised that Governors could choose to recommend lead nonattainment boundaries by using any one, or a combination of the following techniques, the results of which EPA would consider when making a decision as to whether and how to modify the Governors' recommendations: (1) Qualitative analysis, (2) spatial interpolation of air quality monitoring data, or (3) air quality simulation by dispersion modeling. These techniques are more fully described in "Procedures for Estimating Probability of Nonattainment of a PM₁₀ NAAQS Using Total Suspended Particulate or PM₁₀ Data," December 1986 (see 57 FR 13549). In the proposed rule, EPA solicited comments on the use of these factors and modeling techniques, and other approaches, for adjusting county boundaries in designating nonattainment areas.

2. Comments and Responses

Several commenters submitted comments stating that the nonattainment boundaries should be limited to the smallest political boundary that possesses an ambient monitor-based design value above the standard, unless subsequent analyses demonstrate that the boundaries should be larger or smaller. Commenters also stated that because lead does not transport over long distances, monitoring data from upwind and downwind sites illustrate that violations of the lead NAAQS are most commonly isolated within a specific geographic area in close proximity to a major source.

The EPA agrees with the commenter that lead emissions do not generally transport over long distances (as compared, e.g., to fine particulate matter). In the proposed rule, EPA proposed to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard. In the proposed rule, EPA also stated that, at the revised level of the standard, EPA expects stationary sources to be the primary contributor to violations of the NAAQS, although we also believe that nearby area sources may also contribute to concentrations of lead emissions that

may affect a violating monitor. In light of the possibility that a number of smaller sources may collectively contribute to concentrations in excess of the NAAQS, EPA believes that adopting the county boundary as the presumptive boundaries for lead nonattainment areas is appropriate. However, as stated in the proposed rule, a state, Tribe, or EPA may conduct additional area-specific analyses that could lead to the boundary for an area either being increased or decreased from the presumptive county boundary. In situations where a single source, rather than multiple sources, is causing a NAAQS violation, the EPA believes that a state may well be able to use area-specific analyses to identify whether a nonattainment area that is smaller than the county boundary is appropriate.

Several commenters stated that EPA should use the MSA as the presumptive boundary for designating areas for the Pb NAAQS in order for a broader range of source emissions to be taken into consideration when the state develops its SIP for the nonattainment area.

As stated previously, at the revised level of the standard, EPA expects stationary sources to be the primary contributor to violations of the Pb NAAQS, although we also expect that in some areas a number of smaller sources may collectively contribute to concentrations in excess of the NAAQS. MSAs are frequently composed of several counties. Recognizing that lead emissions, particularly ultracoarse particles, deposit relatively short distances from the proximity of their initial source, EPA believes that adopting the county boundary surrounding a violating monitor as the presumptive boundary for any given lead nonattainment area is more appropriate than presuming the larger MSA boundary. Furthermore, as stated in the proposed rule (and the previous response), a state, Tribe, or EPA may conduct additional area-specific analyses that could lead to the boundary for an area either being increased or decreased from the presumptive boundary. Thus, where it appears that emissions from one or more sources are contributing to nonattainment throughout an MSA, the site-specific analysis may result in the boundaries of the nonattainment area overlapping with those of the MSA.

3. Final

The EPA is finalizing the option to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard as proposed.

This presumption was also EPA's recommendation for defining the nonattainment boundaries for the pre-existing Pb NAAQS, and is described in the 1992 General Preamble (57 FR 13549). As a part of the county boundary presumption for nonattainment areas, the state and/or EPA may conduct additional area-specific analyses that could lead EPA to depart from the presumptive county boundary. The EPA is also finalizing the factors relevant to such an analysis as described in the proposed rule because we believe that they will allow for both the State as well as EPA in some cases to define better the appropriate boundaries for an area. The state may, in addition to submitting recommendations for boundaries based on the factor analysis, also choose to recommend lead nonattainment boundaries using any one, or a combination of the following techniques, the results of which EPA would consider when making a decision as to whether and how to modify the Governors' recommendations: (1) Qualitative analysis, (2) spatial interpolation of air quality monitoring data, or (3) air quality simulation by dispersion modeling, as described more fully in "Procedures for Estimating Probability of Nonattainment of a PM₁₀ NAAQS Using Total Suspended Particulate or PM₁₀ Data," December 1986 (see 57 FR 13549).

C. Classifications

1. Proposal

Section 172(a)(1)(A) of the CAA authorizes EPA to classify areas designated as nonattainment for the purpose of applying an attainment date pursuant to section 172(a)(2), or for other reasons. In determining the appropriate classification, EPA may consider such factors as the severity of the nonattainment problem and the availability and feasibility of pollution control measures (see section 172(a)(1)(A) of the CAA). The EPA may classify lead nonattainment areas, but is not required to do so.

While section 172(a)(1)(A) provides a mechanism to classify nonattainment areas, section 172(a)(2)(D) provides that the attainment date extensions described in section 172(a)(2)(A) do not apply to nonattainment areas having specific attainment dates that are addressed under other provisions of the part D of the CAA. Section 192(a), of part D, specifically provides an attainment date for areas designated as nonattainment for the Pb NAAQS. Therefore, EPA has legal authority to classify lead nonattainment areas, but

the 5 year attainment date under section 192(a) cannot be extended pursuant to section 172(a)(2)(D). Based on this limitation, EPA proposed not to establish classifications within the 5 year interval for attaining any new or revised NAAQS. This approach is consistent with EPA's previous classification decision for Pb in the 1992 General Preamble (See 57 FR 13549, April 16, 1992).

2. Comments and Responses

Several commenters stated that they disagreed with EPA's proposal not to classify lead nonattainment areas under CAA section 172(a)(1)(A). The commenters stated that existing nonattainment areas, meaning areas that have not yet achieved the pre-existing Pb NAAQS, would benefit from more rigorous SIP requirements associated with classifications. The commenters stated that such classifications are appropriate not only for deadline extensions (not applicable in this case, as EPA notes), but "for other purposes". The commenters state that such purposes should include lower emissions thresholds for defining major stationary sources, higher offset ratios, and a more ambitious definition of reasonable further progress.

EPA stated in the proposed rule, that while section 172(a)(1)(A) provides a mechanism to classify nonattainment areas, section 172(a)(2)(D) provides that the attainment date extensions described in section 172(a)(2)(A) do not apply to nonattainment areas having specific attainment dates that are addressed under other provisions of part D of the CAA. Based on this limitation, EPA proposed not to establish classifications within the 5 year interval for attaining any new or revised NAAQS. This approach is consistent with EPA's previous classification decision for Pb in the 1992 General Preamble (See 57 FR 13549, April 16, 1992) notes that subpart 2 of part D of the CAA specifies mandatory control measures required for areas with different classifications for the ozone standard, including such items as higher offset ratios and specific percentage requirements for reasonable further progress. Areas with higher classifications are subject to more stringent controls, but also receive additional time to attain the standard. Subpart 5 of part D contains no such provisions, but instead requires submittal of a SIP within 18 months of designation of an area as nonattainment, and requires attainment for all areas as expeditiously as practicable, but no later than 5 years following designation. Although EPA does have authority to

establish classifications for Pb, EPA continues to believe, taking into consideration these differing statutory schemes (and particularly the requirement to attain as expeditiously as practicable, but no later than 5 years from designation) that it is not appropriate or necessary to establish classifications for the revised Pb NAAQS.

3. Final

The EPA is finalizing the guidance for classifications as provided in the proposed rule. Therefore, there will be no classifications under the revised Pb NAAQS.

D. Section 110(a)(2) Lead NAAQS Infrastructure Requirements

1. Proposal

Under section 110(a)(1) and (2) of the CAA, all states are required to submit plans to provide for the implementation, maintenance, and enforcement of any new or revised NAAQS. Section 110(a)(1) and (2) require states to address basic program elements, including requirements for emissions inventories, monitoring, and modeling, among other things. States are required to submit SIPs to EPA which demonstrate that these basic program elements have been addressed within 3 years of the promulgation of any new or revised NAAQS. Subsections (A) through (M) of section 110(a)(2) listed below, set forth the elements that a state's program must contain in the SIP.¹¹³ The list of section 110(a)(2) NAAQS implementation requirements are the following:

- Ambient air quality monitoring/data system: Section 110(a)(2)(B) requires SIPs to provide for setting up and operating ambient air quality monitors, collecting and analyzing data and making these data available to EPA upon request.
- Program for enforcement of control measures: Section 110(a)(2)(C) requires SIPs to include a program providing for enforcement of measures and regulation and permitting of new/modified sources.
- Interstate transport: Section 110(a)(2)(D) requires SIPs to include provisions prohibiting any source or

¹¹³ Two elements identified in section 110(a)(2) are not listed below because, as EPA interprets the CAA, SIPs incorporating any necessary local nonattainment area controls would not be due within 3 years, but rather are due at the time the nonattainment area planning requirements are due. These elements are: (1) Emission limits and other control measures, section 110(a)(2)(A), and (2) Provisions for meeting part D, section 110(a)(2)(I), which requires areas designated as nonattainment to meet the applicable nonattainment planning requirements of part D, title I of the CAA.

other type of emissions activity in the state from contributing significantly to nonattainment in another state or from interfering with measures required to prevent significant deterioration of air quality or to protect visibility.

- Adequate resources: Section 110(a)(2)(E) requires states to provide assurances of adequate funding, personnel and legal authority for implementation of their SIPs.
 - Stationary source monitoring system: Section 110(a)(2)(F) requires states to establish a system to monitor emissions from stationary sources and to submit periodic emissions reports to EPA.
 - Emergency power: Section 110(a)(2)(G) requires states to include contingency plans, and adequate authority to implement them, for emergency episodes in their SIPs.
 - Provisions for SIP revision due to NAAQS changes or findings of inadequacies: Section 110(a)(2)(H) requires states to provide for revisions of their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or in response to an EPA finding that the SIP is inadequate.
 - Section 121 consultation with local and Federal government officials: Section 110(a)(2)(J) requires states to meet applicable local and Federal government consultation requirements of section 121.
 - Section 127 public notification of NAAQS exceedances: Section 110(a)(2)(J) requires states to meet applicable requirements of section 127 relating to public notification of violating NAAQS.
 - PSD and visibility protection: Section 110(a)(2)(J) also requires states to meet applicable requirements of title I part C related to prevention of significant deterioration and visibility protection.
 - Air quality modeling/data: Section 110(a)(2)(K) requires that SIPs provide for performing air quality modeling for predicting effects on air quality of emissions of any NAAQS pollutant and submission of data to EPA upon request.
 - Permitting fees: Section 110(a)(2)(L) requires the SIP to include requirements for each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing and enforcing a permit.
- Consultation/participation by affected local government: Section 110(a)(2)(M) requires states to provide for consultation and participation by local political subdivisions affected by the SIP.

2. Final

The EPA is finalizing the guidance related to the submittal of SIPs to address the infrastructure requirements of section 110(a)(1) and (2) as stated in the proposed rule.

E. Attainment Dates

1. Proposal

As discussed in the proposal, the maximum deadline date by which an area is required to attain the Pb NAAQS is determined by the effective date of the nonattainment designation for the area. For areas designated nonattainment for the revised Pb NAAQS, SIPs must provide for attainment of the NAAQS as expeditiously as practicable, but no later than 5 years from the date of the nonattainment designation for the area (see section 192(a) of the CAA). In the proposed rule, EPA stated it would determine whether an area had demonstrated attainment of the Pb NAAQS by evaluating air quality monitoring data from the one, two, or three previous years as available.

2. Comments and Responses

A commenter stated that the attainment deadline for the current nonattainment and maintenance areas should be three years.

Under the CAA, states are required to attain as expeditiously as practicable (but in no case later than five years). If it is practicable for a nonattainment area to attain the standard within three years, then the SIP must provide for attainment within three years. If, however, attainment within three years is not practicable, then EPA has no authority to require attainment by that deadline.

2. Final

The EPA is generally finalizing the guidance related to attainment dates as provided in the proposed rule. States with nonattainment areas will be required to attain the standard as expeditiously as practicable, but in no event later than five years from the effective date of the nonattainment designation. EPA wishes to clarify that it will be considering air quality monitoring data from the three previous years, as available, in determining whether areas have demonstrated attainment (i.e., EPA would only consider data for less than the three previous years in situations where the data for all three years was unavailable).

F. Attainment Planning Requirements

Any state containing an area designated as nonattainment with

respect to the Pb NAAQS must develop for submission, a SIP meeting the requirements of part D, Title I, of the CAA, providing for attainment by the applicable deadline (see sections 191(a) and 192(a) of the CAA). As indicated in section 191(a) all components of the lead part D SIP must be submitted within 18 months of the effective date of an area's designation as nonattainment. Additional specific plan requirements for lead nonattainment areas are outlined in 40 CFR 51.117.

The general part D nonattainment plan requirements are set forth in section 172 of the CAA. Section 172(c) specifies that SIPs submitted to meet the part D requirements must, among other things, include Reasonably Available Control Measures (RACM) (which includes Reasonably Available Control Technology (RACT)), provide for Reasonable Further Progress (RFP), include an emissions inventory, require permits for the construction and operation of major new or modified stationary sources (see also CAA section 173), contain contingency measures, and meet the applicable provisions of section 110(a)(2) of the CAA related to the general implementation of a new or revised NAAQS. It is important to note that lead nonattainment SIPs must meet all of the requirements related to part D of the CAA, including those specified in section 172(c), even if EPA does not provide separate specific guidance for each provision.

1. RACM/RACT for Lead Nonattainment Areas

a. Proposal

Lead nonattainment area SIPs must contain RACM (including RACT) that address sources of ambient lead concentrations. In general, EPA believes that lead NAAQS violation issues will usually be attributed to emissions from stationary sources. In EPA's 2002 National Emissions Inventory (NEI), there were 12 stationary sources in the country with lead emissions over 5 tons per year, and 124 sources over 1 ton of lead emissions per year.

Some emissions that contribute to violations of the Pb NAAQS may also be attributed to smaller area sources. At primary lead smelters, the process of reducing concentrated ore to lead involves a series of steps, some of which are completed outside of buildings, or inside of buildings that are not totally enclosed. Over a period of time, emissions from these sources have been deposited in neighboring communities (e.g., on roadways, parking lots, yards, and off-plant property). This historically deposited lead, when disturbed, may be

re-entrained into the ambient air and may contribute to violations of the Pb NAAQS in affected areas.

The first step in addressing RACM for lead is identifying potential control measures for sources of lead in the nonattainment area. A suggested starting point for specifying RACM in lead nonattainment area SIPs is outlined in appendix 1 of the guidance entitled "State Implementation Plans for Lead Nonattainment Areas; Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990", 58 FR 67752, December 22, 1993. If a state is aware of facts, or receives substantive public comments, that demonstrate through appropriate documentation, that additional control measures may be reasonably available in a specific area, the measures should be added to the list of available measures for consideration in that particular area.

While EPA does not presume that these control measures are reasonably available in all areas, a reasoned justification for rejection of any available control measure should be prepared. If it can be shown that measures, considered both individually as well as in a group, are unreasonable because emissions from the affected sources are insignificant, then the measures may be excluded from further consideration as they would not be representative of RACM for the affected area. The resulting control measures should then be evaluated for reasonableness, considering their technological feasibility and the cost of control in the area for which the SIP applies. In the case of public sector sources and control measures, this evaluation should consider the impact and reasonableness of the measures on the municipal, or other governmental entity that must assume the responsibility for their implementation. It is important to note that a state should consider the feasibility of implementing measures in part when full implementation would be infeasible. A reasoned justification for partial or full rejection of any available control measure, including those considered or presented during the state's public hearing process, should be prepared. The justification should contain a detailed explanation, with appropriate documentation, as to why each rejected control measure is deemed infeasible or otherwise unreasonable for implementation.

Economic feasibility considers the cost of reducing emissions and the difference between the cost of the emissions reduction approach at the particular source in question and the

costs of emissions reduction approaches that have been implemented at other similar sources. Absent other indications, EPA as a general matter expects that it is reasonable for similar sources to bear similar costs of emissions reduction. Economic feasibility for RACT purposes is largely determined by evidence that other sources in a particular source category have in fact applied the control technology or process change in question. The EPA also encourages the development of innovative measures not previously employed which may also be technically and economically feasible.

The capital costs, annualized costs, and cost effectiveness of an emissions reduction technology should be considered in determining whether a potential control measure is reasonable for an area or state. One available reference for calculating costs is the EPA Air Pollution Control Cost Manual,¹¹⁴ which describes the procedures EPA uses for determining these costs for stationary sources. The above costs should be determined for all technologically feasible emission reduction options. States may give substantial weight to cost effectiveness in evaluating the economic feasibility of an emission reduction technology. The cost effectiveness of a technology is its annualized cost (\$/year) divided by the emissions reduced (i.e., tons/year) which yields a cost per amount of emission reduction (\$/ton). Cost effectiveness provides a value for each emission reduction option that is comparable with other options and other facilities. With respect to a given pollutant, a measure is likely to be reasonable if it has a cost per ton similar to other measures previously employed for that pollutant. In addition, a measure is likely to be reasonable from a cost effectiveness standpoint if it has a cost per ton similar to that of other measures needed to achieve expeditious attainment in the area within the CAA's timeframes.

The fact that a measure has been adopted or is in the process of being adopted by other states is also an indicator (though not a definitive one) that the measure may be technically and economically feasible for another state. We anticipate that states may decide upon RACT and RACM controls that differ from state to state, based on the state's determination of the most effective strategies given the relevant mixture of sources and potential

controls in the relevant nonattainment areas, and differences in difficulty of attaining expeditiously. Nevertheless, states should consider and address RACT and RACM measures developed for other areas, as part of a well reasoned RACT and RACM analysis. The EPA's own evaluation of SIPs for compliance with the RACT and RACM requirements will include comparison of measures considered or adopted by other states.

In considering what level of control is reasonable, EPA is not adopting a specific dollar per ton cost threshold for RACT. Areas with more serious air quality problems typically will need to obtain greater levels of emissions reductions from local sources than areas with less serious problems, and it would be expected that their residents could realize greater public health benefits from attaining the standard as expeditiously as practicable. For these reasons, we believe that it will be reasonable and appropriate for areas with more serious air quality problems and higher design values to impose emission reduction requirements with generally higher costs per ton of reduced emissions than the cost of emissions reductions in areas with lower design values. In addition, where essential reductions are more difficult to achieve (e.g., because many sources are already controlled), the cost per ton of control may necessarily be higher.

The EPA believes that in determining appropriate emission control levels, the state should consider the collective public health benefits that can be realized in the area due to projected improvements in air quality. Because EPA believes that RACT requirements will be met where the state demonstrates timely attainment, and areas with more severe air quality problems typically will need to adopt more stringent controls, RACT level controls in such areas will require controls at higher cost effectiveness levels (\$/ton) than areas with less severe air quality problems.

In identifying the range of costs per ton that are reasonable, information on benefits per ton of emission reduction can be useful as one factor to consider. It should be noted that such benefits estimates are subject to significant uncertainty and that benefits per ton vary in different areas. Nonetheless this information could be used in a way that recognizes these uncertainties. If a per ton cost of implementing a measure is significantly less than the anticipated benefits per ton, this would be an indicator that the cost per ton is reasonable. If a source contends that a source-specific RACT level should be

¹¹⁴ EPA Air Pollution Control Cost Manual—Sixth Edition (EPA 452/B-02-001), EPA Office of Air Quality Planning and Standards, Research Triangle Park, NC, Jan. 2002.

established because it cannot afford the technology that appears to be RACT for other sources in its source category, then the source should support its claim by providing detailed and verified information regarding the impact of imposing RACT on:

- Fixed and variable production costs (\$/unit),
- Product supply and demand elasticity,
- Product prices (cost absorption vs. cost pass-through),
- Expected costs incurred by competitors,
- Company profits, and
- Employment costs.

The technical guidance entitled “Fugitive Dust Background Document and Technical Information Document for Best Available Control Measures” (EPA-450/2-92-004, September 1992) provides an example for states on how to analyze control costs for a given area.

Once the process of determining RACT for an area is completed, the individual measures should then be converted into a legally enforceable vehicle (e.g., a regulation or permit program) (see section 172(c)(6) and section 110(a)(2)(A) of the CAA). The regulations or other measures submitted should meet EPA’s criteria regarding the enforceability of SIPs and SIP revisions. These criteria were stated in a September 23, 1987 memorandum (with attachments) from J. Craig Potter, Assistant Administrator for Air and Radiation; Thomas L. Adams, Jr., Assistant Administrator for Enforcement and Compliance Monitoring; and S. Blake, General Counsel, Office of the General Counsel; entitled “Review of State Implementation Plans and Revisions of Enforceability and Legal Sufficiency.” As stated in this memorandum, SIPs and SIP revisions that fail to satisfy the enforceability criteria should not be forwarded for approval. If they are submitted, they will be disapproved if, in EPA’s judgment, they fail to satisfy applicable statutory and regulatory requirements.

The EPA’s historic definition of RACT is the lowest emissions limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.¹¹⁵ RACT applies to the

“existing sources” of lead in an area including stack emissions, industrial process fugitive emissions, and industrial fugitive dust emissions (e.g., on-site haul roads, unpaved staging areas at the facility, etc.) (see section 172(c)(1)). The EPA’s previous guidance for implementing the pre-existing Pb NAAQS recommends that stationary sources which emit a total of 5 tpy of lead or lead compounds, measured as elemental lead, be the minimum starting point for RACT analysis (see 58 FR 67750, December 22, 1993). Further, EPA’s existing guidance recommends that available control technology be applied to those existing sources in the nonattainment area that are reasonable to control in light of the attainment needs of the area and the feasibility of such controls. Thus, under existing guidance, a state’s control technology analysis may need to include sources which actually emit less than 5 tpy of lead or lead compounds in the area, or other sources in the area that are reasonable to control, in light of the attainment needs and feasibility of control for the area.

Given the proposal to promulgate a revised Pb NAAQS that is significantly lower than the current level of 1.5 $\mu\text{g}/\text{m}^3$, EPA requested comment on the appropriate threshold for the minimum starting point for future Pb RACT analyses for stationary lead sources in nonattainment areas. In the proposed rule, EPA requested comment on the emissions level associated with the minimum network source monitoring requirements. These source levels range from 200 kg/yr to 600 kg/yr. The EPA also stated that one possible approach for RACT is to recommend that RACT analyses for Pb sources be consistent with sources that are required to monitor such that all stationary sources above 200 kg/yr to 600 kg/yr should undergo a RACT review. EPA also requested comment on source monitoring for stationary sources that emit lead emissions in amounts that have potential to cause ambient levels at least one-half the selected NAAQS level. This suggests another potential recommendation for the starting point for the RACT analysis. The EPA sought comment on these ideas as well as any information which commenters could provide that would help inform EPA’s recommendation on an appropriate emissions threshold for initiating RACT analyses.

b. Comments and Responses

Several commenters stated that given the proposed level of the lead NAAQS that EPA should set the threshold for RACT analysis for stationary sources at

a threshold level similar to the level being considered for the source monitoring requirements, which is between 200 kg/yr–600 kg/yr. Several commenters suggested a lower threshold (such as 45 kg/year) or stated that depending on the attainment needs for the affected area, it may be necessary to evaluate control technology that is reasonably available for sources with actual emissions that are lower than the recommended RACT/RACM threshold to take into consideration the actual attainment needs for the affected area. One commenter suggested the threshold should be set only at a level at which an exceedance of the NAAQS is expected, while another suggested it should be set no higher than that level.

The EPA believes that it is appropriate to set the recommended threshold for the RACT analysis for the new standard at 0.5 tpy. The existing Pb NAAQS is set at 1.5 $\mu\text{g}/\text{m}^3$ and the existing threshold for RACT analysis is 5 tpy. Since the standard is being reduced by a factor of ten, from 1.5 $\mu\text{g}/\text{m}^3$ to 0.15 $\mu\text{g}/\text{m}^3$, it is appropriate to also reduce the threshold for RACT analysis by a factor of 10, from 5 tpy to 0.5 tpy. Furthermore, the monitor siting criteria include a requirement for monitoring agencies to conduct monitoring taking into account sources that are expected to exceed the NAAQS, and require monitoring for sources which emit Pb at a rate of one ton per year. Although EPA expects that sources emitting less than one tpy may also contribute to violations of the revised Pb NAAQS, EPA believes that the one tpy requirement in the monitor siting criteria provides a benchmark that is more likely to clearly identify sources that would contribute to exceedances of the NAAQS. Accordingly, using 50% of that figure (0.5 tpy) as the threshold for RACT analysis is generally consistent with EPA’s consideration in the proposal of setting the RACT threshold to include those stationary sources that emit lead emissions in amounts that have the potential to cause ambient levels at least one-half the selected NAAQS.

EPA believes that setting the RACT threshold higher (e.g., at 1 tpy) would not be appropriate because it is likely that in a nonattainment area sources emitting less than one tpy are contributing to the nonattainment of the NAAQS. EPA also does not believe a lower threshold is warranted as a general matter, but EPA agrees with commenters that the state’s control technology analysis should also include, as appropriate, sources which actually emit less than the threshold level of 0.5 tpy of lead or lead compounds in the

¹¹⁵ See for example, 44 FR 53762 (September 17, 1979) and footnote 3 of that notice. Note that EPA’s emissions trading policy statement has clarified that the RACT requirement may be satisfied by achieving “RACT equivalent” emission reductions in the aggregate from the full set of existing stationary sources in the area. See also EPA’s economic incentive proposal which reflects the Agency’s policy guidance with respect to emissions trading, 58 FR 11110, February 23, 1993.

area, or other sources in the area that are reasonable to control, in light of the attainment needs and feasibility of controls for the affected area.

Several commenters stated that in the proposed rule EPA suggests that the 1993 guidance document, which lists control measures as a starting point for states' consideration, puts the burden on the public to demonstrate through appropriate documentation that additional control measures may be reasonably available in a particular circumstance for an area. The commenters further stated that in light of an anticipated substantial reduction in the Pb NAAQS, as well as the failure of the remaining two existing nonattainment areas to achieve attainment of the pre-existing (1978) NAAQS under the 1993 guidance, that both EPA and the states should bear the principal responsibility for developing an updated roster of successful control measures.

As stated in the proposed rule, EPA believes that the regulations, policies, and guidance currently in place for the implementation of the pre-existing Pb NAAQS are still appropriate to address the issues required to implement the revised Pb NAAQS. The EPA believes that these guidance, policies, and regulations should be used by states, local, and Tribal governments as a starting point to begin implementation of the revised Pb NAAQS. The EPA expects that as states gain additional experience with implementing the revised NAAQS, additional information on successful control measures will become available to states, EPA, and the public. The EPA will, as appropriate, review, and revise or update policies, guidance, and regulations to provide for effective implementation of the Pb NAAQS.

c. Final

The EPA is finalizing the guidance related to RACM (including RACT) for lead nonattainment areas consistent with the proposed rule. Based upon the above considerations regarding the scale of the reduction in the standard, the final monitor siting criteria, and the public comments received related to the starting point for a RACT analysis, EPA is recommending a threshold for RACT analysis such that at least all stationary sources emitting 0.5 tpy or more should undergo a RACT review.

2. Demonstration of Attainment for Lead Nonattainment Areas

a. Proposal

The SIPs for lead nonattainment areas should provide for the implementation

of control measures for point and area sources of lead emissions which demonstrate attainment of the Pb NAAQS as expeditiously as practicable, but no later than the applicable statutory attainment date for the area (see also 40 CFR 51.117(a) for additional control strategy requirements). Therefore, if a state adopts less than all available measures in an area but demonstrates, adequately, that reasonable further progress (RFP), and attainment of the Pb NAAQS are assured, and the application of all such available measures would not result in attainment any faster, then a plan which requires implementation of less than all technologically and economically available measures may be approved (see 44 FR 20375 (April 4, 1979) and 56 FR 5460 (February 11, 1991)). The EPA believes that it would be unreasonable to require that a plan which demonstrates attainment include all technologically and economically available control measures even though such measures would not expedite attainment. Thus, for some sources in areas which demonstrate attainment, it is possible that some available control measures may not be "reasonably" available because their implementation would not expedite attainment for the affected area.

b. Final

The EPA is finalizing the guidance related to demonstration of attainment for lead nonattainment areas as stated in the proposed rule. Further discussion of modeling for attainment and other topics is presented below.

3. Reasonable Further Progress (RFP)

a. Proposal

Part D SIPs must provide for RFP (see section 172(c)(2) of the CAA). Section 171 of the CAA defines RFP as "such annual incremental reductions in emissions of the relevant air pollution as are required by part D, or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable attainment date." Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions generally sufficient to maintain linear progress toward attainment by the applicable attainment date. The EPA believes that RFP for lead nonattainment areas should be met by "adherence to an ambitious compliance schedule" which is expected to periodically yield significant emission reductions, and as appropriate, linear

progress.¹¹⁶ The EPA recommends that SIPs for lead nonattainment areas provide a detailed schedule for compliance of RACM (including RACT) in the affected areas and accurately indicate the corresponding annual emission reductions to be achieved. In reviewing the SIP, EPA believes that it is appropriate to expect early implementation of less technology-intensive control measures (e.g., controlling fugitive dust emissions at the stationary source, as well as required controls on area sources) while phasing in the more technology-intensive control measures, such as those involving the installation of new hardware. Finally, failure to implement the SIP provisions required to meet annual incremental reductions in emissions (i.e., RFP) in a particular area could result in the application of sanctions as described in section 179(b) of the CAA (pursuant to a finding under section 179(a)(4)), and the implementation of contingency measures required by section 172(c)(9) of the CAA.

b. Comments and Responses

Several commenters stated that EPA's proposal related to RFP would allow states to avoid the need to demonstrate linear progress towards attainment, departing from the typical method used, and statutorily required in some cases, for other criteria pollutants. These commenters further state that the recognition that some nonattainment urban areas have numerous sources contributing to excessive ambient levels of lead which undermines the reasoning employed to justify a non-linear approach in the context of single source nonattainment areas. If areas with large sources install key controls early on in the attainment process, and thus achieve attainment ahead of schedule, that would advance the goals and requirements of the CAA.

Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions generally sufficient to maintain linear progress toward attainment by the applicable attainment date. As EPA has previously noted, we expect that some nonattainment designations will be attributable to a single stationary source, and others may be attributable to a number of smaller sources. Where a single source is the cause of

¹¹⁶ As previously stated in the proposed rule, EPA believes that most lead nonattainment problems will most likely be due to emissions from stationary sources of lead. For this reason EPA believes that the RFP for Pb should parallel the RFP policy for SO₂ (see General Preamble, 57 FR 13545, April 16, 1992).

nonattainment, EPA would not expect linear progress towards attainment. Rather, there may be relatively less progress while the source adopts non-technological control measures and begins to install necessary technological controls, and then significant progress towards attainment in a short period of time once all the controls are operational. EPA expects that, since states are required to attain the standard as expeditiously as practicable, the SIP will require large sources to install "key controls" as expeditiously as practicable. At the same time, where a number of sources are contributing to nonattainment, it is more reasonable to expect that controls (both technological and non-technological) may be adopted at different times, making linear progress a more reasonable expectation. To accommodate both of these possible situations, EPA concludes it is appropriate that RFP for lead nonattainment areas should be met by the strict adherence to an ambitious compliance schedule which is expected to periodically yield significant emission reductions, and, to the extent appropriate, linear progress.

c. Final

The EPA is finalizing the guidance related to reasonable further progress (RFP) consistent with the proposed rule. The EPA believes that RFP for lead nonattainment areas should be met by the strict adherence to an ambitious compliance schedule which is expected to periodically yield significant emission reductions, and to the extent appropriate, linear progress. The EPA recommends that SIPs for lead nonattainment areas provide a detailed schedule for compliance of RACM (including RACT) and accurately indicate the corresponding annual emission reductions to be achieved. In reviewing the SIP, EPA believes that it is appropriate to expect early implementation of less technology-intensive control measures (e.g., work practices to control fugitive dust emissions at the stationary sources) while phasing in the more technology-intensive control measures, such as those involving the installation of new hardware. The EPA believes that the expeditious implementation of RACM/RACT at affected sources within the nonattainment area is an appropriate approach to assure attainment of the Pb NAAQS in an expeditious manner.

4. Contingency Measures

a. Proposal

Section 172(c)(9) of the CAA defines contingency measures as measures in a

SIP that are to be implemented if an area fails to achieve and maintain RFP, or fails to attain the NAAQS by the applicable attainment date. Contingency measures must be designed to become effective without further action by the state or the Administrator, upon determination by EPA that the area has failed to achieve, or maintain reasonable further progress (RFP), or attain the Pb NAAQS by the applicable statutory attainment date. Contingency measures should consist of available control measures that are not already included in the primary control strategy for the affected area.

Contingency measures are important for lead nonattainment areas, which may violate the NAAQS generally due to emissions from stationary sources, for several reasons. First, process and fugitive emissions from these stationary sources, and the possible re-entrainment of historically deposited emissions, have historically been difficult to quantify. Therefore, the analytical tools for determining the relationship between reductions in emissions, and resulting air quality improvements, can be subject to some uncertainties. Second, emission estimates and attainment analysis can be influenced by overly optimistic assumptions about fugitive emission control efficiency.

Examples of contingency measures for controlling area source fugitive emissions may include measures such as stabilizing additional storage piles. Examples of contingency measures for process-related fugitive emissions include increasing the enclosure of buildings, increasing air flow in hoods, modifying operation and maintenance procedures, etc. Examples of contingency measures for stack sources include reducing hours of operation, changing the feed material to lower lead content, and reducing the occurrence of malfunctions by modifying operation and maintenance procedures, etc.

Section 172(c)(9) provides that contingency measures should be included in the state SIP for a lead nonattainment area and shall "take effect without further action by the state or the Administrator." The EPA interprets this requirement to mean that no further rulemaking actions by the state, or EPA, would be needed to implement the contingency measures (*see generally* 57 FR 12512 and 13543–13544). The EPA recognizes that certain actions, such as the notification of sources, modification of permits, etc., may be needed before a measure could be implemented. However, states must show that their contingency measures can be implemented with only minimal further action on their part and with no

additional rulemaking actions such as public hearings or legislative review. After EPA determines that a lead nonattainment area has failed to maintain RFP or timely attain the Pb NAAQS, EPA generally expects all actions needed to affect full implementation of the measures to occur within 60 days after EPA notifies the state of such failure. The state should ensure that the measures are fully implemented as expeditiously as practicable after the requirement takes effect.

b. Comments and Responses

Several commenters stated that EPA noted in the proposed rulemaking that "contingency measures are important for lead nonattainment areas" and that the CAA requires that contingency measures must "take effect without further action" by the state or the Administrator." However, the commenters stated that EPA then interprets the "take effect without further action" requirement too broadly, indicating that it is satisfied if the contingency measure can take effect without further rulemaking. The EPA would allow contingency measures that require a state to undertake a permit modification before the contingency measures would go into effect.

As stated in the proposed rule, section 172(c)(9) of the CAA defines contingency measures as measures in a SIP that are to be implemented if an area fails to achieve and maintain RFP, or fails to attain the NAAQS by the applicable attainment date. Contingency measures must be designed to become effective without further action by the state or the Administrator, upon determination by EPA that the area has failed to achieve, or maintain reasonable further progress, or attain the Pb NAAQS by the applicable statutory attainment date. As stated in the proposed rule, the EPA believes that this requirement means that no further rulemaking actions by the state, or EPA, would be needed to implement the contingency measures (*see generally* 57 FR 12512 and 13543–13544). The EPA recognizes that in some circumstances minimal actions, such as the notification of sources, modification of permits, etc., may be needed before a measure could be implemented. However, as also stated in the proposed rule, states must show that their contingency measures can be implemented with only minimal further action on their part and that no additional rulemaking actions will be required, such as public hearings or legislative review, which will delay the expeditious implementation of the

contingency measures in the affected area. To the extent that modifications in title V operating permits would be required to implement contingency measures, the SIP should provide that those permits will be issued or modified prior to the time such contingency measures may be needed to include alternative operating scenarios providing for implementation of the contingency measures if necessary. See 40 CFR 70.6(a)(9). The EPA generally expects that all actions, including those actions related to modification of permits, that are needed to affect full implementation of the contingency measures, must occur within 60 days following EPA's notification to the state of such failure.

c. Final

The EPA is finalizing the guidance related to contingency measures for lead nonattainment areas as stated in the proposed rule. The key requirements associated with contingency measures are: (1) Contingency measures must be fully adopted rules or control measures that are ready to be implemented as expeditiously as practicable upon a determination by EPA that the area has failed to achieve, or maintain reasonable further progress, or attain the Pb NAAQS by the applicable statutory attainment date; (2) The SIP should contain trigger mechanisms for the contingency measures and specify a schedule for implementation; and (3) The SIP must indicate that the measures will be implemented without further action (or only minimal action) by the state or by the Administrator. The contingency measures should also consist of control measures for the area that are not already included in the control strategy for the attainment demonstration of the SIP. The EPA believes that the measures should provide for emission reductions that are at least equivalent to one year's worth of reductions needed for the area to meet the requirements of RFP, based on linear progress towards achieving the overall level of reductions needed to demonstrate attainment.

5. Nonattainment New Source Review (NSR) and Prevention of Significant Deterioration (PSD) Requirements

a. Proposal

The PSD and nonattainment NSR programs contained in parts C and D of Title I of the CAA govern preconstruction review and permitting programs for any new or modified major stationary sources of air pollutants regulated under the CAA as well as any precursors to the formation of that

pollutant when identified for regulation by the Administrator. The EPA rules addressing these regulations can be found at 40 CFR 51.165, 51.166, 52.21, 52.24, and part 51, appendix S.

States containing areas designated as nonattainment for the Pb NAAQS must submit SIPs that address the requirements of nonattainment NSR. Specifically, section 172(c)(5) of the CAA requires that states which have areas designated as nonattainment for the Pb NAAQS must submit, as a part of the nonattainment area SIP, provisions requiring permits for the construction and operation of new or modified stationary sources anywhere in the nonattainment area, in accordance with the permit requirements pursuant to section 173 of the CAA. Likewise, areas designated attainment must submit infrastructure SIPs that address the requirements of PSD pursuant to section 110(a)(2)(C).

Stationary sources that emit lead are currently subject to regulation under existing requirements for the preconstruction review and approval of new and modified stationary sources. The existing requirements, referred to collectively as the New Source Review (NSR) program, require all major and certain minor stationary sources of any air pollutant for which there is a NAAQS to undergo review and approval prior to the commencement of construction.¹¹⁷ The NSR program is composed of three different permit programs:

- Prevention of Significant Deterioration (PSD).
- Nonattainment NSR (NA NSR).
- Minor NSR.

The PSD program and nonattainment NSR programs, contained in parts C and D, respectively, of Title I of the CAA, are often referred to as the major NSR program because these programs regulate only major sources.

The PSD program applies when a major source, that is located in an area that is designated as attainment or unclassifiable for any criteria pollutant, is constructed, or undergoes a major modification.¹¹⁸ The nonattainment NSR program applies when a major source of a criteria pollutant that is located in an area that is designated as

¹¹⁷ The terms "major" and "minor" define the size of a stationary source, for applicability purposes, in terms of an annual emissions rate (tons per year, tpy) for a pollutant. Generally, a minor source is any source that is not "major." "Major" is defined by the applicable regulations—PSD or nonattainment NSR.

¹¹⁸ In addition, the PSD program applies to non-criteria pollutants subject to regulation under the Act, except those pollutants regulated under section 112 and pollutants subject to regulation only under section 211(o).

nonattainment for that pollutant is constructed or undergoes a major modification. The minor NSR program addresses both major and minor sources that undergoes construction or modification activities that do not qualify as major, and it applies regardless of the designation of the area in which a source is located.

The national regulations that apply to each of these programs are located in the CFR as shown below:

	Applications
PSD	40 CFR 52.21, 40 CFR 51.166, 40 CFR 51.165(b).
NA NSR	40 CFR 52.24, 40 CFR 51.165, 40 CFR part 51, Appendix S.
Minor NSR	40 CFR 51.160–164.

The PSD requirements include but are not limited to the following:

- Installation of Best Available Control Technology (BACT);
- Air quality monitoring and modeling analyses to ensure that a project's emissions will not cause or contribute to a violation of any NAAQS or maximum allowable pollutant increase (PSD increment);
- Notification of Federal Land Manager of nearby Class I areas; and
- Public comment on permit.

Nonattainment NSR requirements include but are not limited to:

- Installation of Lowest Achievable Emissions Rate (LAER) control technology;
- Offsetting new emissions with creditable emissions reductions;
- A certification that all major sources owned and operated in the state by the same owner are in compliance with all applicable requirements under the CAA;
- An alternative siting analysis demonstrating that the benefits of the proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification; and
- Public comment on the permit.

Minor NSR programs must meet the statutory requirements in section 110(a)(2)(C) of the CAA which requires " * * * regulation of the modification and construction of any stationary source * * * as necessary to assure that the [NAAQS] are achieved."

Areas which are newly designated as nonattainment for the Pb NAAQS as a result of any changes made to the NAAQS will be required to adopt a nonattainment NSR program to address major sources of lead where the program does not currently exist for the Pb NAAQS. Prior to adoption of the SIP

revision addressing NSR for lead nonattainment areas, the requirements of 40 CFR part 51, appendix S will apply.

b. Comments and Responses

Several commenters stated that given the significant changes being proposed for the revised Pb NAAQS, EPA must promptly undertake rulemaking action in order to satisfy the PSD requirements related to the revised Pb NAAQS. The commenters further stated that EPA should revise the current regulations related to the establishment of maximum allowable increases or increments for lead under 40 CFR 51.166(a), and a substantial reduction in the significant/de minimis emissions levels for lead set forth in 40 CFR 51.166(b)(23)(i) and 40 CFR 52.21(b)(23)(i).

As stated previously, the EPA believes that generally, there is sufficient guidance and regulations already in place to fully implement the revised Pb NAAQS. The EPA notes that, under section 110(a)(2)(D), every minor source NSR program must be sufficiently complete and stringent "to assure that the [NAAQS] are achieved." The EPA will as appropriate review and revise and update policies, guidance, and regulations for implementing the revised Pb NAAQS following the promulgation of the NAAQS.

c. Final

The EPA is finalizing the guidance related to nonattainment NSR and PSD requirements for lead nonattainment areas as provided in the proposed rule.

6. Emissions Inventories

a. Proposal

States must develop and periodically update a comprehensive, accurate, current inventory of actual emissions affecting ambient lead concentrations. The emissions inventory is used by states and EPA to determine the nature and extent of the specific control strategy necessary to help bring an area into attainment of the NAAQS. Emissions inventories should be based on measured emissions or documented emissions factors. Generally, the more comprehensive and accurate the inventory, the more effective the evaluation of possible control measures can be for the affected area (see section 172(c)(3) of the CAA).

Pursuant to its authority under section 110 of Title I of the CAA, EPA has long required states to submit emission inventories containing information regarding the emissions of criteria pollutants as well as their precursors. The EPA codified these

requirements in 40 CFR part 51, subpart Q in 1979 and amended them in 1987. The 1990 Clean Air Act Amendments (CAAA) revised many of the provisions of the CAA related to attainment of the NAAQS. These revisions established new emission inventory requirements applicable to certain areas that were designated as nonattainment for certain pollutants.

In June 2002, EPA promulgated the Consolidated Emissions Reporting Rule (CERR) (67 FR 39602, June 10, 2002). The CERR consolidates the various emissions reporting requirements that already exist into one place in the Code of Federal Regulations (CFR), and establishes new requirements for the statewide reporting of area (non-point) source and mobile source emissions. The CERR establishes two types of required emissions inventories: (1) Annual inventories, and (2) 3-year cycle inventories. The annual inventory requirement is limited to reporting statewide emissions data from the larger point sources. For the 3-year cycle inventory, states will need to report data from all of their point sources plus all of the area (non-point) and mobile sources on a statewide basis.

By merging emissions information from relevant point sources, area sources, and mobile sources into a comprehensive emission inventory, the CERR allows State, local and tribal agencies to do the following:

- Set a baseline for SIP development.
- Measure their progress in reducing emissions.
- Answer the public's request for information.

The EPA uses the data submitted by the states to develop the National Emission Inventory (NEI). The NEI is used by EPA to show national emission trends, as modeling input for analysis of potential regulations, and other purposes.

Most importantly, states need these inventories to help in the development of control strategies and demonstrations to attain the Pb NAAQS. While the CERR sets forth requirements for data elements, EPA guidance complements these requirements and indicates how the data should be prepared for SIP submissions. Our current regulations at 40 CFR 51.117(e) require states to include in the SIP inventory all point sources that emit 5 or more tons of lead emissions per year. As stated previously, in the proposed rulemaking EPA took comment on whether the recommended threshold for RACT analysis should be less than the current 5 tons/yr (see section VI.F.1), and proposed that if EPA lowered the recommended threshold for RACT in

the final rulemaking, we would also revise, to be consistent, the emissions threshold for including sources in the inventory pursuant to 40 CFR 51.117(e). In the proposed rule, we solicited comment on the appropriate threshold for Pb point source inventory reporting requirements.

The SIP inventory must be approved by EPA as a SIP element and is subject to public hearing requirements, whereas the CERR inventory is not. Because of the regulatory significance of the SIP inventory, EPA will need more documentation on how the SIP inventory was developed by the state as opposed to the documentation required for the CERR inventory. In addition, the geographic area encompassed by some aspects of the SIP submission inventory will be different from the statewide area covered by the CERR emissions inventory.

The EPA has proposed the Air Emissions Reporting Rule (AERR) at 71 FR 69 (Jan. 3, 2006). When finalized, the AERR will update, consolidate, and harmonize new emissions reporting requirements with preexisting sets of reporting requirements under the CERR and the NO_x SIP Call. The AERR is expected to be a means by which the Agency will implement additional data reporting requirements for the Pb NAAQS SIP emission inventories.

b. Comments and Responses

One commenter stated that states currently work with regional offices in developing nonattainment area inventories and that this approach should be encouraged. The commenter further indicated that states should be allowed to start with the National Emissions Inventory (NEI) and customize their nonattainment area inventories to analyze nonattainment problems.

The EPA encourages the states to continue to work closely with the EPA Regional Offices in developing their nonattainment area emissions inventories as well as any enhancements that need to be made to the NEI. The EPA encourages the use of the NEI as a tool to assist states in developing their nonattainment area SIP emissions inventory. States, however, are reminded that the nonattainment area SIP emissions inventory is required pursuant to 40 CFR 51.117(e) and must be approved by EPA pursuant to the CAA, and is subject to the public hearing requirements pursuant to section 110(a)(2).

One commenter stated that EPA should develop additional guidance on emission inventories related to the nonattainment area SIP submittal

because the requirements under the CERR and the AERR may not be enough to adequately address the emissions inventory requirements related to the attainment demonstration for the SIP.

The EPA will review the need for additional guidance concerning the emissions inventories related to the nonattainment area SIP submittal on an ongoing basis. As stated previously, EPA believes that the current guidance, policies, and regulations provide a sufficient basis for states to implement the revised Pb NAAQS at this time. The EPA, as appropriate, will review and revise or update these policies, guidance, and regulations to provide for effective implementation of the Pb NAAQS.

Several commenters stated that EPA should revise 40 CFR 51.117(e)(1), relating to the emissions reporting threshold level for lead nonattainment area SIPs. The current threshold level as stated in 51.117(e)(1), requires that the point source inventory on which the summary of the baseline lead emissions inventory is based must contain all sources that emit 5 or more tpy of lead.

The EPA agrees with the commenters that the requirement for the emissions inventory reporting threshold for lead nonattainment SIPs, as stated in 40 CFR 51.117(e)(1), should be revised to reflect the stringency of the revised Pb NAAQS. In the proposed rule, EPA proposed to revise the current threshold level for emissions inventory reporting from 5 tpy to be consistent with the threshold for the analysis of RACM/ RACT control measures. As discussed above, EPA is setting the threshold for RACT analysis at 0.5 tpy. EPA concludes it is also appropriate to set the threshold level of the emissions inventory reporting requirement at 0.5 tpy.

c. Final

The EPA is finalizing the guidance contained related to the emissions inventories requirements for the Pb NAAQS as provided in the proposed rule. The EPA is updating the emissions reporting requirements for lead nonattainment area SIPs stated in 40 CFR 51.117(e)(1) by revising the source emission inventory reporting threshold from 5 tpy to 0.5 tpy.

7. Modeling

a. Proposal

The lead SIP regulations found at 40 CFR 51.117 require states to employ atmospheric dispersion modeling for the demonstration of attainment for areas in the vicinity of point sources listed in 40 CFR 51.117(a)(1). To complete the

necessary dispersion modeling, meteorological, and other data are necessary. Dispersion modeling should follow the procedures outlined in EPA's latest guidance document entitled "Guideline on Air Quality Models". This guideline indicates the types and historical records for data necessary for modeling demonstrations (e.g., on-site meteorological stations, 12 months of meteorological data are required in order to demonstrate attainment for the affected area).

b. Comments and Responses

One commenter stated that the SIPs for lead nonattainment areas should provide for the implementation of control measures for point and area sources of lead emissions which demonstrate attainment of the lead NAAQS as expeditiously as practicable, but no later than the applicable statutory attainment date for the area. The commenter further stated that they believe that the requirements currently stated under 40 CFR 51.117(a)(1), related to additional control strategy requirements, should be revised to reflect the stringency of the revised lead NAAQS. The commenter stated that specifically, the threshold level of 25 tpy as stated in 40 CFR 51.117(a)(1), related to modeling for point source emissions, should be revised to reflect the stringency of the revised NAAQS.

The EPA agrees with the commenter that lead nonattainment area SIPs must provide for the implementation of control measures for point and area source emissions of lead in order to demonstrate attainment of the Pb NAAQS as expeditiously as practicable, but no later than the attainment date for the affected area. EPA notes that 40 CFR 51.117(a) provides that states must include, as a part of their attainment modeling demonstration, an analysis showing that the SIP will attain and maintain the standard in areas in the vicinity of certain point sources that are emitting at the level of 25 tpy, and also in "any other area that has lead air concentrations in excess of the national ambient air quality standard concentration." EPA does not believe it is necessary to amend the 25 tpy threshold in 40 CFR 51.117(a)(1) because the provisions of 40 CFR 51.117(a)(2) are sufficient to ensure an adequate attainment demonstration. Accordingly, EPA believes that the current requirements concerning control strategy demonstration as stated in 40 CFR 51.117(a) are adequate for states to develop SIPs which address attainment of the revised Pb NAAQS. In doing the analysis, required under 40 CFR 51.117(a)(2), EPA expects the state will

take into consideration all sources of lead emissions within the nonattainment area that may be required to be controlled, taking into consideration the attainment needs of the area.

c. Final

The EPA is finalizing the guidance related to modeling attainment demonstrations for lead nonattainment area SIPs as proposed. The EPA will continue to review whether any additional changes related to modeling demonstrations or applicable modeling guidance are appropriate.

G. General Conformity

1. Proposal

Section 176(c) of the CAA, as amended (42 U.S.C. 7401 *et seq.*), requires that all Federal actions conform to an applicable implementation plan developed pursuant to section 110 and part D of the CAA. Section 176(c) of the CAA requires EPA to promulgate criteria and procedures for demonstrating and assuring conformity of Federal actions to a SIP. For the purpose of summarizing the general conformity rule, it can be viewed as containing three major parts: Applicability, procedure, and analysis. These are briefly described below.

The general conformity rule covers direct and indirect emissions of criteria pollutants, or their precursors, that are caused by a Federal action, are reasonably foreseeable, and can practicably be controlled by the Federal agency through its continuing program responsibility. The general conformity rule generally applies to Federal actions except: (1) Actions covered by the transportation conformity rule; (2) Actions with respect to associated emissions below specified de minimis levels; and (3) Certain other actions that are exempt or presumed to conform.

The general conformity rule also establishes procedural requirements. Federal agencies must make their conformity determinations available for public review. Notice of draft and final general conformity determinations must be provided directly to air quality regulatory agencies and to the public by publication in a local newspaper.

The general conformity determination examines the impacts of direct and indirect emissions related to Federal actions. The general conformity rule provides several options to satisfy air quality criteria, such as modeling or offsets, and requires the Federal action to also meet any applicable SIP requirements and emissions milestones. Each Federal agency must determine

that any actions covered by the general conformity rule conform to the applicable SIP before the action is taken. The criteria and procedures for conformity apply only in nonattainment and maintenance areas with respect to the criteria pollutants under the CAA: ¹¹⁹ Carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO₂), ozone (O₃), particulate matter (PM_{2.5} and PM₁₀), and sulfur dioxide (SO₂). The general conformity rule establishes procedural requirements for Federal agencies for actions related to all NAAQS pollutants, both nonattainment and maintenance areas and will apply one year following the promulgation of designations for any new or revised Pb NAAQS.¹²⁰

2. Final

The EPA is finalizing the guidance related to general conformity as provided in the proposed rule.

H. Transition From the Current NAAQS to a Revised NAAQS for Lead

1. Proposal

As discussed in the proposal, EPA believes that Congress's intent, as evidenced by section 110(l), 193, and section 172(e) of the CAA, was to ensure that continuous progress, in terms of public health protection, takes place in transitioning from a current NAAQS for a pollutant to a new or revised NAAQS. Therefore, EPA proposed that the existing NAAQS be revoked one year following the promulgation of designations for any new NAAQS, except that the existing NAAQS will not be revoked for any current nonattainment area until the affected area submits, and EPA approves, an attainment demonstration which addresses the attainment of the new Pb NAAQS.

The CAA contains a number of provisions that indicate Congress's intent to not allow states to alter or remove provisions from implementation plans if the plan revision would jeopardize the air quality protection being provided by the plan. For example, section 110(l) provides that EPA may not approve a SIP revision if

it interferes with any applicable requirement concerning attainment and RFP, or any other applicable requirement under the CAA. In addition section 193 of the CAA prohibits the modification of a control, or a control requirement, in effect or required to be adopted as of November 15, 1990 (i.e., prior to the promulgation of the Clean Air Act Amendments (CAAA) of 1990), unless such a modification would ensure equivalent or greater emissions reductions. One other provision of the CAA provides additional insight into Congress's intent related to the need to continue progress towards meeting air quality standards during periods of transition from one standard to another. Section 172(e) of the CAA, related to future modifications of a standard, applies when EPA promulgates a new or revised NAAQS and makes it less stringent than the previous NAAQS. This provision of the CAA specifies that in such circumstances, states may not relax control obligations that apply in nonattainment area SIPs, or avoid adopting those controls that have not yet been adopted as required.

The EPA believes that Congress generally did not intend to permit states to relax levels of pollution control when EPA revises a standard until the new or revised standard is implemented. Therefore, we believe that controls that are required under the current Pb NAAQS, or that are currently in place under the current Pb NAAQS, should generally remain in place until new designations are established and, for current nonattainment areas, new attainment SIPs are approved for any new or revised standard. As a result, EPA proposed that the current Pb NAAQS should stay in place for one year following the effective date of designations for any new or revised NAAQS before being revoked, except in current nonattainment areas, where the existing NAAQS will not be revoked until the affected area submits, and EPA approves, an attainment demonstration for the revised Pb NAAQS. Accordingly, the CAA mechanisms, including sanctions, that help ensure continued progress toward timely attainment would remain in effect for the existing Pb NAAQS, and would apply to existing Pb nonattainment areas.

Pursuant to CAA section 110(l), any proposed SIP revision being considered by EPA after the effective date of the revised Pb NAAQS would be evaluated for its potential to interfere with attainment or maintenance of the new standard. The EPA believes that any area attaining the revised Pb NAAQS would also attain the existing Pb NAAQS, and thus reviewing proposed

SIP revisions for interference with the new standard will be sufficient to prevent backsliding. Consequently, in light of the nature of the proposed revision of the Pb NAAQS, the lack of classifications (and mandatory controls associated with such classifications pursuant to the CAA), and the small number of nonattainment areas, EPA believes that retaining the current standard for a limited period of time until SIPs are approved for the new standard in current nonattainment areas, or one year after designations in other areas, will adequately serve the anti-backsliding goals of the CAA.¹²¹

2. Final

The EPA is finalizing the guidance related to transition from the current NAAQS to the new Pb NAAQS generally consistent with the proposal that the existing standard be retained until one year following the effective date of designations, except that for current nonattainment areas the standard would remain in effect until approval of a SIP for the new standard. EPA notes that the most recent three years of available monitoring data from the East Helena nonattainment area showed no violations of the current standard, although the monitors were shut down in December, 2001 following the shutdown of the large stationary source of lead emissions there. Accordingly, it is unclear whether East Helena will be designated nonattainment for the new standard, or whether it could possibly receive another designation. In the event East Helena is designated unclassifiable or attainment for the new standard, EPA believes it is still appropriate to retain the existing standard until the state submits, and EPA approves, a maintenance SIP for the new standard. Accordingly EPA has amended the proposed text of 40 CFR 50.12 to reflect the possibility that in this specific set of circumstances, the old standard could be revoked upon EPA's approval of a maintenance SIP for the new standard.

VII. Exceptional Events Information Submission Schedule for Lead NAAQS

EPA proposed changes to the original dates for submitting and documenting exceptional event data claims and the Agency is adopting the proposed changes with some minor revisions and they are described below.

Section A presents the information stated in the proposal. Section B

¹²¹ The areas that are currently nonattainment for the pre-existing Pb NAAQS are East Helena, Montana and Jefferson County (part)/Herculaneum, Missouri. (See <http://www.epa.gov/oar/oaqps/greenbk/Inc.html>)

¹¹⁹ Criteria pollutants are those pollutants for which EPA has established a NAAQS under section 109 of the CAA.

¹²⁰ Transportation conformity is required under CAA section 176(c) (42 U.S.C. 7506(c)) to ensure that federally supported highway and transit project activities are consistent with ("conform to") the purpose of the SIP. Transportation conformity applies to areas that are designated nonattainment, and those areas redesignated to attainment after 1990 ("maintenance areas" with plans developed under CAA section 175A) for transportation-related criteria pollutants. In light of the elimination of Pb additives from gasoline, transportation conformity does not apply to the Pb NAAQS.

summarizes and responds to all comments received regarding exceptional events data submission. Section C provides the final preamble text considering comments received and incorporating final revisions to the proposal.

A. Proposal

The EPA proposed Pb-specific changes to the deadlines, in 40 CFR 50.14, by which States must flag ambient air data that they believe has been affected by exceptional events and submit initial descriptions of those events, and the deadlines by which States must submit detailed justifications to support the exclusion of that data from EPA determinations of attainment or nonattainment with the NAAQS. The deadlines in 40 CFR 50.14 are generic, and are not always appropriate for Pb given the anticipated schedule for the designations of areas under the proposed Pb NAAQS.

For the specific case of Pb, EPA anticipates that designations under the revised NAAQS may be made in September 2011 based on 2008–2010 data, (or possibly in September 2010 based on 2007–2009 data if sufficient data are available), and thus will depend in part on air quality data collected as late as December 2010 (or December 2009). (Section IV.C of the proposed preamble had a more detailed discussion of the designation schedule and what data EPA intends to use.) There is no way for a State to flag and submit documentation regarding events that happen in October, November, and December 2010 (or 2009) by one year before designation decisions that are made in September 2011 (or 2010).

The proposed revisions to 40 CFR 50.14 involved only changes in submission dates for information regarding claimed exceptional events affecting Pb data. The proposed rule text showed only the changes that would apply if designations are made three years after promulgation; where a deadline would be different if designations were made at the two-year point, the difference in deadline was noted in the proposed preamble. We proposed to extend the generic deadline for flagging data (and providing a brief initial description of the event) of July 1 of the year following the data collection, to July 1, 2009 for data collected in 2006–2007. The proposed extension included 2006 and 2007 data because Governors’ designation recommendations will consider 2006–2008 data, and possibly EPA will consider 2006–2008 or 2007–2009 data if complete data for 2008–2010 are not available at the time of final designations. EPA noted that it does not intend to use data prior to 2006 in making Pb designation decisions. The generic event flagging deadline in the Exceptional Events Rule would continue to apply to 2008 and later years following the promulgation of the revised Pb NAAQS. The Governor of a State would be required to submit designation recommendations to EPA a year after promulgation of the revised NAAQS (i.e., in Fall 2009). States would therefore have enough time to flag data and submit their demonstrations and know what 2008 data need to be excluded due to exceptional events when formulating their recommendations to EPA.

For data collected in 2010 (or 2009), we proposed to move up the generic

deadline of July 1 for data flagging to May 1, 2011 (or May 1, 2010) (which is also the applicable deadline for certifying data in AQS as being complete and accurate to the best knowledge of the responsible monitoring agency head). This would give a State less time, but EPA believes still sufficient time, to decide what 2010 (or 2009) data to flag, and would allow EPA to have access to the flags in time for EPA to develop its own proposed and final plans for designations.

Finally, EPA proposed to make the deadline for submission of detailed justifications for exclusion of data collected in 2006 through 2008 be September 15, 2010 for the three year designation schedule, or September 15, 2009 under the two year designation schedule. EPA generally does not anticipate data from 2006 and 2007 being used in final Pb designations. Under the three year designation schedule, for data collected in 2010, EPA proposed to make the deadline for submission of justifications be May 1, 2011. This is less than a year before the designation decisions would be made, but we believe it is a good compromise between giving a State a reasonable period to prepare the justifications and EPA a reasonable period to consider the information submitted by the State. Similarly, under the two year designation schedule, for data collected in 2009, EPA proposed to make the deadline for submission of justifications be May 1, 2010. Table 5 summarizes the three year designation deadlines in the proposal and discussed in this section, and Table 6 summarizes the two year designation deadlines.

TABLE 5—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED IN THREE YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009 *	September 15, 2010. *
2007	July 1, 2009 *	September 15, 2010.
2008	July 1, 2009	September 15, 2010. *
2009	July 1, 2010	September 15, 2010. *
2010	May 1, 2011 *	May 1, 2011. *

* Indicates proposed change from generic schedule in 40 CFR 50.14.

TABLE 6—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED IN TWO YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009 *	September 15, 2009.
2007	July 1, 2009 *	September 15, 2009. *
2008	July 1, 2009	September 15, 2009. *

TABLE 6—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED IN TWO YEARS—Continued

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2009	May 1, 2010*	May 1, 2010.*

* Indicates proposed change from generic schedule in 40 CFR 50.14.

EPA invited comment on these proposed changes in the exceptional event flagging and documentation submission deadlines.

B. Comments and Responses

EPA received only one comment on the proposed revision to the schedule for flagging and documenting exceptional event data which could affect Pb designation decisions. The comment from the North Carolina Department of Environment and Natural Resources' (NCDENR) Division of Air Quality (DAQ) stated that: "NCDAQ

believes states need proper time to provide exceptional events documentation before designations are made."

EPA believes that the final schedule provides states with adequate time for flagging exceptional values and providing documentation to support exceptional event claims. Also, NCDAQ did not specifically state either that the proposed deadlines were inadequate or ask for more time; nor did it provide any alternative schedules for the Agency's consideration.

C. Final

EPA's final schedule for flagging and documenting exceptional event data claims is shown in the tables that follow. Table 7 summarizes the final deadlines for areas where final designations occur no later than October 15, 2011 (i.e., no later than three years after promulgation of a new NAAQS). Table 8 summarizes the final dealines for areas where final designations occur no later than October 15, 2010 (i.e., no later than two years after promulgation of a new NAAQS).

TABLE 7—FINAL SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED WITHIN THREE YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009*	October 15 2010.*
2007	July 1, 2009*	October 15, 2010.
2008	July 1, 2009	October 15, 2010.*
2009	July 1, 2010	October 15, 2010.*
2010	May 1, 2011*	May 1, 2011.*

* Indicates change from generic schedule in 40 CFR 50.14.

TABLE 8—FINAL SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED WITHIN TWO YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009*	October 15, 2009.
2007	July 1, 2009*	October 15, 2009.*
2008	July 1, 2009	October 15, 2009.*
2009	May 1, 2010*	May 1, 2010.*

* Indicates change from generic schedule in 40 CFR 50.14.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under section 3(f)(1) of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is an "economically significant regulatory action" because it is likely to have an annual effect on the economy of \$100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and

any changes made in response to OMB recommendations have been documented in the docket for this action (EPA-HQ-OAR-2006-0735). In addition, EPA prepared a Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. A copy of the analysis is available in the RIA docket (EPA-HQ-OAR-2008-0253) and the analysis is briefly summarized here. The RIA estimates the costs and monetized human health and welfare benefits of attaining four alternative Pb NAAQS

nationwide. Specifically, the RIA examines the alternatives of 0.50 µg/m³, 0.40 µg/m³, 0.30 µg/m³, 0.20 µg/m³, 0.15 µg/m³ and 0.10 µg/m³. The RIA contains illustrative analyses that consider a limited number of emissions control scenarios that States and Regional Planning Organizations might implement to achieve these alternative Pb NAAQS. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising

NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing this final rule.

B. Paperwork Reduction Act

The information collection requirements in this final rule will be submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them.

The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). While this final rule amends the requirements for Pb FRM and FEM determinations, they merely provide additional flexibility in meeting the FRM/FEM determination requirements. Furthermore, we do not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with Pb FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 0559.12). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health and ecosystem impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The proposed amendments would revise the technical requirements for Pb monitoring sites, require the siting and operation of additional Pb ambient air monitors, and the reporting of the collected ambient Pb monitoring data to EPA's Air Quality System (AQS). We have estimated the burden based on the final monitoring requirements of this rule. Based on these requirements, the annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) for 150 respondents is estimated to increase by a total of 22,376 labor hours per year

with an increase of \$1,910,059 per year. Burden is defined at 5 CFR 1320.3(b).

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. When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in this final 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 purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of Pb in ambient air as required by section 109 of the CAA. *American Trucking Ass'n v. EPA*, 175 F. 3d 1027, 1044-45 (D.C. cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the amendments to 40 CFR part 58 address the requirements for States to collect information and report compliance with the NAAQS and will not impose any requirements on small entities.

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. Unless otherwise prohibited by law, 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 one year. Before promulgating an EPA rule for which a written statement is required under section 202, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and to 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.

This action is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this final 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 the private sector in any one year. The revisions to the Pb NAAQS impose no enforceable duty on any State, local or tribal governments or the private sector. The expected costs associated with the increased monitoring requirements are described in EPA's ICR document, but those costs are not expected to exceed \$100 million in the aggregate for any year. Furthermore, as

indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards. Because the Clean Air Act prohibits EPA from considering the types of estimates and assessments described in section 202 when setting the NAAQS, the UMRA does not require EPA to prepare a written statement under section 202 for the revisions to the Pb NAAQS.

With regard to implementation guidance, the CAA imposes the obligation for States to submit SIPs to implement the Pb NAAQS. In this final rule, EPA is merely providing an interpretation of those requirements. However, even if this rule did establish an independent obligation for States to submit SIPs, it is questionable whether an obligation to submit a SIP revision would constitute a Federal mandate in any case. The obligation for a State to submit a SIP that arises out of section 110 and section 191 of the CAA is not legally enforceable by a court of law, and at most is a condition for continued receipt of highway funds. Therefore, it is possible to view an action requiring such a submittal as not creating any enforceable duty within the meaning of 2 U.S.C. 658 for purposes of the UMRA. Even if it did, the duty could be viewed as falling within the exception for a condition of Federal assistance under 2 U.S.C. 658.

EPA has determined that this final rule contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments. Therefore, this rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

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

This final 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. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, under CAA section 107, the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS or monitoring requirements for NAAQS. Thus, Executive Order 13175 does not apply to this action.

Although Executive Order 13175 does not apply to this action, EPA contacted tribal environmental professionals during the development of this rule. EPA staff participated in the regularly scheduled Tribal Air Call sponsored by the National Tribal Air Association during the spring of 2008 as the proposal was under development, and also offered several informational briefings on the proposal to Tribal environmental professionals in Summer 2008 during the public comment period on the proposed rule. EPA sent individual letters to all federally recognized Tribes within the lower 48 states and Alaska to give Tribal leaders the opportunity for consultation, and EPA staff also participated in Tribal public meetings, such as the National Tribal Forum meeting in June 2008, where Tribes discussed their concerns regarding the proposed rule. EPA received comments from a number of Tribes on the proposed rule; these comments are addressed in the relevant sections of the preamble and Response to Comments for this rulemaking.

G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks

This action is subject to EO 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by EO 12866, and we believe that the environmental health risk addressed by this action has a disproportionate effect on children. The final rule establishes uniform national ambient air quality standards for Pb; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. However, the protection offered by these standards may be especially important for children because neurological effects in children are among if not the most sensitive health endpoints for Pb exposure. Because children are considered a sensitive population, we have carefully evaluated the environmental health effects of exposure to Pb pollution among children. These effects and the size of the population affected are summarized in chapters 6 and 8 of the Criteria Document and sections 3.3 and 3.4 of the Staff Paper, and the results of our evaluation of the effects of Pb pollution on children are discussed in sections II.B and II.C of the notice of proposed rulemaking, and section II.A of this preamble.

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

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (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 purpose of this rule is to establish revised NAAQS for Pb. The rule does not prescribe specific control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus

standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rule involves technical standards. EPA has established low-volume PM₁₀ samplers coupled with XRF analysis as the FRM for Pb-PM₁₀ measurement. While EPA identified the ISO standard "Determination of the particulate lead content of aerosols collected on filters" (ISO 9855: 1993) as being potentially applicable, the final rule does not permit its use. EPA determined that the use of this voluntary consensus standard would be impractical because the analysis method does not provide for the method detection limits necessary to adequately characterize ambient Pb concentrations for the purpose of determining compliance with the revisions to the Pb NAAQS.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The final rule establishes uniform national standards for Pb in ambient air. In the Administrator's judgment, the revised Pb NAAQS protect public health, including the health of sensitive groups,

with an adequate margin of safety. As discussed earlier in this preamble (see section II) and in the Response to Comments, the Administrator expressly considered the available information regarding health effects among vulnerable and susceptible populations in making the determination about which standards are requisite.

Some commenters expressed concerns that EPA had failed to adequately assess the environmental justice implications of its proposed decision. These commenters asserted specifically that low-income and minority populations constitute susceptible subpopulations and that the proposed revisions to the primary Pb standards would be insufficient to protect these subpopulations with an adequate margin of safety. In addition, some commenters stated that EPA had failed to adequately evaluate or address the disproportionate adverse impact of Pb exposure on poor and minority populations as required by EO 12898. These commenters assert that in spite of significant scientific evidence indicating that the burden of lead exposure is higher in poor communities and communities of color, EPA has not taken the differing impacts of lead exposure into account in revising the Pb NAAQS.

At the time of proposal, EPA prepared a technical memo to assess the socio-demographic characteristics of populations living near ambient air Pb monitors and stationary sources of Pb emissions (Pekar *et al.*, 2008). Due to limitations in the available data, most significantly limitations on information regarding whether current ambient air concentrations of Pb (as measured by fixed-site monitors or proximity to stationary sources of Pb) are associated with elevated exposure or increased risk for any socio-demographic group, EPA was not able to draw conclusions regarding the impact of Pb air pollution on minority and low-income populations in this analysis [or "memo"]. However, EPA believes that the newly strengthened Pb standards and the new requirements for ambient air monitoring for Pb will have the greatest benefit in reducing health risks associated with exposure to ambient air Pb in those areas where ambient air concentrations are currently the highest. Thus, to the extent that any population groups, including minorities or low-income populations, are currently experiencing disproportionate exposure to ambient air-related Pb, those groups can be expected to experience relatively greater air quality improvements under the revised standards. Nationwide, these revised, more stringent standards will

not have adverse health impacts on any population, including any minority or low-income population.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective January 12, 2009.

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

40 CFR Part 53

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 15, 2008.

Stephen L. Johnson,
Administrator.

■ For the reasons stated in the preamble, title 40, chapter I of the code of Federal regulations is amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

■ 1. The authority citation for part 50 continues to read as follows:

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

■ 2. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (e.g., micrograms per cubic meter) other than for particulate matter (PM_{2.5}) standards contained in §§ 50.7 and 50.13 and lead standards contained in § 50.16 shall be corrected to a reference temperature of 25 (deg) C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of PM_{2.5} for purposes of comparison to the standards contained in §§ 50.7 and 50.13 and of lead for purposes of comparison to the standards contained in § 50.16 shall be reported based on actual ambient air volume measured at the actual ambient temperature and pressure at the monitoring site during the measurement period.

■ 3. Section 50.12 is amended by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

§ 50.12 National primary and secondary ambient air quality standards for lead.

(b) The standards set forth in this section will remain applicable to all areas notwithstanding the promulgation of lead national ambient air quality standards (NAAQS) in § 50.16. The lead NAAQS set forth in this section will no longer apply to an area one year after the effective date of the designation of that area, pursuant to section 107 of the Clean Air Act, for the lead NAAQS set forth in § 50.16; except that for areas designated nonattainment for the lead NAAQS set forth in this section as of the effective date of § 50.16, the lead NAAQS set forth in this section will apply until that area submits, pursuant to section 191 of the Clean Air Act, and EPA approves, an implementation plan providing for attainment and/or maintenance of the lead NAAQS set forth in § 50.16.

- 4. Section 50.14 is amended by:
 - a. Revising paragraph (a)(2);
 - b. Revising paragraph (c)(2)(iii);
 - c. Redesignating paragraph (c)(2)(v) as paragraph (c)(2)(vi) and adding a new paragraph (c)(2)(v); and
 - d. Redesignating existing paragraphs (c)(3)(iii) and (c)(3)(iv) as paragraphs

(c)(3)(iv) and (c)(3)(v), respectively, and adding a new paragraph (c)(3)(iii).

The additions and revisions read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

(a) * * *

(2) Demonstration to justify data exclusion may include any reliable and accurate data, but must demonstrate a clear causal relationship between the measured exceedance or violation of such standard and the event in accordance with paragraph (c)(3)(iv) of this section.

* * * * *

(c) * * *

(2) * * *

(iii) Flags placed on data as being due to an exceptional event together with an initial description of the event shall be submitted to EPA not later than July 1st of the calendar year following the year in which the flagged measurement occurred, except as allowed under paragraph (c)(2)(iv) or (c)(2)(v) of this section.

* * * * *

(v) For lead (Pb) data collected during calendar years 2006–2008, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than July 1, 2009. For Pb data collected during calendar year 2009, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than July 1, 2010. For Pb data collected during calendar year 2010, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than May 1, 2011.

* * * * *

(3) * * *

(iii) A State that flags Pb data collected during calendar years 2006–2009, pursuant to paragraph (c)(2)(v) of this section shall, after notice and opportunity for public comment, submit to EPA a demonstration to justify exclusion of the data not later than October 15, 2010. A State that flags Pb data collected during calendar year 2010 shall, after notice and opportunity for public comment, submit to EPA a demonstration to justify the exclusion of the data not later than May 1, 2011. A state must submit the public comments it received along with its demonstration to EPA.

* * * * *

■ 5. Section 50.16 is added to read as follows:

§ 50.16 National primary and secondary ambient air quality standards for lead.

(a) The national primary and secondary ambient air quality standards for lead (Pb) and its compounds are 0.15 micrograms per cubic meter, arithmetic mean concentration over a 3-month period, measured in the ambient air as Pb either by:

(1) A reference method based on Appendix G of this part and designated in accordance with part 53 of this chapter or;

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The national primary and secondary ambient air quality standards for Pb are met when the maximum arithmetic 3-month mean concentration for a 3-year period, as determined in accordance with Appendix R of this part, is less than or equal to 0.15 micrograms per cubic meter.

■ 6. Appendix G is amended as follows:
 ■ a. In section 10.2 the definition of the term “V_{STP}” in the equation is revised,
 ■ b. In section 14 reference 10 is added and reference 15 is revised:

Appendix G to Part 50—Reference Method for the Determination of Lead in Suspended Particulate Matter Collected From Ambient Air

* * * * *

10.2 * * *

V_{STP} = Air volume from section 10.1.

* * * * *

14. * * *

10. Intersociety Committee (1972). *Methods of Air Sampling and Analysis*. 1015 Eighteenth Street, N.W. Washington, D.C.: American Public Health Association. 365–372. * * *

15. Sharon J. Long, et al., “Lead Analysis of Ambient Air Particulates: Interlaboratory Evaluation of EPA Lead Reference Method” *APCA Journal*, 29, 28–31 (1979).

* * * * *

■ 7. Appendix Q is added to read as follows:

Appendix Q to Part 50—Reference Method for the Determination of Lead in Particulate Matter as PM₁₀ Collected From Ambient Air

This Federal Reference Method (FRM) draws heavily from the specific analytical protocols used by the U.S. EPA.

1. Applicability and Principle

1.1 This method provides for the measurement of the lead (Pb) concentration in particulate matter that is 10 micrometers or less (PM₁₀) in ambient air. PM₁₀ is collected on an acceptable (see section 6.1.2) 46.2 mm diameter polytetrafluoroethylene (PTFE) filter for 24 hours using active

sampling at local conditions with a low-volume air sampler. The low-volume sampler has an average flow rate of 16.7 liters per minute (Lpm) and total sampled volume of 24 cubic meters (m³) of air. The analysis of Pb in PM₁₀ is performed on each individual 24-hour sample. Gravimetric mass analysis of PM_{10c} filters is not required for Pb analysis. For the purpose of this method, PM₁₀ is defined as particulate matter having an aerodynamic diameter in the nominal range of 10 micrometers (10 μm) or less.

1.2 For this reference method, PM₁₀ shall be collected with the PM_{10c} federal reference method (FRM) sampler as described in Appendix O to Part 50 using the same sample period, measurement procedures, and requirements specified in Appendix L of Part 50. The PM_{10c} sampler is also being used for measurement of PM_{10-2.5} mass by difference and as such, the PM_{10c} sampler must also meet all of the performance requirements specified for PM_{2.5} in Appendix L. The concentration of Pb in the atmosphere is determined in the total volume of air sampled and expressed in micrograms per cubic meter (μg/m³) at local temperature and pressure conditions.

1.3 The FRM will serve as the basis for approving Federal Equivalent Methods (FEMs) as specified in 40 CFR Part 53 (Reference and Equivalent Methods). This FRM specifically applies to the analysis of Pb in PM₁₀ filters collected with the PM_{10c} sampler. If these filters are analyzed for elements other than Pb, then refer to the guidance provided in the EPA Inorganic Compendium Method IO–3.3 (Reference 1 of section 8) for multi-element analysis.

1.4 The PM_{10c} air sampler draws ambient air at a constant volumetric flow rate into a specially shaped inlet and through an inertial particle size separator, where the suspended particulate matter in the PM₁₀ size range is separated for collection on a PTFE filter over the specified sampling period. The Pb content of the PM₁₀ sample is analyzed by energy-dispersive X-ray fluorescence spectrometry (EDXRF). Energy-dispersive X-ray fluorescence spectrometry provides a means for identification of an element by measurement of its characteristic X-ray emission energy. The method allows for quantification of the element by measuring the intensity of X-rays emitted at the characteristic photon energy and then relating this intensity to the elemental concentration. The number or intensity of X-rays produced at a given energy provides a measure of the amount of the element present by comparisons with calibration standards. The X-rays are detected and the spectral signals are acquired and processed with a personal computer. EDXRF is commonly used as a non-destructive method for quantifying trace elements in PM. A detailed explanation of quantitative X-ray spectrometry is described in references 2, 3 and 4.

1.5 Quality assurance (QA) procedures for the collection of monitoring data are contained in Part 58, Appendix A.

2. *PM₁₀ Pb Measurement Range and Detection Limit.* The values given below in section 2.1 and 2.2 are typical of the method capabilities. Absolute values will vary for

individual situations depending on the instrument, detector age, and operating conditions used. Data are typically reported in ng/m³ for ambient air samples; however, for this reference method, data will be reported in μg/m³ at local temperature and pressure conditions.

2.1 *EDXRF Pb Measurement Range.* The typical ambient air measurement range is 0.001 to 30 μg Pb/m³, assuming an upper range calibration standard of about 60 μg Pb per square centimeter (cm²), a filter deposit area of 11.86 cm², and an air volume of 24 m³. The top range of the EDXRF instrument is much greater than what is stated here. The top measurement range of quantification is defined by the level of the high concentration calibration standard used and can be increased to expand the measurement range as needed.

2.2 *Detection Limit (DL).* A typical estimate of the one-sigma detection limit (DL) is about 2 ng Pb/cm² or 0.001 μg Pb/m³, assuming a filter size of 46.2 mm (filter deposit area of 11.86 cm²) and a sample air volume of 24 m³. The DL is an estimate of the lowest amount of Pb that can be reliably distinguished from a blank filter. The one-sigma detection limit for Pb is calculated as the average overall uncertainty or propagated error for Pb, determined from measurements on a series of blank filters from the filter lot(s) in use. Detection limits must be determined for each filter lot in use. If a new filter lot is used, then a new DL must be determined. The sources of random error which are considered are calibration uncertainty; system stability; peak and background counting statistics; uncertainty in attenuation corrections; and uncertainty in peak overlap corrections, but the dominating source by far is peak and background counting statistics. At a minimum, laboratories are to determine annual estimates of the DL using the guidance provided in Reference 5.

3. Factors Affecting Bias and Precision of Lead Determination by EDXRF

3.1 *Filter Deposit.* X-ray spectra are subject to distortion if unusually heavy deposits are analyzed. This is the result of internal absorption of both primary and secondary X-rays within the sample; however, this is not an issue for Pb due to the energetic X-rays used to fluoresce Pb and the energetic characteristic X-rays emitted by Pb. The optimum mass filter loading for multi-element EDXRF analysis is about 100 μg/cm² or 1.2 mg/filter for a 46.2-mm filter. Too little deposit material can also be problematic due to low counting statistics and signal noise. The particle mass deposit should minimally be 15 μg/cm². The maximum PM₁₀ filter loading or upper concentration limit of mass expected to be collected by the PM_{10c} sampler is 200 μg/m³ (Appendix O to Part 50, Section 3.2). This equates to a mass loading of about 400 μg/cm² and is the maximum expected loading for PM_{10c} filters. This maximum loading is acceptable for the analysis of Pb and other high-Z elements with very energetic characteristic X-rays. A properly collected sample will have a uniform deposit over the entire collection area. Samples with physical deformities (including a visually non-

uniform deposit area) should not be quantitatively analyzed. Tests on the uniformity of particle deposition on PM_{10C} filters showed that the non-uniformity of the filter deposit represents a small fraction of the overall uncertainty in ambient Pb concentration measurement. The analysis beam of the XRF analyzer does not cover the entire filter collection area. The minimum allowable beam size is 10 mm.

3.2 Spectral Interferences and Spectral Overlap. Spectral interference occurs when the entirety of the analyte spectral lines of two species are nearly 100% overlapped. The presence of arsenic (As) is a problematic interference for EDXRF systems which use the Pb L_α line exclusively to quantify the Pb concentration. This is because the Pb L_α line and the As K_α lines severely overlap. The use of multiple Pb lines, including the L_β and/or the L_γ lines for quantification must be used to reduce the uncertainty in the Pb determination in the presence of As. There can be instances when lines partially overlap the Pb spectral lines, but with the energy resolution of most detectors these overlaps are typically de-convoluted using standard spectral de-convolution software provided by the instrument vendor. An EDXRF protocol for Pb must define which Pb lines are used for quantification and where spectral overlaps occur. A de-convolution protocol must be used to separate all the lines which overlap with Pb.

3.3 Particle Size Effects and Attenuation Correction Factors. X-ray attenuation is dependent on the X-ray energy, mass sample loading, composition, and particle size. In some cases, the excitation and fluorescent X-rays are attenuated as they pass through the sample. In order to relate the measured intensity of the X-rays to the thin-film calibration standards used, the magnitude of any attenuation present must be corrected for. See references 6, 7, and 8 for more discussion on this issue. Essentially no attenuation corrections are necessary for Pb in PM_{10C}. Both the incoming excitation X-rays used for analyzing lead and the fluoresced Pb X-rays are sufficiently energetic that for particles in this size range and for normal filter loadings, the Pb X-ray yield is not significantly impacted by attenuation.

4. Precision

4.1 Measurement system precision is assessed according to the procedures set forth in Appendix A to part 58. Measurement method precision is assessed from collocated sampling and analysis. The goal for acceptable measurement uncertainty, as precision, is defined as an upper 90 percent confidence limit for the coefficient of variation (CV) of 20 percent.

5. Bias

5.1 Measurement system bias for monitoring data is assessed according to the procedures set forth in Appendix A of part 58. The bias is assessed through an audit using spiked filters. The goal for measurement bias is defined as an upper 95 percent confidence limit for the absolute bias of 15 percent.

6. Measurement of PTFE Filters by EDXRF

6.1 Sampling

6.1.1 Low-Volume PM_{10C} Sampler. The low-volume PM_{10C} sampler shall be used for

PM₁₀ sample collection and operated in accordance with the performance specifications described in Part 50, Appendix L.

6.1.2 PTFE Filters and Filter Acceptance Testing. The PTFE filters used for PM_{10C} sample collection shall meet the specifications provided in Part 50, Appendix L. The following requirements are similar to those currently specified for the acceptance of PM_{2.5} filters that are tested for trace elements by EDXRF. For large filter lots (greater than 500 filters) randomly select 20 filters from a given lot. For small lots (less than 500 filters) a lesser number of filters may be taken. Analyze each blank filter separately and calculate the average lead concentration in ng/cm². Ninety percent, or 18 of the 20 filters, must have an average lead concentration that is less than 4.8 ng Pb/cm².

6.1.2.1 Filter Blanks. Field blank filters shall be collected along with routine samples. Field blank filters will be collected that are transported to the sampling site and placed in the sampler for the duration of sampling without sampling. Laboratory blank filters from each filter lot used shall be analyzed with each batch of routine sample filters analyzed. Laboratory blank filters are used in background subtraction as discussed below in Section 6.2.4.

6.2 Analysis. The four main categories of random and systematic error encountered in X-ray fluorescence analysis include errors from sample collection, the X-ray source, the counting process, and inter-element effects. These errors are addressed through the calibration process and mathematical corrections in the instrument software. Spectral processing methods are well established and most commercial analyzers have software that can implement the most common approaches (references 9–11) to background subtraction, peak overlap correction, counting and deadtime corrections.

6.2.1 EDXRF Analysis Instrument. An energy-dispersive XRF system is used. Energy-dispersive XRF systems are available from a number of commercial vendors. Examples include Thermo (www.thermo.com), Spectro (<http://www.spectro.com>), Xenometrix (<http://www.xenometrix.com>) and PANalytical (<http://www.panalytical.com>).¹ The analysis is performed at room temperature in either vacuum or in a helium atmosphere. The specific details of the corrections and calibration algorithms are typically included in commercial analytical instrument software routines for automated spectral acquisition and processing and vary by manufacturer. It is important for the analyst to understand the correction procedures and algorithms of the particular system used, to ensure that the necessary corrections are applied.

6.2.2 Thin film standards. Thin film standards are used for calibration because they most closely resemble the layer of particles on a filter. Thin film standards are typically deposited on Nuclepore substrates.

¹These are examples of available systems and is not an all inclusive list. The mention of commercial products does not imply endorsement by the U.S. Environmental Protection Agency.

The preparation of thin film standards is discussed in reference 8, and 10. The NIST SRM 2783 (Air Particulate on Filter Media) is currently available on polycarbonate filters and contains a certified concentration for Pb. Thin film standards at 15 and 50 µg/cm² are commercially available from MicroMatter Inc. (Arlington, WA).

6.2.3 Filter Preparation. Filters used for sample collection are 46.2-mm PTFE filters with a pore size of 2 microns and filter deposit area 11.86 cm². Cold storage is not a requirement for filters analyzed for Pb; however, if filters scheduled for XRF analysis were stored cold, they must be allowed to reach room temperature prior to analysis. All filter samples received for analysis are checked for any holes, tears, or a non-uniform deposit which would prevent quantitative analysis. Samples with physical deformities are not quantitatively analyzable. The filters are carefully removed with tweezers from the Petri dish and securely placed into the instrument-specific sampler holder for analysis. Care must be taken to protect filters from contamination prior to analysis. Filters must be kept covered when not being analyzed. No other preparation of filter samples is required.

6.2.4 Calibration. In general, calibration determines each element's sensitivity, *i.e.*, its response in x-ray counts/sec to each µg/cm² of a standard and an interference coefficient for each element that causes interference with another one (See section 3.2 above). The sensitivity can be determined by a linear plot of count rate versus concentration (µg/cm²) in which the slope is the instrument's sensitivity for that element. A more precise way, which requires fewer standards, is to fit sensitivity versus atomic number. Calibration is a complex task in the operation of an XRF system. Two major functions accomplished by calibration are the production of reference spectra which are used for fitting and the determination of the elemental sensitivities. Included in the reference spectra (referred to as "shapes") are background-subtracted peak shapes of the elements to be analyzed (as well as interfering elements) and spectral backgrounds. Pure element thin film standards are used for the element peak shapes and clean filter blanks from the same lot as routine filter samples are used for the background. The analysis of Pb in PM filter deposits is based on the assumption that the thickness of the deposit is small with respect to the characteristic Pb X-ray transmission thickness. Therefore, the concentration of Pb in a sample is determined by first calibrating the spectrometer with thin film standards to determine the sensitivity factor for Pb and then analyzing the unknown samples under identical excitation conditions as used to determine the calibration. Calibration shall be performed annually or when significant repairs or changes occur (e.g., a change in fluorescers, X-ray tubes, or detector). Calibration establishes the elemental sensitivity factors and the magnitude of interference or overlap coefficients. See reference 7 for more detailed discussion of calibration and analysis of shapes standards for background correction, coarse particle absorption corrections, and spectral overlap.

6.2.4.1 Spectral Peak Fitting. The EPA uses a library of pure element peak shapes

(shape standards) to extract the elemental background-free peak areas from an unknown spectrum. It is also possible to fit spectra using peak stripping or analytically defined functions such as modified Gaussian functions. The EPA shape standards are generated from pure, mono-elemental thin film standards. The shape standards are acquired for sufficiently long times to provide a large number of counts in the peaks of interest. It is not necessary for the concentration of the standard to be known. A slight contaminant in the region of interest in a shape standard can have a significant and serious effect on the ability of the least squares fitting algorithm to fit the shapes to the unknown spectrum. It is these elemental peak shapes that are fitted to the peaks in an unknown sample during spectral processing by the analyzer. In addition to this library of elemental shapes there is also a background shape spectrum for the filter type used as discussed below in section 6.2.4.2 of this section.

6.2.4.2 Background Measurement and Correction. A background spectrum generated by the filter itself must be subtracted from the X-ray spectrum prior to extracting peak areas. Background spectra must be obtained for each filter lot used for sample collection. The background shape standards which are used for background fitting are created at the time of calibration. If a new lot of filters is used, new background spectra must be obtained. A minimum of 20 clean blank filters from each filter lot are kept in a sealed container and are used exclusively for background measurement and correction. The spectra acquired on individual blank filters are added together to produce a single spectrum for each of the secondary targets or fluorescers used in the analysis of lead. Individual blank filter spectra which show atypical contamination are excluded from the summed spectra. The summed spectra are fitted to the appropriate background during spectral processing. Background correction is automatically included during spectral processing of each sample.

7. Calculation.

7.1 PM_{10} Pb concentrations. The PM_{10} Pb concentration in the atmosphere ($\mu\text{g}/\text{m}^3$) is calculated using the following equation:

$$M_{Pb} = \frac{C_{Pb} \times A}{V_{LC}}$$

Where,

M_{Pb} is the mass per unit volume for lead in $\mu\text{g}/\text{m}^3$;

C_{Pb} is the mass per unit area for lead in $\mu\text{g}/\text{cm}^2$ as measured by XRF;

A is the filter deposit area in cm^2 ;

V_{LC} is the total volume of air sampled by the PM_{10c} sampler in actual volume units measured at local conditions of temperature and pressure, as provided by the sampler in m^3 .

7.2 PM_{10} Pb Uncertainty Calculations.

The principal contributors to total uncertainty of XRF values include: field sampling; filter deposit area; XRF calibration; attenuation or loss of the x-ray signals due to the other components of the particulate

sample; and determination of the Pb X-ray emission peak area by curve fitting. See reference 12 for a detailed discussion of how uncertainties are similarly calculated for the $PM_{2.5}$ Chemical Speciation program.

The model for calculating total uncertainty is:

$$\delta_{tot} = (\delta_f^2 + \delta_a^2 + \delta_c^2 + \delta_v^2)^{1/2}$$

Where,

δ_f = fitting uncertainty (XRF-specific, from 2 to 100+%)

δ_a = attenuation uncertainty (XRF-specific, insignificant for Pb)

δ_c = calibration uncertainty (combined lab uncertainty, assumed as 5%)

δ_v = volume/deposition size uncertainty (combined field uncertainty, assumed as 5%)

8. References

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■ 8. Appendix R is added to read as follows:

Appendix R to Part 50—Interpretation of the National Ambient Air Quality Standards for Lead

1. General.

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary and secondary national ambient air quality standards (NAAQS) for lead (Pb) specified in § 50.16 are met. The NAAQS indicator for Pb is defined as: lead and its compounds, measured as elemental lead in total suspended particulate (Pb-TSP), sampled and analyzed by a Federal reference method (FRM) based on appendix G to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Although Pb-TSP is the lead NAAQS indicator, surrogate Pb-TSP concentrations shall also be used for NAAQS comparisons; specifically, valid surrogate Pb-TSP data are concentration data for lead and its compounds, measured as elemental lead, in particles with an aerodynamic size of 10 microns or less (Pb- PM_{10}), sampled and analyzed by an FRM based on appendix Q to this part or by an FEM designated in accordance with part 53 of this chapter. Surrogate Pb-TSP data (i.e., Pb- PM_{10} data), however, can only be used to show that the Pb NAAQS were violated (i.e., not met); they can not be used to demonstrate that the Pb NAAQS were met. Pb- PM_{10} data used as surrogate Pb-TSP data shall be processed at face value; that is, without any transformation or scaling. Data handling and computation procedures to be used in making comparisons between reported and/or surrogate Pb-TSP concentrations and the level of the Pb NAAQS are specified in the following sections.

(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, is determined by the requirements and process deadlines specified in §§ 50.1, 50.14, and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual monitoring network plan refers to the plan required by section 58.10 of this chapter.

Creditable samples are samples that are given credit for data completeness. They include valid samples collected on required sampling days and valid "make-up" samples taken for missed or invalidated samples on required sampling days.

Daily values for Pb refer to the 24-hour mean concentrations of Pb (Pb-TSP or Pb- PM_{10}), measured from midnight to midnight (local standard time), that are used in NAAQS computations.

Design value is the site-level metric (i.e., statistic) that is compared to the NAAQS level to determine compliance; the design value for the Pb NAAQS is selected according to the procedures in this appendix from among the valid three-month Pb-TSP and surrogate Pb-TSP (Pb-PM₁₀) arithmetic mean concentration for the 38-month period consisting of the most recent 3-year calendar period plus two previous months (i.e., 36 3-month periods) using the last month of each 3-month period as the period of report.

Extra samples are non-creditable samples. They are daily values that do not occur on scheduled sampling days and that can not be used as "make-up samples" for missed or invalidated scheduled samples. Extra samples are used in mean calculations. For purposes of determining whether a sample must be treated as a make-up sample or an extra sample, Pb-TSP and Pb-PM₁₀ data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

Make-up samples are samples taken to replace missed or invalidated required scheduled samples. Make-ups can be made by either the primary or collocated (same size fraction) instruments; to be considered a valid make-up, the sampling must be conducted with equipment and procedures that meet the requirements for scheduled sampling. Make-up samples are either taken before the next required sampling day or exactly one week after the missed (or voided) sampling day. Make-up samples can not span years; that is, if a scheduled sample for December is missed (or voided), it can not be made up in January. Make-up samples, however, may span months, for example a missed sample on January 31 may be made up on February 1, 2, 3, 4, 5, or 7 (with an assumed sampling frequency of every sixth day). Section 3(e) explains how such month-spanning make-up samples are to be treated for purposes of data completeness and mean calculations. Only two make-up samples are permitted each calendar month; these are counted according to the month in which the miss and not the makeup occurred. For purposes of determining whether a sample must be treated as a make-up sample or an extra sample, Pb-TSP and Pb-PM₁₀ data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

Monthly mean refers to an arithmetic mean, calculated as specified in section 6(a) of this appendix. Monthly means are computed at each monitoring site separately for Pb-TSP and Pb-PM₁₀ (i.e., by site-parameter-year-month).

Parameter refers either to Pb-TSP or to Pb-PM₁₀.

Pollutant Occurrence Code (POC) refers to a numerical code (1, 2, 3, etc.) used to distinguish the data from two or more monitors for the same parameter at a single monitoring site.

Scheduled sampling day means a day on which sampling is scheduled based on the required sampling frequency for the monitoring site, as provided in section 58.12 of this chapter.

Three-month means are arithmetic averages of three consecutive monthly

means. Three-month means are computed on a rolling, overlapping basis. Each distinct monthly mean will be included in three different 3-month means; for example, in a given year, a November mean would be included in: (1) The September-October-November 3-month mean, (2) the October-November-December 3-month mean, and (3) the November-December-January (of the following year) 3-month mean. Three-month means are computed separately for each parameter per section 6(a) (and are referred to as 3-month parameter means) and are validated according to the criteria specified in section 4(c). The parameter-specific 3-month means are then prioritized according to section 2(a) to determine a single 3-month site mean.

Year refers to a calendar year.

2. Use of Pb-PM₁₀ Data as Surrogate Pb-TSP Data.

(a) As stipulated in section 2.10 of Appendix C to 40 CFR part 58, at some mandatory Pb monitoring locations, monitoring agencies are required to sample for Pb as Pb-TSP, and at other mandatory Pb monitoring sites, monitoring agencies are permitted to monitor for Pb-PM₁₀ in lieu of Pb-TSP. In either situation, valid collocated Pb data for the other parameter may be produced. Additionally, there may be non-required monitoring locations that also produce valid Pb-TSP and/or valid Pb-PM₁₀ data. Pb-TSP data and Pb-PM₁₀ data are always processed separately when computing monthly and 3-month parameter means; monthly and 3-month parameter means are validated according to the criteria stated in section 4 of this appendix. Three-month "site" means, which are the final valid 3-month mean from which a design value is identified, are determined from the one or two available valid 3-month parameter means according to the following prioritization which applies to all Pb monitoring locations.

(i) Whenever a valid 3-month Pb-PM₁₀ mean shows a violation and either is greater than a corresponding (collocated) 3-month Pb-TSP mean or there is no corresponding valid 3-month Pb-TSP mean present, then that 3-month Pb-PM₁₀ mean will be the site-level mean for that (site's) 3-month period.

(ii) Otherwise (i.e., there is no valid violating 3-month Pb-PM₁₀ that exceeds a corresponding 3-month Pb-TSP mean),

(A) If a valid 3-month Pb-TSP mean exists, then it will be the site-level mean for that (site's) 3-month period, or

(B) If a valid 3-month Pb-TSP mean does not exist, then there is no valid 3-month site mean for that period (even if a valid non-violating 3-month Pb-PM₁₀ mean exists).

(b) As noted in section 1(a) of this appendix, FRM/FEM Pb-PM₁₀ data will be processed at face value (i.e., as reported concentrations) without adjustment when computing means and making NAAQS comparisons.

3. Requirements for Data Used for Comparisons With the Pb NAAQS and Data Reporting Considerations.

(a) All valid FRM/FEM Pb-TSP data and all valid FRM/FEM Pb-PM₁₀ data submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter

including appendices A, C, and E shall be used in design value calculations. Pb-TSP and Pb-PM₁₀ data representing sample collection periods prior to January 1, 2009 (i.e., "pre-rule" data) will also be considered valid for NAAQS comparisons and related attainment/nonattainment determinations if the sampling and analysis methods that were utilized to collect that data were consistent with previous or newly designated FRMs or FEMs and with either the provisions of part 58 of this chapter including appendices A, C, and E that were in effect at the time of original sampling or that are in effect at the time of the attainment/nonattainment determination, and if such data are submitted to AQS prior to September 1, 2009.

(b) Pb-TSP and Pb-PM₁₀ measurement data are reported to AQS in units of micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) at local conditions (local temperature and pressure, LC) to three decimal places; any additional digits to the right of the third decimal place are truncated. Pre-rule Pb-TSP and Pb-PM₁₀ concentration data that were reported in standard conditions (standard temperature and standard pressure, STP) will not require a conversion to local conditions but rather, after truncating to three decimal places and processing as stated in this appendix, shall be compared "as is" to the NAAQS (i.e., the LC to STP conversion factor will be assumed to be one). However, if the monitoring agency has retroactively resubmitted Pb-TSP or Pb-PM₁₀ pre-rule data converted from STP to LC based on suitable meteorological data, only the LC data will be used.

(c) At each monitoring location (site), Pb-TSP and Pb-PM₁₀ data are to be processed separately when selecting daily data by day (as specified in section 3(d) of this appendix), when aggregating daily data by month (per section 6(a)), and when forming 3-month means (per section 6(b)). However, when deriving (i.e., identifying) the design value for the 38-month period, 3-month means for the two data types may be considered together; see sections 2(a) and 4(e) of this appendix for details.

(d) Daily values for sites will be selected for a site on a size cut (Pb-TSP or Pb-PM₁₀, i.e., "parameter") basis; Pb-TSP concentrations and Pb-PM₁₀ concentrations shall not be commingled in these determinations. Site level, parameter-specific daily values will be selected as follows:

(i) The starting dataset for a site-parameter shall consist of the measured daily concentrations recorded from the designated primary FRM/FEM monitor for that parameter. The primary monitor for each parameter shall be designated in the appropriate state or local agency annual Monitoring Network Plan. If no primary monitor is designated, the Administrator will select which monitor to treat as primary. All daily values produced by the primary sampler are considered part of the site-parameter data record (i.e., that site-parameter's set of daily values); this includes all creditable samples and all extra samples. For pre-rule Pb-TSP and Pb-PM₁₀ data, valid data records present in AQS for the monitor with the lowest occurring Pollutant Occurrence Code (POC), as selected on a site-parameter-daily basis, will constitute the site-

parameter data record. Where pre-rule Pb-TSP data (or subsequent non-required Pb-TSP or Pb-PM₁₀ data) are reported in "composite" form (i.e., multiple filters for a month of sampling that are analyzed together), the composite concentration will be used as the site-parameter monthly mean concentration if there are no valid daily Pb-TSP data reported for that month with a lower POC.

(ii) Data for the primary monitor for each parameter shall be augmented as much as possible with data from collocated (same parameter) FRM/FEM monitors. If a valid 24-hour measurement is not produced from the primary monitor for a particular day (scheduled or otherwise), but a valid sample is generated by a collocated (same parameter) FRM/FEM instrument, then that collocated value shall be considered part of the site-parameter data record (i.e., that site-parameter's monthly set of daily values). If more than one valid collocated FRM/FEM value is available, the mean of those valid collocated values shall be used as the daily value. Note that this step will not be necessary for pre-rule data given the daily identification presumption for the primary monitor.

(e) All daily values in the composite site-parameter record are used in monthly mean calculations. However, not all daily values are given credit towards data completeness requirements. Only "creditable" samples are given credit for data completeness. Creditable samples include valid samples on scheduled sampling days and valid make-up samples. All other types of daily values are referred to as "extra" samples. Make-up samples taken in the (first week of the) month after the one in which the miss/void occurred will be credited for data capture in the month of the miss/void but will be included in the month actually taken when computing monthly means. For example, if a make-up sample was taken in February to replace a missed sample scheduled for January, the make-up concentration would be included in the February monthly mean but the sample credited in the January data capture rate.

4. Comparisons With the Pb NAAQS.

(a) The Pb NAAQS is met at a monitoring site when the identified design value is valid and less than or equal to 0.15 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$). A Pb design value that meets the NAAQS (i.e., 0.15 $\mu\text{g}/\text{m}^3$ or less), is considered valid if it encompasses 36 consecutive valid 3-month site means (specifically for a 3-year calendar period and the two previous months). For sites that begin monitoring Pb after this rule is effective but before January 15, 2010 (or January 15, 2011), a 2010–2012 (or 2011–2013) Pb design value that meets the NAAQS will be considered valid if it encompasses at least 34 consecutive valid 3-month means (specifically encompassing only the 3-year calendar period). See 4(c) of this appendix for the description of a valid 3-month mean and section 6(d) for the definition of the design value.

(b) The Pb NAAQS is violated at a monitoring site when the identified design value is valid and is greater than 0.15 $\mu\text{g}/\text{m}^3$, no matter whether determined from Pb-TSP or Pb-PM₁₀ data. A Pb design value greater

than 0.15 $\mu\text{g}/\text{m}^3$ is valid no matter how many valid 3-month means in the 3-year period it encompasses; that is, a violating design value is valid even if it (i.e., the highest 3-month mean) is the only valid 3-month mean in the 3-year timeframe. Further, a site does not have to monitor for three full calendar years in order to have a valid violating design value; a site could monitor just three months and still produce a valid (violating) design value.

(c)(i) A 3-month parameter mean is considered valid (i.e., meets data completeness requirements) if the average of the data capture rate of the three constituent monthly means (i.e., the 3-month data capture rate) is greater than or equal to 75 percent. Monthly data capture rates (expressed as a percentage) are specifically calculated as the number of creditable samples for the month (including any make-up samples taken the subsequent month for missed samples in the month in question, and excluding any make-up samples taken in the month in question for missed samples in the previous month) divided by the number of scheduled samples for the month, the result then multiplied by 100 but not rounded. The 3-month data capture rate is the sum of the three corresponding unrounded monthly data capture rates divided by three and the result rounded to the nearest integer (zero decimal places). As noted in section 3(c), Pb-TSP and Pb-PM₁₀ daily values are processed separately when calculating monthly means and data capture rates; a Pb-TSP value cannot be used as a make-up for a missing Pb-PM₁₀ value or vice versa. For purposes of assessing data capture, Pb-TSP and Pb-PM₁₀ data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

(ii) A 3-month parameter mean that does not have at least 75 percent data capture and thus is not considered valid under 4(c)(i) shall be considered valid (and complete) if it passes either of the two following "data substitution" tests, one such test for validating an above NAAQS-level (i.e., violating) 3-month Pb-TSP or Pb-PM₁₀ mean (using actual "low" reported values from the same site at about the same time of the year (i.e., in the same month) looking across three or four years), and the second test for validating a below-NAAQS level 3-month Pb-TSP mean (using actual "high" values reported for the same site at about the same time of the year (i.e., in the same month) looking across three or four years). Note that both tests are merely diagnostic in nature intending to confirm that there is a very high likelihood if not certainty that the original mean (the one with less than 75% data capture) reflects the true over/under NAAQS-level status for that 3-month period; the result of one of these data substitution tests (i.e., a "test mean", as defined in section 4(c)(ii)(A) or 4(c)(ii)(B)) is not considered the actual 3-month parameter mean and shall not be used in the determination of design values. For both types of data substitution, substitution is permitted only if there are available data points from which to identify the high or low 3-year month-specific values, specifically if there are at least 10 data points

total from at least two of the three (or four for November and December) possible year-months. Data substitution may only use data of the same parameter type.

(A) The "above NAAQS level" test is as follows: Data substitution will be done in each month of the 3-month period that has less than 75 percent data capture; monthly capture rates are temporarily rounded to integers (zero decimals) for this evaluation. If by substituting the lowest reported daily value for that month (year non-specific; e.g., for January) over the 38-month design value period in question for missing scheduled data in the deficient months (substituting only enough to meet the 75 percent data capture minimum), the computation yields a recalculated test 3-month parameter mean concentration above the level of the standard, then the 3-month period is deemed to have passed the diagnostic test and the level of the standard is deemed to have been exceeded in that 3-month period. As noted in section 4(c)(ii), in such a case, the 3-month parameter mean of the data actually reported, not the recalculated ("test") result including the low values, shall be used to determine the design value.

(B) The "below NAAQS level" test is as follows: Data substitution will be performed for each month of the 3-month period that has less than 75 percent but at least 50 percent data capture; if any month has less than 50% data capture then the 3-month mean can not utilize this substitution test. Also, incomplete 3-month Pb-PM₁₀ means can not utilize this test. A 3-month Pb-TSP mean with less than 75% data capture shall still be considered valid (and complete) if, by substituting the highest reported daily value, month-specific, over the 3-year design value period in question, for all missing scheduled data in the deficient months (i.e., bringing the data capture rate up to 100%), the computation yields a recalculated 3-month parameter mean concentration equal or less than the level of the standard (0.15 $\mu\text{g}/\text{m}^3$), then the 3-month mean is deemed to have passed the diagnostic test and the level of the standard is deemed not to have been exceeded in that 3-month period (for that parameter). As noted in section 4(c)(ii), in such a case, the 3-month parameter mean of the data actually reported, not the recalculated ("test") result including the high values, shall be used to determine the design value.

(d) Months that do not meet the completeness criteria stated in 4(c)(i) or 4(c)(ii), and design values that do not meet the completeness criteria stated in 4(a) or 4(b), may also be considered valid (and complete) with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The site-level design value for a 38-month period (three calendar years plus two previous months) is identified from the available (between one and 36) valid 3-month site means. In a situation where there are valid 3-month means for both parameters

(Pb-TSP and Pb-PM₁₀), the mean originating from the reported Pb-TSP data will be the one deemed the site-level monthly mean and used in design value identifications unless the Pb-PM₁₀ mean shows a violation of the NAAQS and exceeds the Pb-TSP mean; see section 2(a) for details. A monitoring site will have only one site-level 3-month mean per 3-month period; however, the set of site-level 3-month means considered for design value identification (i.e., one to 36 site-level 3-month means) can be a combination of Pb-TSP and Pb-PM₁₀ data.

(f) The procedures for calculating monthly means and 3-month means, and identifying Pb design values are given in section 6 of this appendix.

5. *Rounding Conventions.*

(a) Monthly means and monthly data capture rates are not rounded.

(b) Three-month means shall be rounded to the nearest hundredth µg/m³ (0.xx). Decimals 0.xx5 and greater are rounded up, and any decimal lower than 0.xx5 is rounded down. E.g., a 3-month mean of 0.104925 rounds to 0.10 and a 3-month mean of .105000 rounds to 0.11. Three-month data capture rates, expressed as a percent, are round to zero decimal places.

(c) Because a Pb design value is simply a (highest) 3-month mean and because the NAAQS level is stated to two decimal places, no additional rounding beyond what is specified for 3-month means is required before a design value is compared to the NAAQS.

6. *Procedures and Equations for the Pb NAAQS.*

(a)(i) A monthly mean value for Pb-TSP (or Pb-PM₁₀) is determined by averaging the daily values of a calendar month using equation 1 of this appendix, unless the Administrator chooses to exercise his discretion to use the alternate approach described in 6(a)(ii).

Equation 1

$$\bar{X}_{m,y,s} = \frac{1}{n_m} \sum_{i=1}^{n_m} X_{i,m,y,s}$$

Where:

- X_{m,y,s} = the mean for month m of the year y for sites; and
- n_m = the number of daily values in the month (creditable plus extra samples); and
- X_{i,m,y,s} = the ith value in month m for year y for site s.

(a)(ii) The Administrator may at his discretion use the following alternate approach to calculating the monthly mean concentration if the number of extra sampling days during a month is greater than the number of successfully completed scheduled and make-up sample days in that month. In exercising his discretion, the Administrator will consider whether the approach specified in 6(a)(i) might in the Administrator's judgment result in an unrepresentative value for the monthly mean concentration. This provision is to protect the integrity of the monthly and 3-month mean concentration values in situations in which, by intention or otherwise, extra sampling days are concentrated in a period

during which ambient concentrations are particularly high or low. The alternate approach is to average all extra and make-up samples (in the given month) taken after each scheduled sampling day ("Day X") and before the next scheduled sampling day (e.g., "Day X+6", in the case of one-in-six sampling) with the sample taken on Day X (assuming valid data was obtained on the scheduled sampling day), and then averaging these averages to calculate the monthly mean. This approach has the effect of giving approximately equal weight to periods during a month that have equal number of days, regardless of how many samples were actually obtained during the periods, thus mitigating the potential for the monthly mean to be distorted. The first day of scheduled sampling typically will not fall on the first day of the calendar month, and there may be make-up and/or extra samples (in that same calendar month) preceding the first scheduled day of the month. These samples will not be shifted into the previous month's mean concentration, but rather will stay associated with their actual calendar month as follows. Any extra and make-up samples taken in a month before the first scheduled sampling day of the month will be associated with and averaged with the last scheduled sampling day of that same month.

(b) Three-month parameter means are determined by averaging three consecutive monthly means of the same parameter using Equation 2 of this appendix.

Equation 2

$$\bar{X}_{m1,m2,m3;s} = \frac{1}{n_m} \sum_{i=1}^{n_m} \bar{X}_{m,y;zs}$$

Where:

- $\bar{X}_{m1, m2, m3; s}$ = the 3-month parameter mean for months m1, m2, and m3 for site s; and
- n_m = the number of monthly means available to be averaged (typically 3, sometimes 1 or 2 if one or two months have no valid daily values); and
- X_{m, y; z, s} = The mean for month m of the year y (or z) for site s.

(c) Three-month site means are determined from available 3-month parameter means according to the hierarchy established in 2(a) of this appendix.

(d) The site-level Pb design value is the highest valid 3-month site-level mean over the most recent 38-month period (i.e., the most recent 3-year calendar period plus two previous months). Section 4(a) of this appendix explains when the identified design value is itself considered valid for purposes of determining that the NAAQS is met or violated at a site.

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 9. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

■ 10. Section 51.117 is amended by revising paragraph (e)(1) to read as follows:

§ 51.117 Additional provisions for lead.

* * * * *

(e) * * *

(1) The point source inventory on which the summary of the baseline for lead emissions inventory is based must contain all sources that emit 0.5 or more tons of lead per year.

* * * * *

PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

■ 11. The authority citation for part 53 continues to read as follows:

Authority: Sec. 301(a) of the Clean Air Act (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

Subpart C—[Amended]

■ 12. Section 53.33 is revised to read as follows:

§ 53.33 Test Procedure for Methods for Lead (Pb).

(a) *General.* The reference method for Pb in TSP includes two parts, the reference method for high-volume sampling of TSP as specified in 40 CFR 50, Appendix B and the analysis method for Pb in TSP as specified in 40 CFR 50, Appendix G. Correspondingly, the reference method for Pb in PM₁₀ includes the reference method for low-volume sampling of PM₁₀ in 40 CFR 50, Appendix O and the analysis method of Pb in PM₁₀ as specified in 40 CFR 50, Appendix Q. This section explains the procedures for demonstrating the equivalence of either a candidate method for Pb in TSP to the high-volume reference methods, or a candidate method for Pb in PM₁₀ to the low-volume reference methods.

(1) Pb in TSP—A candidate method for Pb in TSP specifies reporting of Pb concentrations in terms of standard temperature and pressure. Comparisons of candidate methods to the reference method in 40 CFR 50, Appendix G must be made in a consistent manner with regard to temperature and pressure.

(2) Pb in PM₁₀—A candidate method for Pb in PM₁₀ must specify reporting of Pb concentrations in terms of local conditions of temperature and pressure, which will be compared to similarly reported concentrations from the reference method in 40 CFR 50 Appendix Q.

(b) *Comparability.* Comparability is shown for Pb methods when the differences between:

(1) Measurements made by a candidate method, and

(2) Measurements made by the reference method on simultaneously collected Pb samples (or the same sample, if applicable), are less than or equal to the values specified in table C-3 of this subpart.

(c) *Test measurements.* Test measurements may be made at any number of test sites. Augmentation of pollutant concentrations is not permitted, hence an appropriate test site or sites must be selected to provide Pb concentrations in the specified range.

(d) *Collocated samplers.* The ambient air intake points of all the candidate and reference method collocated samplers shall be positioned at the same height above the ground level, and between 2 meters (1 meter for samplers with flow rates less than 200 liters per minute (L/min)) and 4 meters apart. The samplers shall be oriented in a manner that will minimize spatial and wind directional effects on sample collection.

(e) *Sample collection.* Collect simultaneous 24-hour samples of Pb at the test site or sites with both the reference and candidate methods until at least 10 sample pairs have been obtained.

(1) A candidate method for Pb in TSP which employs a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method in 40 CFR part 50, Appendix B, but uses a different analytical procedure than specified in 40 CFR Appendix G, may be tested by analyzing pairs of filter strips taken from a single TSP reference sampler operated according to the procedures specified by that reference method.

(2) A candidate method for Pb in PM₁₀ which employs a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method in 40 CFR part 50, Appendix O, but uses a different analytical procedure than specified in 40 CFR Appendix Q, requires the use of two PM₁₀ reference samplers because a single 46.2-mm filter from a reference sampler may not be divided prior to analysis. It is possible to analyze a 46.2-mm filter first with the non-destructive X-ray Fluorescence (XRF) FRM and subsequently extract the filter for other analytical techniques. If the filter is subject to XRF with subsequent extraction for other analyses, then a single PM₁₀ reference sampler may be used for sample collection.

(3) A candidate method for Pb in TSP or Pb in PM₁₀ which employs a direct reading (e.g., continuous or semi-

continuous sampling) method that uses the same sampling inlet and flow rate as the FRM and the same or different analytical procedure may be tested. The direct measurements are then aggregated to 24-hour equivalent concentrations for comparison with the FRM. For determining precision in section (k), two collocated direct reading devices must be used.

(f) *Audit samples.* Three audit samples must be obtained from the address given in § 53.4(a). For Pb in TSP collected by the high-volume sampling method, the audit samples are ¾ × 8-inch glass fiber strips containing known amounts of Pb in micrograms per strip (µg/strip) equivalent to the following nominal percentages of the National Ambient Air Quality Standard (NAAQS): 30%, 100%, and 250%. For Pb in PM₁₀ collected by the low-volume sampling method, the audit samples are 46.2-mm polytetrafluorethylene (PTFE) filters containing known amounts of Pb in micrograms per filter (µg/filter) equivalent to the same percentages of the NAAQS: 30%, 100%, and 250%. The true amount of Pb (T_{qi}), in total µg/strip (for TSP) or total µg/filter (for PM₁₀), will be provided for each audit sample.

(g) *Filter analysis.*

(1) For both the reference method samples (e) and the audit samples (f), analyze each filter or filter extract three times in accordance with the reference method analytical procedure. This applies to both the Pb in TSP and Pb in PM₁₀ methods. The analysis of replicates should not be performed sequentially, i.e., a single sample should not be analyzed three times in sequence. Calculate the indicated Pb concentrations for the reference method samples in micrograms per cubic meter (µg/m³) for each analysis of each filter. Calculate the indicated total Pb amount for the audit samples in µg/strip for each analysis of each strip or µg/filter for each analysis of each audit filter. Label these test results as R_{1A}, R_{1B}, R_{1C}, R_{2A}, R_{2B}, etc., Q_{1A}, Q_{1B}, Q_{1C}, etc., where R denotes results from the reference method samples; Q denotes results from the audit samples; 1, 2, 3 indicate the filter number, and A, B, C indicate the first, second, and third analysis of each filter, respectively.

(2) For the candidate method samples, analyze each sample filter or filter extract three times and calculate, in accordance with the candidate method, the indicated Pb concentration in µg/m³ for each analysis of each filter. The analysis of replicates should not be performed sequentially. Label these test results as C_{1A}, C_{1B}, C_{2C}, etc., where C denotes results from the candidate

method. For candidate methods which provide a direct reading or measurement of Pb concentrations without a separable procedure, C_{1A}=C_{1B}=C_{1C}, C_{2A}=C_{2B}=C_{2C}, etc.

(h) *Average Pb concentration.* For the reference method, calculate the average Pb concentration for each filter by averaging the concentrations calculated from the three analyses as described in (g)(1) using equation 1 of this section:

Equation 1

$$R_{iave} = \frac{(R_{iA} + R_{iB} + R_{iC})}{3}$$

Where, i is the filter number.

(i) *Analytical Bias.*

(1) For the audit samples, calculate the average Pb concentration for each strip or filter analyzed by the reference method by averaging the concentrations calculated from the three analyses as described in (g)(1) using equation 2 of this section:

Equation 2

$$Q_{iave} = \frac{(Q_{iA} + Q_{iB} + Q_{iC})}{3}$$

Where, i is audit sample number.

(2) Calculate the percent difference (D_{qi}) between the average Pb concentration for each audit sample and the true Pb concentration (T_{qi}) using equation 3 of this section:

Equation 3

$$D_{qi} = \frac{Q_{iave} - T_{qi}}{T_{qi}} \times 100$$

(3) If any difference value (D_{qi}) exceeds ±5 percent, the bias of the reference method analytical procedure is out-of-control. Corrective action must be taken to determine the source of the error(s) (e.g., calibration standard discrepancies, extraction problems, etc.) and the reference method and audit sample determinations must be repeated according to paragraph (g) of this section, or the entire test procedure (starting with paragraph (e) of this section) must be repeated.

(j) *Acceptable filter pairs.* Disregard all filter pairs for which the Pb concentration, as determined in paragraph (h) of this section by the average of the three reference method determinations, falls outside the range of 30% to 250% of the Pb NAAQS level in µg/m³ for Pb in both TSP and PM₁₀. All remaining filter pairs must be subjected to the tests for precision and comparability in paragraphs (k) and (l) of this section. At least five filter pairs

must be within the specified concentration range for the tests to be valid.

(k) *Test for precision.*

(1) Calculate the precision (P) of the analysis (in percent) for each filter and for each method, as the maximum minus the minimum divided by the average of the three concentration values, using equation 4 or equation 5 of this section:

Equation 4

$$P_{Ri} = \frac{R_{i\max} - R_{i\min}}{R_{iave}} \times 100$$

or

Equation 5

$$P_{Ci} = \frac{C_{i\max} - C_{i\min}}{C_{iave}} \times 100$$

Where, i indicates the filter number.

(2) If a direct reading candidate method is tested, the precision is determined from collocated devices using equation 5 above.

(3) If any reference method precision value (P_{Ri}) exceeds 15 percent, the precision of the reference method analytical procedure is out-of-control. Corrective action must be taken to determine the source(s) of imprecision, and the reference method determinations must be repeated according to paragraph (g) of this section, or the entire test procedure (starting with paragraph (e) of this section) must be repeated.

(4) If any candidate method precision value (P_{Ci}) exceeds 15 percent, the candidate method fails the precision test.

(5) The candidate method passes this test if all precision values (i.e., all P_{Ri}'s and all P_{Ci}'s) are less than 15 percent.

(l) *Test for comparability.*

(1) For each filter or analytical sample pair, calculate all nine possible percent differences (D) between the reference and candidate methods, using all nine possible combinations of the three determinations (A, B, and C) for each method using equation 6 of this section:

Equation 6

$$D_m = \frac{C_{ij} - R_{jk}}{R_{jk}} \times 100$$

Where, i is the filter number, and n numbers from 1 to 9 for the nine possible difference combinations for the three determinations for each method (j = A, B, C, candidate; k = A, B, C, reference).

(2) If none of the percent differences (D) exceeds ±20 percent, the candidate method passes the test for comparability.

(3) If one or more of the percent differences (D) exceed ±20 percent, the candidate method fails the test for comparability.

(4) The candidate method must pass both the precision test (paragraph (k) of this section) and the comparability test (paragraph (l) of this section) to qualify for designation as an equivalent method.

(m) *Method Detection Limit (MDL).* Calculate the estimated MDL using the guidance provided in 40 CFR, Part 136 Appendix B. It is essential that all sample processing steps of the analytical method be included in the determination of the method detection limit. Take a minimum of seven blank filters from each lot to be used and calculate the detection limit by processing each through the entire candidate analytical method. Make all computations according to the defined method with the final results in µg/m³. The MDL of the candidate method must be equal to, or less than 5% of the level of the Pb NAAQS.

■ 13. Table C-3 to Subpart C of Part 53 is revised to read as follows:

TABLE C-3 TO SUBPART C OF PART 53—TEST SPECIFICATIONS FOR PB IN TSP AND PB IN PM₁₀ METHODS

Concentration range equivalent to percentage of NAAQS in µg/m ³ .	30% to 250%
Minimum number of 24-hr measurements.	5
Maximum reference method analytical bias, D _q .	±5%
Maximum precision, P _R or P _C ..	≤15%
Maximum difference (D)	±20%
Estimated Method Detection Limit (MDL), µg/m ³ .	5% of NAAQS level.

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

■ 14. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7410, 7601(a), 7611, and 7619.

Subpart B—[Amended]

■ 15. Section 58.10, is amended by added paragraph subsections (a)(4) and adding paragraph (b)(9) to read as follows:

§ 58.10 Annual monitoring network plan and periodic network assessment.

* * * * *

(a) * * *

(4) A plan for establishing Pb monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the EPA Regional Administrator no later than July 1, 2009

as part of the annual network plan required in paragraph (a)(1) of this section. The plan shall provide for the required source-oriented Pb monitoring sites to be operational by January 1, 2010, and for all required non-source-oriented Pb monitoring sites to be operational by January 1, 2011. Specific site locations for the sites to be operational by January 1, 2011 are not required as part of the July 1, 2009 annual network plan, but shall be included in the annual network plan due to be submitted to the EPA Regional Administrator on July 1, 2010.

* * * * *

(b) * * *

(9) The designation of any Pb monitors as either source-oriented or non-source-oriented according to Appendix D to 40 CFR part 58.

(10) Any source-oriented monitors for which a waiver has been requested or granted by the EPA Regional Administrator as allowed for under paragraph 4.5(a)(ii) of Appendix D to 40 CFR part 58.

(11) Any source-oriented or non-source-oriented site for which a waiver has been requested or granted by the EPA Regional Administrator for the use of Pb-PM₁₀ monitoring in lieu of Pb-TSP monitoring as allowed for under paragraph 2.10 of Appendix C to 40 CFR part 58.

* * * * *

■ 16. Section 58.13 is amended by revising paragraph (b) to read as follows:

§ 58.13 Monitoring network completion.

* * * * *

(b) Notwithstanding specific dates included in this part, beginning January 1, 2008, when existing networks are not in conformance with the minimum number of required monitors specified in this part, additional required monitors must be identified in the next applicable annual monitoring network plan, with monitoring operation beginning by January 1 of the following year. To allow sufficient time to prepare and comment on Annual Monitoring Network Plans, only monitoring requirements effective 120 days prior to the required submission date of the plan (i.e., 120 days prior to July 1 of each year) shall be included in that year's annual monitoring network plan.

■ 17. Section 58.16 is amended by revising paragraph (a) to read as follows:

§ 58.16 Data submittal and archiving requirements.

(a) The State, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO₂; CO; O₃; NO₂;

NO; NO_y; NO_x; Pb-TSP mass concentration; Pb-PM₁₀ mass concentration; PM₁₀ mass concentration; PM_{2.5} mass concentration; for filter-based PM_{2.5} FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated PM_{2.5} mass concentration data; PM_{10-2.5} mass concentration; chemically speciated PM_{10-2.5} mass concentration data; meteorological data from NCore and PAMS sites; average daily temperature and average daily pressure for Pb sites if not already reported from sampler generated records; and metadata records and information specified by the AQS Data Coding Manual (<http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm>). The State, or where appropriate, local agency, may report site specific meteorological measurements generated by onsite equipment (meteorological instruments, or sampler generated) or measurements from the nearest airport reporting ambient pressure and temperature. Such air quality data and information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.

* * * * *

Subpart D—[Amended]

■ 18. Section 58.20 is amended by revising paragraph (e) to read as follows:

§ 58.20 Special purpose monitors (SPM).

* * * * *

(e) If an SPM using an FRM, FEM, or ARM is discontinued within 24 months of start-up, the Administrator will not designate an area as nonattainment for the CO, SO₂, NO₂, or 24-hour PM₁₀ NAAQS solely on the basis of data from the SPM. Such data are eligible for use in determinations of whether a nonattainment area has attained one of these NAAQS.

* * * * *

■ 19. Appendix A to Part 58 is amended to read as follows:

- a. Revising paragraph 1,
- b. Adding paragraph 2.3.1.4,
- c. Revising paragraph 3.3.4,
- d. Revising paragraph 4c,
- e. Revising paragraph 4.4,
- f. Removing paragraph 4.5 and
- g. Revising Table A-2.

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

1. General Information.

This appendix specifies the minimum quality system requirements applicable to

SLAMS air monitoring data and PSD data for the pollutants SO₂, NO₂, O₃, CO, Pb, PM_{2.5}, PM₁₀ and PM_{10-2.5} submitted to EPA. This appendix also applies to all SPM stations using FRM, FEM, or ARM methods which also meet the requirements of Appendix E of this part. Monitoring organizations are encouraged to develop and maintain quality systems more extensive than the required minimums. The permit-granting authority for PSD may require more frequent or more stringent requirements. Monitoring organizations may, based on their quality objectives, develop and maintain quality systems beyond the required minimum. Additional guidance for the requirements reflected in this appendix can be found in the “Quality Assurance Handbook for Air Pollution Measurement Systems”, volume II, part 1 (see reference 10 of this appendix) and at a national level in references 1, 2, and 3 of this appendix.

* * * * *

2.3.1.4 *Measurement Uncertainty for Pb Methods.* The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient variation (CV) of 20 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

* * * * *

3.3.4 Pb Methods.

3.3.4.1 *Flow Rates.* For the Pb Reference Methods (40 CFR Part 50, appendix G and appendix Q) and associated FEMs, the flow rates of the Pb samplers shall be verified and audited using the same procedures described in sections 3.3.2 and 3.3.3 of this appendix.

3.3.4.2 *Pb Analysis Audits.* Each calendar quarter or sampling quarter (PSD), audit the Pb Reference Method analytical procedure using filters containing a known quantity of Pb. These audit filters are prepared by depositing a Pb solution on unexposed filters and allowing them to dry thoroughly. The audit samples must be prepared using batches of reagents different from those used to calibrate the Pb analytical equipment being audited. Prepare audit samples in the following concentration ranges:

Range	Equivalent ambient Pb concentration, µg/m ³
1	30–100% of Pb NAAQS.
2	200–300% of Pb NAAQS.

(a) Audit samples must be extracted using the same extraction procedure used for exposed filters.

(b) Analyze three audit samples in each of the two ranges each quarter samples are analyzed. The audit sample analyses shall be distributed as much as possible over the entire calendar quarter.

(c) Report the audit concentrations (in µg Pb/filter or strip) and the corresponding measured concentrations (in µg Pb/filter or strip) using AQS unit code 077. The percent differences between the concentrations are used to calculate analytical accuracy as described in section 4.1.3 of this appendix.

(d) The audits of an equivalent Pb method are conducted and assessed in the same manner as for the reference method. The flow auditing device and Pb analysis audit samples must be compatible with the specific requirements of the equivalent method.

3.3.4.3 *Collocated Sampling.* The collocated sampling requirements for Pb-TSP and Pb-PM₁₀ shall be determined using the same procedures described in sections 3.3.1 of this appendix with the exception that the first collocated Pb site selected must be the site measuring the highest Pb concentrations in the network. If the site is impractical, alternative sites, approved by the EPA Regional Administrator, may be selected. If additional collocated sites are necessary, collocated sites may be chosen that reflect average ambient air Pb concentrations in the network.

3.3.4.4 *Pb Performance Evaluation Program (PEP) Procedures.* Each year, one performance evaluation audit, as described in section 3.2.7 of this appendix, must be performed at one Pb site in each primary quality assurance organization that has less than or equal to 5 sites and two audits at primary quality assurance organizations with greater than 5 sites. In addition, each year, four collocated samples from primary quality assurance organizations with less than or equal to 5 sites and six collocated samples at primary quality assurance organizations with greater than 5 sites must be sent to an independent laboratory, the same laboratory as the performance evaluation audit, for analysis.

* * * * *

4. Calculations for Data Quality Assessment.

* * * * *

(c) At low concentrations, agreement between the measurements of collocated samplers, expressed as relative percent difference or percent difference, may be relatively poor. For this reason, collocated measurement pairs are selected for use in the precision and bias calculations only when both measurements are equal to or above the following limits:

- (1) TSP: 20 µg/m³.
- (2) Pb: 0.02 µg/m³.
- (3) PM₁₀ (Hi-Vol): 15 µg/m³.
- (4) PM₁₀ (Lo-Vol): 3 µg/m³.
- (5) PM_{10-2.5} and PM_{2.5}: 3 µg/m³.

* * * * *

4.4 Statistics for the Assessment of Pb.

4.4.1 *Precision Estimate.* Follow the same procedures as described for PM₁₀ in section 4.2.1 of this appendix using the data from the collocated instruments. The data pair would only be considered valid if both concentrations are greater than the minimum values specified in section 4(c) of this appendix.

4.4.2 *Bias Estimate.* For the Pb analysis audits described in section 3.3.4.2 and the Pb Performance Evaluation Program described in section 3.3.4.4, follow the same procedure as described in section 4.1.3 for the bias estimate.

4.4.3 *Flow rate calculations.* For the one point flow rate verifications, follow the same procedures as described for PM₁₀ in section 4.2.2; for the flow rate audits, follow the

same procedures as described in section 4.2.3.

* * * * *

TABLE A-2 OF APPENDIX A TO PART 58—MINIMUM DATA ASSESSMENT REQUIREMENTS FOR SLAMS SITES

Method	Assessment method	Coverage	Minimum frequency	Parameters reported
Automated Methods				
1-Point QC for SO ₂ , NO ₂ , O ₃ , CO.	Response check at concentration 0.01–0.1 ppm SO ₂ , NO ₂ , O ₃ , and 1–10 ppm CO.	Each analyzer	Once per 2 weeks	Audit concentration ¹ and measured concentration ² .
Annual performance evaluation for SO ₂ , NO ₂ , O ₃ , CO.	See section 3.2.2 of this appendix.	Each analyzer	Once per year	Audit concentration ¹ and measured concentration ² for each level.
Flow rate verification PM ₁₀ , PM _{2.5} , PM _{10-2.5} .	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM ₁₀ , PM _{2.5} , PM _{10-2.5} .	Check of sampler flow rate using independent standard.	Each sampler	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Collocated sampling PM _{2.5} , PM _{10-2.5} .	Collocated samplers	15%	Every 12 days	Primary sampler concentration and duplicate sampler concentration.
Performance evaluation program PM _{2.5} , PM _{10-2.5} .	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites. 2. 8 valid audits for primary QA orgs, with >5 sites. 3. All samplers in 6 years	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Manual Methods				
Collocated sampling PM ₁₀ , TSP, PM _{10-2.5} , PM _{2.5} , Pb-TSP, Pb-PM ₁₀ .	Collocated samplers	15%	Every 12 days PSD—every 6 days.	Primary sampler concentration and duplicate sampler concentration.
Flow rate verification PM ₁₀ (low Vol), PM _{10-2.5} , PM _{2.5} , Pb-PM ₁₀ .	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Flow rate verification PM ₁₀ (High-Vol), TSP, Pb-TSP.	Check of sampler flow rate	Each sampler	Once every quarter	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM ₁₀ , TSP, PM _{10-2.5} , PM _{2.5} , Pb-TSP, Pb-PM ₁₀ .	Check of sampler flow rate using independent standard.	Each sampler, all locations	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Pb audit strips Pb-TSP, Pb-PM ₁₀ .	Check of analytical system with Pb audit strips.	Analytical	Each quarter	Actual concentration and audit concentration.
Performance evaluation program PM _{2.5} , PM _{10-2.5} .	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites. 2. 8 valid audits for primary QA orgs, with >5 sites. 3. All samplers in 6 years	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Performance evaluation program Pb-TSP, Pb-PM ₁₀ .	Collocated samplers	1. 1 valid audit and 4 collocated samples for primary QA orgs, with >5 sites. 2. 2 valid audits and 6 collocated samples for primary QA orgs, with >5 sites.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration. Primary sampler concentration and duplicate sampler concentration.

¹ Effective concentration for open path analyzers.
² Corrected concentration, if applicable, for open path analyzers.

■ 20. Appendix C to Part 58 is amended by adding paragraph 2.10 to read as follows:

* * * * *

2.10 Use of Pb-PM₁₀ at SLAMS Sites.
 2.10.1 The EPA Regional Administrator may approve the use of a Pb-PM₁₀ FRM or Pb-PM₁₀ FEM sampler in lieu of a Pb-TSP

sampler as part of the network plan required under part 58.10(a)(4) in the following cases.
 2.10.1.1 Pb-PM₁₀ samplers can be approved for use at the non-source-oriented sites required under paragraph 4.5(b) of

Appendix D to part 58 if there is no existing monitoring data indicating that the maximum arithmetic 3-month mean Pb concentration (either Pb-TSP or Pb-PM₁₀) at the site was equal to or greater than 0.10 micrograms per cubic meter during the previous 3 years.

2.10.1.2 Pb-PM₁₀ samplers can be approved for use at source-oriented sites required under paragraph 4.5(a) if the monitoring agency can demonstrate (through modeling or historic monitoring data from the last 3 years) that Pb concentrations (either Pb-TSP or Pb-PM₁₀) will not equal or exceed 0.10 micrograms per cubic meter on an arithmetic 3-month mean and the source is expected to emit a substantial majority of its Pb in the fraction of PM with an aerodynamic diameter of less than or equal to 10 micrometers.

2.10.2 The approval of a Pb-PM₁₀ sampler in lieu of a Pb-TSP sampler as allowed for in paragraph 2.10.1 above will be revoked if measured Pb-PM₁₀ concentrations equal or exceed 0.10 micrograms per cubic meter on an arithmetic 3-month mean. Monitoring agencies will have up to 6 months from the end of the 3-month period in which the arithmetic 3-month Pb-PM₁₀ mean concentration equaled or exceeded 0.10 micrograms per cubic meter to install and begin operation of a Pb-TSP sampler at the site.

■ 22. Appendix D to Part 58 is amended by revising paragraph 4.5 to read as follows:

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

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4.5 *Lead (Pb) Design Criteria.* (a) State and, where appropriate, local agencies are required to conduct ambient air Pb monitoring taking into account Pb sources which are expected to or have been shown to contribute to a maximum Pb concentration in ambient air in excess of the NAAQS, the potential for population exposure, and logistics. At a minimum, there must be one source-oriented SLAMS site located to measure the maximum Pb concentration in ambient air resulting from each Pb source which emits 1.0 or more tons per year based on either the most recent National Emission Inventory (<http://www.epa.gov/ttn/chieff/eiinformation.html>) or other scientifically justifiable methods and data (such as

improved emissions factors or site-specific data) taking into account logistics and the potential for population exposure.

(i) One monitor may be used to meet the requirement in paragraph 4.5(a) for all sources involved when the location of the maximum Pb concentration due to one Pb source is expected to also be impacted by Pb emissions from a nearby source (or multiple sources). This monitor must be sited, taking into account logistics and the potential for population exposure, where the Pb concentration from all sources combined is expected to be at its maximum.

(ii) The Regional Administrator may waive the requirement in paragraph 4.5(a) for monitoring near Pb sources if the State or, where appropriate, local agency can demonstrate the Pb source will not contribute to a maximum Pb concentration in ambient air in excess of 50% of the NAAQS (based on historical monitoring data, modeling, or other means). The waiver must be renewed once every 5 years as part of the network assessment required under 58.10(d).

(b) State and, where appropriate, local agencies are required to conduct Pb monitoring in each CBSA with a population equal to or greater than 500,000 people as determined by the latest available census figures. At a minimum, there must be one non-source-oriented SLAMS site located to measure neighborhood scale Pb concentrations in urban areas impacted by re-entrained dust from roadways, closed industrial sources which previously were significant sources of Pb, hazardous waste sites, construction and demolition projects, or other fugitive dust sources of Pb.

(c) The EPA Regional Administrator may require additional monitoring beyond the minimum monitoring requirements contained in 4.5(a) and 4.5(b) where the likelihood of Pb air quality violations is significant or where the emissions density, topography, or population locations are complex and varied.

(d) The most important spatial scales for source-oriented sites to effectively characterize the emissions from point sources are microscale and middle scale. The most important spatial scale for non-source-oriented sites to characterize typical lead concentrations in urban areas is the neighborhood scale. Monitor siting should be conducted in accordance with 4.5(a)(i) with respect to source-oriented sites.

(1) Microscale—This scale would typify areas in close proximity to lead point

sources. Emissions from point sources such as primary and secondary lead smelters, and primary copper smelters may under fumigation conditions likewise result in high ground level concentrations at the microscale. In the latter case, the microscale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Pb monitors in areas where the public has access, and particularly children have access, are desirable because of the higher sensitivity of children to exposures of elevated Pb concentrations.

(2) Middle scale—This scale generally represents Pb air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may for example, include schools and playgrounds in center city areas which are close to major Pb point sources. Pb monitors in such areas are desirable because of the higher sensitivity of children to exposures of elevated Pb concentrations (reference 3 of this appendix). Emissions from point sources frequently impact on areas at which single sites may be located to measure concentrations representing middle spatial scales.

(3) Neighborhood scale—The neighborhood scale would characterize air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Sites of this scale would provide monitoring data in areas representing conditions where children live and play. Monitoring in such areas is important since this segment of the population is more susceptible to the effects of Pb. Where a neighborhood site is located away from immediate Pb sources, the site may be very useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

(d) Technical guidance is found in references 4 and 5 of this appendix. These documents provide additional guidance on locating sites to meet specific urban area monitoring objectives and should be used in locating new sites or evaluating the adequacy of existing sites.

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