Tuesday,
May 20, 2008

Part II

Environmental Protection Agency

40 CFR Parts 50, 51, 53 et al.
National Ambient Air Quality Standards
for Lead; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 51, 53 and 58

[EPA–HQ–OAR–2006–0735; FRL–8563–9]

RIN 2060–AN83

National Ambient Air Quality Standards for Lead

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for lead (Pb), EPA proposes to make revisions to the primary and secondary NAAQS for Pb to provide requisite protection of public health and welfare, respectively. EPA proposes to revise various elements of the primary standard to provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurocognitive and neurobehavioral effects, in children. With regard to the level and indicator of the standard, EPA proposes to revise the level to within the range of 0.10 to 0.30 $\mu g/m^3$ in conjunction with retaining the current indicator of Pb in total suspended particles (Pb-TSP) but with allowance for the use of $Pb-PM_{10}$ data, and solicits comment on alternative levels up to 0.50 $\mu g/m^3$ and down below 0.10 $\mu g/m^3$. With regard to the averaging time and form of the standard, EPA proposes 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. EPA also solicits comment on revising the indicator to $Pb-PM_{10}$ and on the same broad range of levels on which EPA is soliciting comment for the Pb-TSP indicator (up to 0.50 $\mu g/m^3$). EPA also invites comment on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero. EPA proposes to make the secondary standard identical in all respects to the proposed primary standard.

EPA is also proposing corresponding changes to data handling procedures, including the treatment of exceptional events, and to 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 providing guidance on

its proposed approach for implementing the proposed revised primary and secondary standards for Pb.

Consistent with the terms of a court order, by September 15, 2008 the Administrator will sign a notice of final rulemaking for publication in the **Federal Register**.

DATES: Comments must be received by July 21, 2008. Under the Paperwork Reduction Act, comments on the information collection provisions must be received by OMB on or before June 19, 2008.

Public Hearings: EPA intends to hold public hearings on this proposed rule in June 2008 in St. Louis, Missouri and Baltimore, Maryland. These will be announced in a separate **Federal Register** notice that provides details, including specific times and addresses, for these hearings.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2006–0735 by one of the following methods:

• *http://www.regulations.gov:* Follow the online instructions for submitting comments.

• *E-mail: a-and-r-Docket@epa.gov.*

• *Fax:* 202–566–9744.

• *Mail:* Docket No. EPA–HQ–OAR–2006–0735, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies.

• *Hand Delivery:* Docket No. EPA–HQ–OAR–2006–0735, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2006–0735. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly

to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the 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.

FOR FURTHER INFORMATION CONTACT: For further information in general or specifically with regard to sections I through III or VII, contact Dr. Deirdre Murphy, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C504–06, Research Triangle Park, NC 27711; telephone: 919–541–0729; fax: 919–541–0237; e-mail: *Murphy.deirdre@epa.gov.* With regard to Section IV, contact Mr. Mark Schmidt, Air Quality Analysis Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C304–04, Research Triangle Park, NC 27711; telephone: 919–541–2416; fax: 919–541–1903; e-mail: *Schmidt.mark@epa.gov.* With regard to Section V, contact Mr. Kevin Cavender,

Air Quality Analysis Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C304–06, Research Triangle Park, NC 27711; *telephone:* 919–541–2364; fax: 919–541–1903; e-mail: *Cavender.kevin@epa.gov.* With regard to Section VI, contact Mr. Larry Wallace, Ph.D., Air Quality Policy Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C539–01, Research Triangle Park, NC 27711; *telephone:* 919–541–0906; fax: 919–541–0824; e-mail: *Wallace.larry@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

What Should I Consider as I Prepare My Comments for EPA?

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

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

• Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

• Follow directions—the agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

• Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.

• Describe any assumptions and provide any technical information and/ or data that you used.

• If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

• Provide specific examples to illustrate your concerns, and suggest alternatives.

• Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

• Make sure to submit your comments by the comment period deadline identified.

Availability of Related Information

A number of documents relevant to this rulemaking, including the advance notice of proposed rulemaking (72 FR 71488), the *Air Quality Criteria for Lead* (Criteria Document) (USEPA, 2006a), the Staff Paper, related risk assessment reports, and other related technical documents are available on EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site at *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_index.html.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

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I. Background

A. 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 that ''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 [a] 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 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 pollution 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

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[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).

[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. 531 U.S. at 466. Thus, EPA may not take into account possible public health impacts from the economic cost of implementation. *Id*.

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.

B. History of Lead NAAQS Reviews

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 (μg/m³), 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 μg/m³, 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).

C. 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).[4] 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 increased awareness that children face disproportionate risks from environmental health and safety hazards (62 FR 19885).[5] 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 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.[6] Further, in 1991, EPA lowered the maximum levels of Pb permitted in public water systems from 50 parts per billion (ppb) to 15 ppb (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, 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

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[4] As described in Section III below the CDC stated in 2005 that no "safe" threshold for blood Pb levels in young children has been identified (CDC, 2005a).

[5] 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.

[6] See "Criteria for Classification of Solid Waste Disposal Facilities and Practices and Criteria for Municipal Solid Waste Landfills: Disposal of Residential Lead-Based Paint Waste; Final Rule" EPA–HQ–RCRA–2001–0017.

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) 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. States and tribes may become authorized to implement this rule, and 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.[7] For example, 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 conservation of energy and materials. These include the Resource Conservation Challenge (*http://www.epa.gov/epaoswer/osw/conserve/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#crts*), and activities to reduce the practice of backyard trash burning (*http://www.epa.gov/msw/backyard/pubs.htm*).

Efforts such as those programs described above have been successful in that 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 children [9] are at the low end of the historic range of blood Pb levels for general population of children aged 1–5 years. However, as discussed in Section II.B.1.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 decline in blood Pb levels in the United States has resulted from coordinated, intensive efforts at the national, state, and local levels. The Agency has continued to grapple with soil and dust Pb levels from the historical use of Pb in paint and gasoline and other sources.

EPA's research program, with other Federal agencies, defines, 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

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[7] See, e.g., ''Hazardous Waste Management System; Identification and Listing of Hazardous Waste: Inorganic Chemical Manufacturing Wastes; Land Disposal Restrictions for Newly Identified Wastes and CERCLA Hazardous Substance Designation and Reportable Quantities; Final Rule'', *http://www.epa.gov/epaoswer/hazwaste/state/revision/frs/fr195.pdf* and *http://www.epa.gov/epaoswer/hazwaste/ldr/basic.htm.*

[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/conserve/resources/msw-2005.pdf.*

[9] The 95th percentile value for the 2003–2004 NHANES is 5.1 µg/dL (Axelrad, 2008).

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*).

D. Current Lead NAAQS Review

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. 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 criteria from previous reviews.

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

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,[10] averaging time, form,[11] 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 71488–71544). 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. The substantial number of comments we received on the Pb NAAQS ANPR helped inform the narrower range of options we are proposing and taking comment on today. The new process (described at *http://www.epa.gov/ttn/naaqs/*.) is being incorporated into the various ongoing NAAQS reviews being conducted by the Agency, including the current review of the Pb NAAQS.

A public meeting of the 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. Information about this meeting was published in the **Federal Register** on November 20, 2007 (72 FR 65335–65336), transcripts of the meeting are in the Docket for this review and CASAC's letter to the Administrator (Henderson, 2008) is also available on the EPA Web site (*http://www.epa.gov/sab*).

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

[11] The "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.

A public comment period for the ANPR extended from December 17, 2007 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 campaign), 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 industries or industry organizations. Although the Agency has not developed formal responses to comments received on the ANPR, these comments have been considered in the development of this notice and are generally described in subsequent sections on proposed conclusions with regard to the adequacy of the standards and with regard to the Administrator's proposed decisions on revisions to the standards.

The schedule for completion of this review is governed by a judicial order in *Missouri Coalition for the Environment*, v. *EPA* (No. 4:04CV00660 ERW, Sept. 14, 2005). The order governing this review, entered by the court on September 14, 2005 and amended on April 29, 2008, specifies that EPA sign, for publication, notices of proposed and final rulemaking concerning its review of the Pb NAAQS no later than May 1, 2008 and September 15, 2008, respectively. In light of the compressed schedule ordered by the court for issuing the final rule, EPA may be able to respond only to those comments submitted during the public comment period on this proposal. EPA has considered all of the comments submitted to date in preparing this proposal, but if commenters believe that comments submitted on the ANPR are fully applicable to the proposal and wish to ensure that those comments are addressed by EPA as part of the final rulemaking, the earlier comments should be resubmitted during the comment period on this proposal.

This action presents the Administrator's proposed decisions on the review of the current primary and secondary Pb standards. Throughout this preamble a number of judgments, conclusions, findings, and determinations proposed by the Administrator are noted. While they identify the reasoning that supports this proposal, they are not intended to be final or conclusive in nature. The EPA invites general, specific, and/or technical comments on all issues involved with this proposal, including

all such proposed judgments, conclusions, findings, and determinations.

II. Rationale for Proposed Decision on the Primary Standard

This section presents the rationale for the Administrator's proposed 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. With regard to the primary standard for Pb, EPA is proposing options for the revision of 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, particularly neurocognitive and neurobehavioral effects. With regard to the level and indicator of the standard, EPA proposes to revise the level of the standard to a level within the range of 0.10 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-PM$_{10}$ data. With regard to the form and averaging time of the standard, EPA proposes the following options: (1) To retain the current averaging time of a calendar quarter and the current not-to-be-exceeded form, revised so as to apply across a 3-year span, and (2) to revise the averaging time to a calendar month and the form to be the second-highest monthly average across a 3-year span. EPA also solicits comment on revising the indicator to Pb-PM$_{10}$.

As discussed more fully below, this proposal is based on a thorough review, in the Criteria Document, of the latest scientific information on human health effects associated with the presence of Pb in the ambient air. This proposal also takes into account: (1) Staff assessments of the most policy-relevant information in the Criteria Document and staff analyses of air quality, human exposure, and health risks presented in the Staff Paper, upon which staff recommendations for revisions to the primary Pb standard are based; (2) CASAC advice and recommendations, as reflected in discussions of the ANPR and drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in CASAC's letters to the Administrator; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately.

In developing this proposal, EPA has drawn upon an integrative synthesis of the entire body of evidence, published

through late 2006, on human health effects associated with Pb exposure. Some 6000 newly available studies were considered in this review. As discussed below in section II.B, 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). This proposal also draws upon the results of the quantitative exposure and risk assessments, discussed below in section II.C. Evidence- and exposure/risk-based considerations that form the basis for the Administrator's proposed decisions on the adequacy of the current standard and on the elements of the proposed alternative standards are discussed below in section II.D.2 and II.D.3, respectively.

A. Multimedia, Multipathway Considerations and Background

1. Atmospheric Emissions and Distribution of Lead

Lead is emitted into the air from many sources encompassing a wide variety of source types (Staff Paper, Section 2.2). Further, once deposited out of the air, Pb can subsequently be resuspended into the air (CD, pp. 2–62 to 2–66). There are over 100 categories of sources of Pb emissions included in the EPA's 2002 National Emissions Inventory (NEI),[12] the top five of which include: Mobile sources (leaded aviation gas)[13]; industrial, commercial, institutional and process boilers; utility boilers; iron and steel foundries; and primary Pb smelting (Staff Paper Section 2.2). Further, there are some 13,000 industrial, commercial or institutional point sources in the 2002 NEI, each with one or more processes that emit Pb to the atmosphere. In addition to these 13,000 sources, there are approximately 3,000 airports at which leaded gasoline is used (Staff Paper, p. 2–8). Among these sources, more than one thousand are estimated to emit at least a tenth of a ton of Pb per year (Staff Paper, Section 2.2.3). Because of its persistence, Pb emissions contribute to media

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[12] As noted in the Staff Paper, quantitative estimates of emissions associated with resuspension of soil-bound Pb particles and contaminated road dust are not included in the 2002 NEI.

[13] The emissions estimates identified as mobile sources in the current NEI are currently limited to combustion of leaded aviation gas in piston-engine aircraft. Lead emissions estimates for other mobile source emissions of Pb (e.g., brake wear, tire wear, loss of Pb wheel weights and others) are not included in the current NEI.

concentrations for some time into the future.

Lead emitted to the air is predominantly in particulate form, with the particles occurring in many sizes. Once emitted, Pb 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. Additionally, once deposited, Pb particles can be resuspended back into the air and undergo a second dispersal. Thus, the atmospheric transport processes of Pb contribute to its broad dispersal, with larger particles generally occurring as a greater contribution to total airborne Pb at locations closer to the point of emission than at more distant locations where the relative contribution from smaller particles is greater (CD, Section 2.3.1 and p. 3–3).

Airborne concentrations of Pb in total suspended particulate matter (Pb-TSP) in the United States have fallen substantially since the current Pb NAAQS was set in 1978.[14] Despite this decline, there have still been a small number of areas, associated with large stationary sources of Pb, that have not met the NAAQS over the past few years. The average maximum quarterly mean concentration for the time period 2003–2005 among source-oriented monitoring sites in the U.S. is 0.48 µg/m³, while the corresponding average for non-source-oriented sites is 0.03 µg/m³.[15] The average and median among all monitoring-site-specific maximum quarterly mean concentrations for this time period are 0.17 µg/m³ and 0.03 µg/m³, respectively. Coincident with the historical trend in reduction in Pb levels, however, there has also been a substantial reduction in number of Pb-TSP monitoring sites. As described below in section II.B.3.b, many of the highest Pb emitting sources in the 2002 NEI do not have nearby Pb-TSP monitors, which may lead to underestimates of the extent of occurrences of relatively higher Pb concentrations (as recognized in the Staff Paper, Section 2.3.2 and, with

[14] Air Pb concentrations nationally are estimated to have declined more than 90% since the early 1980s, in locations not known to be directly influenced by stationary sources (Staff Paper, pp. 2–22 to 2–23).

[15] The data set included data for 189 monitor sites meeting the data analysis screening criteria. Details with regard to the data set and analyses supporting the values provided here are presented in Section 2.3.2 of the Staff Paper.

regard to more recent analysis, in section II.B.3.b below).

2. Air-Related Human Exposure Pathways

As when the standard was set in 1978, we recognize that exposure to air Pb can occur directly by inhalation, or indirectly by ingestion of Pb-contaminated food, water or nonfood materials including dust and soil (43 FR 46247). 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 (CD, pp. 3–1 to 3–2). Accordingly, people are exposed to Pb emitted into ambient air by both inhalation and ingestion pathways. In general, air-related pathways include those pathways where Pb passes through ambient air on its path from a source to human exposure. EPA considers risks to public health from exposure to Pb that was emitted into the air as relevant to our consideration of the primary standard. Therefore , we consider these air-related pathways to be policy-relevant in this review. Air-related Pb exposure pathways include: Inhalation of airborne Pb (that may include Pb emitted into the air and deposited and then resuspended); and ingestion of Pb that, once airborne, has made its way into indoor dust, outdoor dust or soil, dietary items (e.g., crops and livestock), and drinking water (e.g., CD, Figure 3–1).

Ambient air Pb contributes to Pb in indoor dust through transport of Pb suspended in ambient air that is then deposited indoors and through transport of Pb that has deposited outdoors from ambient air and is transported indoors in ways other than through ambient air (CD, Section 3.2.3; Adgate et al., 1998). For example, infiltration of ambient air into buildings brings airborne Pb indoors where deposition of particles contributes to Pb in dust on indoor surfaces (CD, p. 3–28; Caravanos et al., 2006a). Indoor dust may be ingested (e.g., via hand-to-mouth activity by children; CD, p. 8–12) or may be resuspended through household activities and inhaled (CD, p. 8–12). Ambient air Pb can also deposit onto outdoor surfaces (including surface soil) with which humans may come into contact (CD, Section 2.3.2; Farfel et al., 2003; Caravanos et al., 2006a, b). Human contact with this deposited Pb may result in incidental ingestion from this exposure pathway and may also result in some of this Pb being carried indoors (e.g., on clothes and shoes) adding to indoor dust Pb (CD, p. 3–28;

von Lindern et al., 2003a, b). Additionally, Pb from ambient air that deposits on outdoor surfaces may also be resuspended and carried indoors in the air where it can be inhaled. Thus, indoor dust receives air-related Pb directly from ambient air coming indoors and also more indirectly, after deposition from ambient air onto outdoor surfaces.

As mentioned above, humans may contact Pb in dust on outdoor surfaces, including surface soil and other materials, that has deposited from ambient air (CD, Section 3.2; Caravanos et al., 2006a; Mielke et al., 1991; Roels et al., 1980). Human exposure to this deposited Pb can occur through incidental ingestion, and, when the deposited Pb is resuspended, by inhalation. Atmospheric deposition of Pb also contributes to Pb in vegetation, both as a result of contact with above ground portions of the plant and through contributions to soil and transport of Pb into roots (CD, pp. 7–9 and AXZ7–39; USEPA, 1986a, Sections 6.5.3 and 7.2.2.2.1). Livestock may subsequently be exposed to Pb in vegetation (e.g., grasses and silage) and in surface soils via incidental ingestion of soil while grazing (USEPA 1986a, Section 7.2.2.2.2). Atmospheric deposition is estimated to comprise a significant proportion of Pb in food (CD, p. 3–48; Flegel et al., 1990; Juberg et al., 1997; Dudka and Miller, 1999). Atmospheric deposition outdoors also contributes to Pb in surface waters, although given the widespread use of settling or filtration in drinking water treatment, air-related Pb is generally a small component of Pb in treated drinking water (CD, Section 2.3.2 and p. 3–33).

Air-related exposure pathways are affected by changes to air quality, including changes in concentrations of Pb in air and/or 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 (CD, pp. 3–18 to 3–19, pp. 3–23 to 2–24). Thus, because of the roles in human exposure pathways of both air concentration and air deposition, and 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 (CD, pp. 3–18 to 3–19).

Exposure pathways tied most directly to ambient air, and that consequently have the potential to respond relatively more quickly to changes in air Pb, include inhalation of ambient air, and ingestion of Pb in indoor dust directly contaminated with Pb from ambient air.[16] Lead from ambient air contaminates indoor dust directly when outdoor air comes inside (through open doors or windows, for example) and Pb in that air deposits to indoor surfaces (Caravanos *et al.*, 2006a; CD, p. 8–22). This includes Pb that was previously deposited outdoors and is then resuspended and transported indoors. Lead in dust on outdoor surfaces also responds to air deposition (Caravanos *et al.*, 2006). Pathways in which the air quality impact is reflected over a somewhat longer time frame generally are associated with outdoor atmospheric deposition, and include ingestion pathways such as the following: (1) Ingestion of Pb in outdoor soil; (2) ingestion of Pb in indoor dust indirectly contaminated with Pb from the outdoor air (e.g, ''tracking in'' of Pb deposited to outdoor surface soil, as compared to ambient air transport of resuspended outdoor soil); (3) ingestion of Pb in diet that is attributable to deposited air Pb, and; (4) ingestion of Pb in drinking water that is attributable to deposited air Pb (e.g., Pb entering water bodies used for drinking supply).

3. Nonair-Related and Air-Related Background Human Exposure Pathways

As when the standard was set in 1978, there continue to be multiple sources of exposure, both air-related and others (nonair-related). 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. In the context of NAAQS for other criteria pollutants which are not multimedia in nature, such as ozone, the term policy-relevant background is used to distinguish anthropogenic air emissions from naturally occurring non-anthropogenic emissions to separate pollution levels that can be controlled by U.S. regulations from levels that are generally uncontrollable by the United States (USEPA, 2007d). In the case of Pb, however, due to the multimedia, multipathway nature of human exposures to Pb, policy-relevant

background is defined more broadly to include not only the ''quite low'' levels of naturally occurring Pb emissions into the air from non-anthropogenic sources such as volcanoes, sea salt, and windborne soil particles from areas free of anthropogenic activity (see below), but also Pb from nonair sources. These are collectively referred to as ''policy-relevant background.''

The pathways of human exposure to Pb that are not air-related include ingestion of Pb from indoor Pb paint [17], Pb in diet as a result of inadvertent additions during food processing, and Pb in drinking water attributable to Pb in distribution systems (CD, Chapter 3). Other less prevalent, potential pathways of Pb exposure that are not air-related include ingestion of some calcium supplements or of food contaminated during storage in some Pb glazed glassware, and hand-to-mouth contact with some imported vinyl miniblinds or with some hair dyes containing Pb acetate, as well as some cosmetics and folk remedies (CD, pp. 3–50 to 3–51).

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 (CD, Section 2.2.1). The impact of these sources on current air concentrations is expected to be quite low (relative to current concentrations) and has been estimated to fall within the range from 0.00002 µg/m³ and 0.00007 µg/m³ based on mass balance calculations for global emissions (CD, Section 3.1 and USEPA 1986, Section 7.2.1.1.3). The midpoint in this range, 0.00005 µg/m³, has been used in the past to represent the contribution of naturally occurring air Pb to total human exposure (USEPA 1986, Section 7.2.1.1.3). The data available to derive such an estimate are limited and such a value might be expected to vary geographically with the natural distribution of Pb. Comparing this to reported air Pb measurements is complicated by limitations of the common analytical methods and by inconsistent reporting practices. This value is one half the lowest reported nonzero value in AQS. Little information is available regarding 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, any credible estimate of policy-relevant background in air is likely insignificant

in comparison to the contributions from exposures to nonair media.

4. Contributions to Children's Lead Exposures

As when the standard was set in 1978, EPA recognizes that there remain today contributions to blood Pb levels from nonair sources. The relative contribution of Pb in 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 (CD, p. 3–43).[18] For young children, however, ingestion of indoor dust can be a significant Pb exposure pathway, such that dust ingested via hand-to-mouth activity can be a more important source of Pb exposure than inhalation, although indoor dust can also be resuspended through household activities and pose an inhalation risk as well (CD, p. 3–27 to 3–28; Melnyk *et al.* 2000).[19]

Estimating contributions from nonair sources is complicated by the existence of multiple and varied air-related pathways (as described in section II.A.2 above), 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 outdoor dust/soil, do

[16] We note that in the risk assessment, we only assessed alternate standard impacts on the subset of air-related pathways that respond relatively quickly to changes in air Pb.

[17] Weathering of outdoor Pb paint may also contribute to soil Pb levels adjacent to the house.

[18] ''Some recent exposure studies have evaluated the relative importance of diet to other routes of Pb exposure. In reports from the NHEXAS, Pb concentrations measured in households throughout the Midwest were significantly higher in solid food compared to beverages and tap water (Clayton *et al.*, 1999; Thomas *et al.*, 1999). However, beverages appeared to be the dominant dietary pathway for Pb according to the statistical analysis (Clayton *et al.*, 1999), possibly indicating greater bodily absorption of Pb from liquid sources (Thomas *et al.*, 1999). Dietary intakes of Pb were greater than those calculated for intake from home tap water or inhalation on a µg/day basis (Thomas *et al.*, 1999). The NHEXAS study in Arizona showed that, for adults, ingestion was a more important Pb exposure route than inhalation (O'Rourke *et al.*, 1999).'' (CD, p. 3–43)

[19] For example, the Criteria Document states the following: ''Given the large amount of time people spend indoors, exposure to Pb in dusts and indoor air can be significant. For children, dust ingested via hand-to-mouth activity is often a more important source of Pb exposure than inhalation. Dust can be resuspended through household activities, thereby posing an inhalation risk as well. House dust Pb can derive both from Pb-based paint and from other sources outside the home. The latter include Pb-contaminated airborne particles from currently operating industrial facilities or resuspended soil particles contaminated by deposition of airborne Pb from past emissions.'' (CD, p. E–6)

not usually distinguish between outdoor soil/dust Pb resulting from historical emissions and outdoor soil/dust Pb resulting from recent emissions. Further, while indoor dust Pb has been identified as being a predominant contributor to children's blood Pb, available studies do not generally distinguish the different pathways (air-related and other) contributing to indoor dust Pb. The exposure assessment for children performed for this review has employed available data and methods to develop estimates intended to inform a characterization of these pathways (as described in section II.C below).

Relative contributions to a child's total Pb exposure from air-related exposure pathways (such as those identified in the sections above) 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), access to other sources of Pb exposure such as Pb paint, tap water affected by plumbing containing Pb and access to Pb-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 (CD, section 3.2). In other cases, such as children living in older housing with peeling paint or where renovations have occurred, the dominant source may be lead paint used in the house in the past (CD, pp. 3–50 and 3–51). Depending on Pb levels in a home's tap water, drinking water can sometimes be a significant source (CD, section 3.3). And in still other cases, there may be more of a mixture of contributions from multiple sources, with no one source dominating (CD, Chapter 3).

As recognized in sections B.1.1 and II.B.3.a, blood Pb levels are the commonly used index of exposure for Pb and they reflect external sources of exposure, behavioral characteristics and physiological factors. Lead derived from differing sources or taken into the body as a result of differing exposure pathways (e.g., air- as compared to nonair-related), is not easily distinguished. As mentioned above, complications to consideration of estimates of air-related or conversely, nonair, blood Pb levels are the roles of air Pb in human exposure pathways and the persistence of Pb in the environment. As described in section II.A.2, air-related pathways (those in which Pb passes through the air on its path from source to human exposure) are varied, including inhalation and ingestion, indoor dust, outdoor dust/soil

and diet, Pb suspended in and deposited from air, and encompassing a range of time frames from more immediate to less so. Estimates of blood Pb levels associated with air-related exposure pathways or only with nonair exposure pathways will vary depending on how completely the air-related pathways are characterized.

Consistent with reductions in air Pb concentrations (as described in section II.A.1 above) which contribute to blood Pb, nonair contributions have also been reduced. For example, the use of Pb paint in new houses has declined substantially over the 20th century, such that according to the *National Survey of Lead and Allergens in Housing* (USHUD, 2002) an estimated 24% of U.S. housing constructed between 1960 and 1978; 69% of the housing constructed between 1940 and 1959; and 87% of the pre-1940 housing contains lead-based paint. Additionally, Pb contributions to diet have been reported to have declined significantly since 1978, perhaps as much as 70% or more between then and 1990 (WHO, 1995) and the 2006 Criteria Document identifies a drop in dietary Pb intake by 2 to 5 year olds of 96% between the early 1980s and mid 1990s (CD, Section 3.4 and p. 8–14).[20] These reductions are generally attributed to reductions in gasoline-related airborne Pb as well as the reduction in use of Pb solder in canning food products (CD, Section 3.4).[21] There have also been reductions in tap water Pb levels (CD, section 3.3 and pp. 8–13 to 8–14). Contamination from the distribution/plumbing system appears to remain the predominant source of Pb in the drinking water (CD, section 3.3 and pp. 8–013 to 8–14).

The availability of estimates of blood Pb levels resulting only from air-related sources and exposures or only from those unrelated to air is limited and, given the discussion above, would be expected to vary for different populations. In addition to potential differences in air-related and nonair-related blood Pb levels among populations with different exposure circumstances (e.g., relatively more or lesser exposure to air-related Pb), the

absolute levels may also vary among different age groups. As described in section II.B.1.b, average total blood Pb levels in the U.S. differ among age groups, with levels being highest in children aged one to five years old. We also note that behavioral characteristics that influence Pb exposures vary among age groups. For example as noted above, the predominant Pb exposure pathways may differ between adults and children. The extent of any quantitative impact of these differences on estimates of nonair blood Pb levels is unknown.[22]

In their advice to the Agency on levels for the standard, the CASAC Pb Panel explored several approaches to deriving a level, one of which required an estimate of the nonair component of blood Pb for the average child. They recommended consideration of 1.0 to 1.4 µg/dL or lower for such an estimate for the average nonair blood Pb level for young children (Henderson, 2007a, p. D–1). This range was developed with consideration of simulations of the integrated exposure and uptake biokinetic (IEUBK) model for lead for which the exposure concentration inputs included zero air concentration and concentrations for soil and dust of 50 ppm and 35 ppm, respectively (Henderson, 2007a, p. F–60).[23][24][25]

As is evident from the prior discussion, the many different exposure pathways contributing to children's blood Pb levels, and other factors, complicate our consideration of the available data with regard to characterization of levels particular to specific pathways, air-related or otherwise.

B. Health Effects Information

The following summary focuses on health endpoints associated with the range of exposures considered to be most relevant to current exposure levels and makes note of several key aspects of the health evidence for Pb. First (as

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[20] Additionally, the 1977 Criteria Document included a dietary Pb intake estimate for the general population of 100 to 350 µg Pb/day, with estimates near and just below 100 µg/day for young children (USEPA 1977, pp. 1–2 and 12–32) and the 2006 Criteria Document cites recent studies (for the mid-1990s) indicating a dietary intake ranging from 2 to 10 µg Pb/day for children (CD, Section 3.4 and p. 8–14).

[21] Sources of Pb in food were identified in the 1986 Criteria Document as including air-related sources, metals used in processing raw foodstuffs, solder used in packaging and water used in cooking (1986a, section 3.1.2).

[22] As noted earlier in this section, for children, dust ingestion by hand-to-mouth activity can be an important source of Pb exposure, while for adults, dietary Pb can be predominant.

[23] The soil and dust levels are described as "typical geochemical non-air input levels for dust and soil" (Henderson, 2007a, p. F–60). The values used for these levels in this simulation fall within the range of 1 to 200 ppm described in the Criteria Document for soil not influenced by sources (CD, p. 3–18).

[24] The other IEUBK inputs (e.g., exposure and biokinetic factors) were those used in the IEUBK modeling for the risk assessment in this review (Henderson, 2007a, p. F–60).

[25] Individual CASAC member comments describing the IEUBK simulations stated that the modeling produced a nonair blood Pb level of "1.4 µg/dL as a geometric mean" (Henderson, 2007a, p. F–61).

described in Section II.A, above), because exposure to atmospheric Pb particles occurs not only via direct inhalation of airborne particles, but also via ingestion of deposited ambient Pb, the exposure considered is multimedia and multipathway in nature, occurring via both the inhalation and ingestion routes. Second, the exposure index or dose metric most commonly used and associated with health effects information is an internal biomarker (*i.e.*, blood Pb). Additionally, the exposure duration of interest (*i.e.*, that influencing internal dose pertinent to health effects of interest) may span months to potentially years, as does the time scale of the environmental processes influencing Pb deposition and fate. Lastly, the nature of the evidence for the health effects of greatest interest for this review, neurological effects, particularly neurocognitive and neurobehavioral effects, in young children, are epidemiological data substantiated by toxicological data that provide biological plausibility and insights on mechanisms of action (CD, sections 5.3, 6.2 and 8.4.2).

In recognition of the multi-pathway aspects of Pb, and the use of an internal exposure metric in health risk assessment, the next section describes the internal disposition or distribution of Pb, and the use of blood Pb as an internal exposure or dose metric. This is followed by a discussion of the nature of Pb-induced health effects that emphasizes those with the strongest evidence. Potential impacts of Pb exposures on public health, including recognition of potentially susceptible or vulnerable subpopulations, are then discussed. Finally, key observations about Pb-related health effects are summarized.

1. Blood Lead

The health effects of Pb are remote from the portals of entry to the body (i.e., the respiratory system and gastrointestinal tract). Consequently, the internal disposition and distribution of Pb in the blood is an integral aspect of the relationship between exposure and effect. Additionally, the focus on blood Pb as the dose metric in consideration of the Pb health effects evidence, while reducing our uncertainty with regard to causality, leads to an additional consideration with regard to contribution of air-related sources and exposure pathways to blood Pb.

a. Internal Disposition of Lead

This section briefly summarizes the current state of knowledge of Pb disposition pertaining to both inhalation and ingestion routes of exposure as described in the Criteria Document.

Inhaled Pb particles deposit in the different regions of the respiratory tract as a function of particle size (CD, pp. 4–3 to 4–4). Lead associated with smaller particles, which are predominantly deposited in the pulmonary region, may, depending on solubility, be absorbed into the general circulation or transported to the gastrointestinal tract (CD, pp. 4–3). Lead associated with larger particles, which are predominantly deposited in the head and conducting airways (e.g., nasal pharyngeal and tracheobronchial regions of respiratory tract), may be transported into the esophagus and swallowed, thus making its way to the gastrointestinal tract (CD, pp. 4–3 to 4–4), where it may be absorbed into the blood stream. Thus, Pb can reach the gastrointestinal tract either directly through the ingestion route or indirectly following inhalation.

Once in the blood stream, where approximately 99% of the Pb associates with red blood cells, the Pb is quickly distributed throughout the body (e.g., within days) with the bone serving as a large, long-term storage compartment, and soft tissues (e.g., kidney, liver, brain, etc.) serving as smaller compartments, in which Pb may be more mobile (CD, sections 4.3.1.4 and 8.3.1.). Additionally, the epidemiologic evidence indicates that Pb freely crosses the placenta resulting in continued fetal exposure throughout pregnancy, and that exposure increases during the later half of pregnancy (CD, section 6.6.2).

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). Accordingly, levels of Pb in bone are indicative of a person's long-term, cumulative exposure to Pb. In contrast, blood Pb levels are usually indicative of recent exposures. Depending on exposure dynamics, however, blood Pb may—through its interaction with bone—be indicative of past exposure or of cumulative body burden (CD, section 4.3.1.5).

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). Past exposures that contribute Pb to the bone, consequently, may influence current levels of Pb in blood. Where past exposures were elevated in

comparison to recent exposures, this influence may complicate interpretations with regard to recent exposure (CD, sections 4.3.1.4 to 4.3.1.6). That is, higher blood Pb concentrations may be indicative of higher cumulative exposures or of a recent elevation in exposure (CD, pp. 4–34 and 4–133).

In several studies investigating the relationship between Pb exposure and blood Pb in children (e.g., Lanphear and Roghmann 1997; Lanphear *et al.*, 1998), blood Pb levels have been shown to reflect Pb exposures, with particular influence associated with exposures to Pb in surface dust. Further, as stated in the Criteria Document "these and other studies of populations near active sources of air emissions (e.g., smelters, etc.) substantiate the effect of airborne Pb and resuspended soil Pb on interior dust and blood Pb" (CD, p. 8–22).

b. Use of Blood Lead 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 prevalence of the use of blood Pb as an exposure index or biomarker is related to both the ease of blood sample collection (CD, p. 4–19; Section 4.3.1) and by findings of association with a variety of health effects (CD, Section 8.3.2). For example, 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). In 1978, when the current Pb NAAQS was established, the CDC recognized a blood Pb level of 30 μg/dL as a level warranting individual intervention (CDC, 1991). In 1985, the CDC recognized a level of 25 μg/dL for individual child intervention, and in 1991, they recognized a level of 15 μg/dL for individual intervention and a level of 10 μg/dL for implementing community-wide prevention activities (CDC, 1991; CDCa, 2005). In 2005, with consideration of a review of the evidence by their advisory committee, CDC revised their statement on Preventing Lead Poisoning in Young Children, specifically recognizing the evidence of adverse health effects in children with blood Pb levels below 10 μg/dL [26] and the data demonstrating that

[26] As described by the Advisory Committee on Childhood Lead Poisoning Prevention, "In 1991,

no ''safe'' threshold for blood Pb had been identified, and emphasizing the importance of preventative measures (CDC, 2005a, ACCLPP, 2007).[27]

Since 1976, the CDC has been monitoring blood Pb levels nationally through the National Health and Nutrition Examination Survey (NHANES). This survey monitors blood Pb levels in multiple age groups in the U.S. This information indicates variation in mean blood Pb levels across the various age groups monitored. For example, mean values 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, respectively (CD, p. 4–22).

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 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 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). For example, while the 2001–2004 median blood level for children aged 1–5 of all races and ethnic

groups is 1.6 µg/dL, the median for the subset living below the poverty level is 2.3 µg/dL and 90th percentile values for these two groups are 4.0 µg/dL and 5.4 µg/dL, respectively. Similarly, the 2001–2004 median blood level for black, non-Hispanic children aged 1–5 is 2.5 µg/dL, while the median level for the subset of that group living below the poverty level is 2.9 µg/dL and the median level for the subset living in more well-off households (i.e., with income more than 200% of the poverty level) is 1.9 µg/dL. Associated 90th percentile values for 2001–2004 are 6.4 µg/dL (for black, non-Hispanic children aged 1–5), 7.7 µg/dL (for the subset of that group living below the poverty level) and 4.1 µg/dL (for the subset living in a household with income more than 200% of the poverty level).[28] The recently released RRP rule (discussed above in section I.C) is expected to contribute to further reductions in BLL for children living in houses with Pb paint.

Bone measurements, as a result of the generally slower Pb turnover in bone, are recognized as providing a better measure of cumulative Pb exposure (CD, Section 8.3.2). The bone pool of Pb in children, however, 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).

c. Air-to-Blood Relationships

As described in Section II.A, 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, which is often termed a slope or ratio, describes the increase in blood Pb (in µg/dL) per unit of air Pb (in µg/m³).[29]

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,[30] 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 exposure pathways affects the magnitude of the resultant air-to-blood estimates, such that fewer pathways included as ''air-related'' yield 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 slopes[31] include

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).

[27] 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 already 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). 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).

[28] This information is available at: *http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm* (click on ''Download a universal spreadsheet file of the Body Burdens data tables'').

[29] 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.

[30] We note that the 2006 Criteria Document did not include a discussion of more recent studies on air-to-blood ratios.

[31] Brunekreef *et al.* (1984) discusses potential confounders to the relationship between air Pb and
Continued

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, we note 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 six years of 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).[32] 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).

Sources of uncertainty related to air-to-blood ratios obtained from Hilts (2003) study have been identified. 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.[33]

In addition to the study by Hilts (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.[34] 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 µg/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 (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 µg/m³ and a ratio of 1:16 for ambient air Pb levels in the range of 0.25 µg/m³, indicating a pattern of higher ratios with lower ambient air Pb and blood Pb levels consistent with conclusions in the 1986 Criteria Document.[35]

In their advice to the Agency, 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).[36]

Beyond considering the evidence presented in the published literature and that reviewed in Pb Criteria Documents, we have also considered air-to-blood ratios derived from the exposure assessment for this review (discussed below in section II.C). 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

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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). Note, 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 for underestimating ambient air Pb levels due to the use of low volume British Smoke air monitors and the potential for ongoing (higher historical) ambient air Pb levels to have influenced blood Pb levels (see Section V.B.2 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).

[32] This 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).

[33] 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).

[34] EPA is not basing its proposed 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 accordingly considered by CASAC and the public.

[35] 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.

[36] 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 µg/dL of blood Pb in children. Their estimate is based on their coefficient of 2.14 µg/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 µg/m³ (24). These two facts imply a ratio of 9–10 µg/dL per µg/m³ reduction in air Pb, taking all pathways into account.'' (Henderson, 2007a, pp. D–2 to D–3).

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 µg/m³ down to a level of 0.02 µg/m³. 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 HUD 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 (see Section Attachment G–1 of the Risk Assessment, Volume II). Given this application of the HUD dataset, there is the potential that the non-linear 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 µg/m³.[37] 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 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, in EPA's view, 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. In light of the uncertainties that remain in the available information on air-to-blood ratios, EPA requests comment on this range and on the appropriate weight to place on specific ratios within this range.

2. Nature of Effects

a. Broad Array of Effects

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).[38]

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. Tables 8–5 and 8–6 in the Criteria Document highlight the key such effects observed in children and adults, respectively (CD, pp. 8–60 to 8–62). The effects include neurological, hematological and immune effects for children, and hematological, cardiovascular and renal effects for adults. 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).[39] 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 have, in investigating effects at lower blood Pb levels, utilized the CDC advisory level for individual children (10 µg/dL) 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

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[37] As noted below in section II.C.3.a, air-to-blood ratios for the primary Pb smelter (full study area) range from 1:3 to 1:7 across the same range of alternative standard levels (from 1.5 down to 0.02 µg/m³).

[38] Lead has been classified as a probable human carcinogen by the International Agency for Research on Cancer, based mainly on sufficient animal evidence, and as reasonably anticipated to be a human carcinogen by the U.S. National Toxicology Program (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).

[39] 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)

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).[40]

In summary, the Agency has identified neurological, hematological and immune effects in children and neurological, hematological, cardiovascular and renal effects in adults as the effects observed at blood Pb levels near or below 10 µg/dL and further considers neurological effects in children and cardiovascular effects in adults to be categories of effects that ''are currently clearly of greatest public health concern'' (CD, pp. 8–60 to 8–62). Neurological effects in children are discussed further below.

b. 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 young children is among, if not, the most sensitive. As described in the Criteria Document, neurotoxic effects in children and cardiovascular effects in adults are categories of effects that are ''currently clearly of greatest public health concern'' (CD, p. 8–60).[41] While also recognizing the occurrence of adult cardiovascular effects at somewhat similarly low blood Pb levels [42],

neurological effects in children are considered to be the sentinel effects in this review and are the focus of the quantitative risk assessment conducted for this review (discussed below in section III.C).

The nervous system has long been recognized as a target of Pb toxicity, with the developing nervous system affected at lower exposures than the mature system (CD, Sections 5.3, 6.2.1, 6.2.2, and 8.4). While blood Pb levels in U.S. children ages one to five years 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 µg/dL (CD, Sections 6.2 and 8.4). [43] 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).

The evidence for neurotoxic effects in children is a robust combination of epidemiological and toxicological evidence (CD, Sections 5.3, 6.2 and 8.5). The epidemiological evidence is supported by animal studies that substantiate the biological plausibility of the associations, and contributes to our understanding of mechanisms of action for the effects (CD, Section 8.4.2).

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).

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 µg/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. With regard to persistence of effects the Criteria Document states the following (CD, p. 8–67):

Persistence or apparent ''irreversibility'' of effects can result from two different scenarios: (1) Organic damage has occurred without adequate repair or compensatory offsets, or (2) exposure somehow persists. As Pb exposure can also derive from endogenous sources (e.g., bone), a performance deficit that remains detectable after external exposure has ended, rather than indicating irreversibility, could reflect ongoing toxicity due to Pb remaining at the critical target organ or Pb deposited at the organ post-exposure as the result of redistribution of Pb among body pools. The persistence of effect appears to depend on the duration of exposure as well as other factors that may affect an individual's ability to recover from an insult. The likelihood of reversibility also seems to be related, at least for the adverse effects observed in certain organ systems, to both the age-at-exposure and the age-at-assessment.

The evidence with regard to persistence of Pb-induced deficits observed in animal and epidemiological studies is described in discussion of those studies in the Criteria Document (CD, Sections 5.3.5, 6.2.11, and 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).

As discussed in the Criteria Document, while there is no direct animal test parallel to human IQ tests, ''in animals a wide variety of tests that assess attention, learning, and memory suggest that Pb exposure {of animals} results in a global deficit in functioning,

[40] 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).

[41] The Criteria Document states ''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 of effects are currently clearly of greatest public health concern (CD, p. 8–60).''

[42] For example, the Criteria Document describes associations of blood Pb in adults with blood pressure in studies with population mean blood Pb

levels ranging from approximately 2 to 6 µg/dL (CD, section 6.5.2 and Table 6–2).

[43] 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).

just as it is indicated by decrements in IQ scores in children'' (CD, p. 8–27). The animal and epidemiological evidence for this endpoint are consistent and complementary (CD, p. 8–44). As stated in the Criteria Document (p. 8–44):

Findings from numerous experimental studies of rats and of nonhuman primates, as discussed in Chapter 5, parallel the observed human neurocognitive deficits and the processes responsible for them. Learning and other higher order cognitive processes show the greatest similarities in Pb-induced deficits between humans and experimental animals. Deficits in cognition are due to the combined and overlapping effects of Pb-induced perseveration, inability to inhibit responding, inability to adapt to changing behavioral requirements, aversion to delays, and distractibility. Higher level neurocognitive functions are affected in both animals and humans at very low exposure levels (<10 µg/dL), more so than simple cognitive functions.

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 (CD, p. 6–64). This is supported by multiple studies performed over the past 15 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 µg/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 µg/dL (CD, Sections 6.2, 8.4.2 and 8.4.2.6).[44] That is, 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 blood Pb levels (CD, Chapter 6).

The evidence described in the Criteria Document with regard to the effect on children's cognitive function of blood Pb levels at the lower concentration range includes the international pooled analysis by Lanphear and others (2005),

studies of individual cohorts such as the Rochester, Boston, and Mexico City cohorts (Canfield *et al.*, 2003a; Canfield *et al.*, 2003b; Bellinger and Needleman, 2003; Tellez-Rojo *et al.*, 2006), the study of African-American inner-city children from Detroit (Chiodo *et al.*, 2004), the cross-sectional study of young children in three German cities (Walkowiak *et al.*, 1998) and the cross-sectional analysis of a nationally representative sample from the NHANES III [45] (Lanphear *et al.*, 2000). These studies included differing adjustments for different important potential confounders (e.g., parental IQ or HOME score) or surrogates of these measures (e.g., parental education and SES factors) through multivariate analyses.[46][47] Each of these studies has

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[45] The NHANES III survey was conducted in 1988–1994.

[46] Some studies also employed exclusion criteria which limited variation in socioeconomic status across the study population. Further, with regard to adjustment for potential confounders in the large pooled international analysis (Lanphear *et al.* 2005), discussed below, the authors adjusted for HOME score, birth weight, maternal IQ and maternal education. Canfield *et al.* (2003) adjusted for maternal IQ, maternal education, HOME score, birth weight, race, tobacco use during pregnancy, household income, gender, and iron status. Bellinger and Needleman (2003) adjusted for maternal IQ, HOME score, SES, child stress, maternal age, race, gender, birth order, marital status. Chiodo *et al.* (2004) adjusted for primary care-giver education and vocabulary, HOME score, family environment scale, SES, gender, number of children under 18, birth order. Tellez-Rojo *et al.* (2006) adjusted for maternal IQ, birth weight and gender; the authors also state that other potentially confounding variables that were not found to be significant at p<.10 were not adjusted for. Walkoviak *et al.* (1998) adjusted for parental education, breastfeeding, nationality and gender. In Lanphear *et al.* (2000), the authors adjusted for race/ethnicity and poverty index ratio, as surrogates for HOME score/SES status, and adjusted for the parental education level as a surrogate for maternal IQ; they also adjusted for gender, serum ferritin level and serum cotinine level.

[47] The Criteria Document notes that a ''major challenge to observational studies examining the impact of Pb on parameters of child development has been the assessment and control for confounding factors'' (CD, p. 6–73). However, the Criteria Document further recognizes that ''[m]ost of the important confounding factors in Pb studies have been identified, and efforts have been made to control them in studies conducted since the 1990 Supplement'' (CD, p. 6–75). On this subject, the Criteria Document further concludes the following: ''Invocation of the poorly measured confounder as an explanation for positive findings is not substantiated in the database as a whole when evaluating the impact of Pb on the health of U.S. children (Needleman, 1995). Of course, it is often the case that following adjustment for factors such as social class, parental neurocognitive function, and child rearing environment using covariates such as parental education, income, and occupation, parental IQ, and HOME scores, the Pb coefficients are substantially reduced in size and statistical significance (Dietrich *et al.*, 1991). This has sometimes led investigators to be quite cautious in interpreting their study results as being positive (Wasserman *et al.*, 1997). This is a reasonable way of appraising any single study, and such extreme

individual strengths and limitations, however, a pattern of positive findings is demonstrated across the studies. In these studies, statistically significant associations of neurocognitive decrement [48] with blood Pb were found in the full study cohorts, as well as in some subgroups restricted to children with lower blood Pb levels for which mean blood Pb levels extended below 5 µg/dL. More specifically, a statistically significant association was reported for full-scale IQ with blood Pb at age five in a subset analysis (n=71) of the Rochester cohort for which the population mean blood Pb level was 3.32 µg/dL, as well as in the full study group (mean=5.8 µg/dL, n=171) (Canfield *et al.*, 2003a; Canfield, 2008). Full-scale IQ was also significantly associated with blood Pb at age seven and a half in a subset analysis (n=200) in the Detroit inner-city study for which the population mean blood Pb level was 4.1 µg/dL, as well as the other subgroup with higher blood Pb levels (mean=4.6 µg/dL, n=224) and in the full study group (mean=5.4 µg/dL, n=246); additionally, performance IQ was significantly associated with blood Pb in those analyses as well as in the subset analysis (n=120) for which the population mean blood Pb level was 3 µg/dL (although full-scale IQ was not significantly associated with blood Pb in this lowest blood Pb subgroup) (Chiodo *et al.*, 2004, Chiodo, 2008). Vocabulary, one of ten subtests of the full-scale IQ, was significantly associated with blood

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caution would certainly be warranted if forced to rely on a single study to confirm the Pb effects hypothesis. 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)

[48] The tests for cognitive function in these studies include age-appropriate Wechsler intelligence tests (Lanphear *et al.*, 2005), the Stanford-Binet intelligence test (Canfield *et al.*, 2003a), and the Bayley Scales of Infant Development (Tellez-Rojo *et al.*, 2006). In some cases, individual subtests of the Wechsler intelligence tests (Lanphear *et al.*, 2000; Walkowiak *et al.*, 1998), and individual subtests of the Wide Range Achievement Test (Lanphear *et al.*, 2000) were used. The Wechsler and Stanford-Binet tests are widely used to assess neurocognitive function in children and adults, however, these tests are not 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. See footnote 63 for further information.

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[44] ''The overall weight of the available evidence provides clear substantiation of neurocognitive decrements being associated in young children with blood-Pb concentrations in the range of 5–10 µg/dL, and possibly somewhat lower. Some newly available analyses appear to show 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)

Pb at age six in the German three-city study (n=384) in which the mean blood Pb level was 4.2 µg/dL (Walkowiak *et al.*, 1998). In a Mexico City cohort of infants age two, the mental development index (MDI) and psychomotor development index (PDI) were significantly associated with blood Pb in the full study group (mean=4.28 µg/dL, n=294); further, the MDI (but not the PDI) was significantly associated with blood Pb in the subset analysis (n=193) for which the population mean blood Pb level was 2.9 µg/dL, and PDI (but not the MDI) was significantly associated with blood Pb in the subset analysis (n=101) for which the population mean blood Pb was 6.9 µg/dL (Tellez-Rojo *et al.*, 2006; Tellez-Rojo, 2008). Scores on academic achievement tests for reading and math were significantly associated with blood Pb at age six through sixteen in a subgroup analysis (n=4043) of the NHANES III data for which the population mean blood Pb level was 1.7 µg/dL, as discussed below (Lanphear *et al.* 2000; Auinger, 2008).

The study by Lanphear *et al.* (2000) is a large cross-sectional study using NHANES III dataset, with 4853 subjects in the full study and more than 4000 in the subgroup analyses, that reports statistically significant [49] associations of concurrent blood Pb levels [50] with neurocognitive decrements in the full study population and in subgroup analyses down to and including the subgroup with individual blood Pb levels below 5 µg/dL (CD, pp. 6–31 to 6–32; Lanphear *et al.*, 2000). Specifically the study by Lanphear *et al.* (2000) reported a statistically significant association between math (p<0.001), reading (p<0.001), block design (p=0.009), and digit span (p=0.04) scores and blood Pb levels in the analysis that included all study subjects. Additionally, the study reports statistically significant associations for block design and digit span scores down

to and including the subgroup with individual blood Pb levels below 7.5 µg/dL and 10 µg/dL, respectively.[51] Further, statistically significant associations were observed for reading and math scores down to and including the subgroup with individual blood Pb levels below 5 µg/dL, which included 4043 of the 4853 children.[52] A similar pattern in the magnitude of the effect estimates was observed across all the subgroup analyses and for all four tests, including the subgroup with individual blood Pb levels less than 2.5 µg/dL, although not all the effect estimates were statistically significant (Lanphear *et al.*, 2000).[53] In particular, the lack of statistical significance in the subset of individuals with blood Pb levels less than 2.5 µg/dL may be attributable to the smaller sample size (2467 children) and reduced variability of blood Pb levels.[54] Blood Pb levels in the full study population ranged from below detection to above 10 µg/dL, with a population geometric mean of 1.9 µg/dL, and the subgroups were composed of children with blood Pb levels less than 10 µg/dL (geometric mean of 1.8 µg/dL), less than 7.5 µg/dL (geometric mean of 1.8 µg/dL), less than 5 µg/dL (geometric mean of 1.7 µg/dL), and less than 2.5 µg/dL (geometric mean of 1.2 µg/dL), respectively (Lanphear *et al.*, 2000; Auinger, 2008).[55]

The epidemiological studies that have investigated blood Pb effects on IQ (as discussed in the CD, Section 6.2.3) have considered a variety of specific blood Pb metrics, including: (1) Blood concentration ''concurrent'' with the

response assessment (e.g., at the time of IQ testing), (2) average blood concentration over the ''lifetime'' of the child at the time of response assessment (e.g., average of measurements taken over child's first 6 or 7 years), (3) peak blood concentration during a particular age range, and (4) early childhood blood concentration (e.g., the mean of measurements between 6 and 24 months age). With regard to the latter two, the Criteria Document (e.g., CD, chapters 3 and 6) has noted that age has been observed to strongly predict the period of peak exposure (around 18–27 months when there is maximum hand-to-mouth activity). The CD further notes, this maximum exposure period coincides with a period of time in which major events are occurring in central nervous system (CNS) development (CD, p. 6–60). Accordingly, the belief that the first few years of life are a critical window of vulnerability is evident particularly in the earlier literature (CD, p. 6–60). However, more recent analyses have found even stronger associations between blood Pb at school age and IQ at school age (i.e., concurrent blood Pb), indicating the important role that is continued to be played by Pb exposures later in life. In fact, concurrent and lifetime averaged measurements were stronger predictors of adverse neurobehavioral effects (better than the peak or 24 month metrics) in all but one of the prospective cohort studies (CD, pp. 6–61 to 6–62). While all four specific blood Pb metrics were correlated with IQ in the international pooled analysis by Lanphear and others (2005), the concurrent blood Pb level exhibited the strongest relationship with intellectual deficits (CD, p. 6–29).

The Criteria Document presentation on toxicological evidence also recognizes neurological effects elicited by exposures subsequent to earliest childhood (CD, sections 5.3.5 and 5.3.7). For example, research with monkeys has indicated that while exposure only during infancy may elicit a response, exposures (with similar blood Pb levels) that only occurred post-infancy also elicit responses. Further, in the monkey research, exposures limited to post-infancy resulted in a greater response than exposures limited to infancy (Rice and Gilbert, 1990; Rice, 1992).

A study by Chen and others (2005) involving 622 children has attempted to directly address the question regarding periods of enhanced susceptibility to Pb effects (CD, pp. 6–62 to 6–64).[56] The authors found that the concurrent blood

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[49] The statistical significance refers to the effect estimate of the linear relationship across the range of data, as presented in Table 4 of Lanphear *et al.* (2000).

[50] A limitation noted for this study is with regard to the use of concurrent blood Pb levels in children of this age. The authors state that ''it is not clear whether the cognitive and academic deficits observed in the present analysis are due to lead exposure that occurred during early childhood or due to concurrent exposure'', however, they further note that ''concurrent blood lead concentration was the best predictor of adverse neurobehavioral effects of lead exposure in all but one of the published prospective studies''. The average blood Pb level for 1–5 year olds was approximately 15 µg/dL in the 1976–1980 NHANES. When in that age range, some of the children included in the NHANES III dataset may have had blood Pb levels comparable to those of the earlier NHANES. The general issue regarding blood Pb metrics is further discussed in subsequent text.

[51] The associations with block design score were not statistically significant for subgroups limited to blood Pb of <5 and <2.5 µg/dL. The associations with digit span score were not statistically significant for the blood Pb subgroups of <7.5 and lower.

[52] The associations with math and reading scores were not statistically significant for the subgroup limited to blood Pb <2.5 µ/dL.

[53] For example, for reading scores, effect estimates were −0.99, −1.44, −1.53, −1.66, and −1.71 points per µg/dL for all children, the subgroup with blood Pb <10 µg/dL, the subgroup with blood Pb <7.5, the subgroup with blood Pb <5 and the subgroup with blood Pb<2.5, respectively (Lanphear *et al.*, 2000, Table 4).

[54] The authors state ''Indeed, while the average effects of lead exposure on reading scores were not significant for blood lead concentrations less that 2.5 µg/dL, the size of the effect and the borderline significance level (β = −1.71, p=0.07) suggests that the smaller sample size and the imprecision of the relationship of blood Pb concentration with performance on the reading subtest—as indicated by the large standard error—may be the reason we did not find a statistically significant association for children in that range.''

[55] We note that the datasets for each subgroup include children for the lower blood Pb subgroups (in Table 4 of Lanphear *et al.*, 2000). For example, the dataset of children with blood Pb levels <2.5 is a component of the dataset of children with blood Pb levels <5 (Lanphear *et al.*, 2000).

[56] In the children in this study, the mean blood Pb concentration was 26.2 µg/dL at age 2, 12.0 µg/dL at age 5 and 8.0 µg/dL at age 7 (Chen *et al.* 2005).

Pb association with IQ was always stronger than that for 24-month blood Pb. As children aged, the relationship with concurrent blood Pb grew stronger while that with 24-month blood Pb grew weaker. Further, in models including both prior blood Pb (at 24-months age) and concurrent blood Pb (at 7-years age), concurrent blood Pb was always more predictive of IQ. In fact, concurrent blood Pb explained most of Pb-related variation in IQ such that prior blood Pb (at 24-months age) was rendered nonsignificant and nearly null.[57] The effect estimate for concurrent blood Pb was robust and remained significant, little changed from its value without adjustment for 24-month blood Pb level. The Criteria Document concluded the following regarding the results of this study (CD, pp. 6–63 to 6–64).

These results support the idea that Pb exposure continues to be toxic to children as they reach school age, and do not lend support to the interpretation that all the damage is done by the time the child reaches 2 to 3 years of age. These findings also imply that cross-sectional associations seen in children, such as the study recently conducted by Lanphear *et al.* (2000) using data from NHANES III, should not be dismissed. Chen *et al.* (2005) concluded that if concurrent blood Pb remains important until school age for optimum cognitive development, and if 6- and 7-year-olds are as or more sensitive to Pb effects than 2-year-olds, then the difficulties in preventing Pb exposure are magnified but the potential benefits of prevention are greater.

In addition to findings of association with neurocognitive decrement (including IQ) at study group mean blood Pb levels well below 10 µg/dL, the evidence indicates that the slope for Pb effects on IQ is steeper at lower blood Pb levels (CD, section 6.2.13). As stated in the CD, "the most compelling evidence for effects at blood Pb levels <10 µg/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).[58] 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 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 measurements [59] 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).

The impact of the nonlinear slope is illustrated by the log-linear model-based estimates of IQ decrements for similar changes in blood Pb level at different absolute values of blood Pb level (Lanphear *et al.*, 2005). These estimates of IQ decrement are 3.9 (with 95% confidence interval, CI, of 2.4–5.3), 1.9 (95% CI, 1.2–2.6) and 1.1 IQ points per µg/dL blood Pb (95% CI, 0.7–1.5), for increases in concurrent blood Pb from 2.4 to 10 µg/dL, 10 to 20 µg/dL, and 20 to 30 µg/dL, respectively (Lanphear *et al.*, 2005). For an increase in concurrent blood Pb levels from <1 to 10 µg/dL, the log-linear model estimates a decline of 6.2 points in full scale IQ which is comparable to the 7.4 point decrement in IQ for an increase in lifetime mean blood Pb levels up to 10 µg/dL observed in the Rochester study (CD, pp. 6–30 to 6–31).

A nonlinear blood Pb concentration-response relationship is also suggested

by several other analyses that have observed that each µg/dL increase in blood Pb may have a greater effect on IQ at lower blood Pb levels (e.g., below 10 µg/dL) than at higher levels (CD, pp. 8–63 to 8–64; Figure 8–7). As noted in the Criteria Document, while this may at first seem at odds with certain fundamental toxicological concepts, 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 CD 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 with regard to Pb as follows (CD, p. 8–39).

In the case of Pb, this nonlinear dose-effect relationship occurs in the pattern of glutamate release (Section 5.3.2), in the capacity for long term potentiation (LTP; Section 5.3.3), and in conditioned operant responses (Section 5.3.5). The 1986 Lead AQCD also reported U-shaped dose-effect relationships for maze performance, discrimination learning, auditory evoked potential, and locomotor activity. Davis and Svendsgaard (1990) reviewed U-shaped dose-response curves and their implications for Pb risk assessment. An important implication is the uncertainty created in identification of thresholds and "no-observed-effect-levels" (NOELS). As a nonlinear relationship is observed between IQ and low blood Pb levels in humans, as well as in new toxicologic studies wherein neurotransmitter release and LTP show this same relationship, it is plausible that these nonlinear cognitive outcomes may be due, in part, to nonlinear mechanisms underlying these observed Pb neurotoxic effects.

More specifically, various findings within the toxicological evidence presented in the Criteria Document provides 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 µg/dL.[60]

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[57] We note that blood Pb levels at any point in time are influenced by current as well as past exposures, e.g., through exchanges between blood and bone (as summarized in section II.B.1 above and discussed in more detail in the Criteria Document).

[58] We note that a public comment submitted on March 19, 2008 on behalf of the Association of Battery Recyclers described concerns the commenter had with the conclusion by Lanphear *et al.* (2005) of a nonlinear relationship of blood Pb with IQ, citing a publication by Surkan *et al.* (2007), a study published since the completion of the Criteria Document, and the Tellez-Rojo *et al.* (2006) finding, discussed in the Criteria Document, of two different slopes for their study subgroups of young

children with blood Pb levels below 5 µg/d (n=193, for which the slope of −1.7 was statistically significant, p=0.01) and those with blood Pb levels between 5 and 10 µg/dL (n=101, for which the slope of −0.94 was not statistically significant, p=0.12). The commenter also cites another publication published since the completion of the Criteria Document, Jusko *et al.* (2007) related to this issue. EPA notes that it is not basing its proposed decisions on studies that are not included in the Criteria Document.

[59] The geometric mean of the concurrent blood Pb levels modeled was 9.7 µg/dL; the 5th and 95th percentile values were 2.5 and 33.2 µg/dL, respectively (Lanphear *et al.*, 2005).

[60] The toxicological evidence presented in the Criteria Document of biphasic dose-effect relationships includes: Suppression of stimulated hippocampal glutamate release at low exposure levels and induction of glutamate exocytosis at higher exposure levels (CD, Section 5.3.2); downregulation of NMDA receptors at low blood Pb levels and upregulation at higher levels (CD, section 5.3.2); Pb causes elevated induction threshold and

Continued

In addition to the observed associations between neurocognitive decrement (including IQ) and blood Pb at study group mean levels well below 10 µg/dL (described above), 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 µg/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 µg/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 µg/dL and also where an analysis was performed on a subset of children whose blood Pb levels have never exceeded 10 µg/dL (CD, Table 6–1). The datasets for three of these studies included concurrent blood Pb levels above 10 µg/dL; the C–R relationship reported for one of the three was linear while it was log-linear for the other two. For the one of these three studies with the linear C–R relationship, the highest blood Pb level was just below 12 µg/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 µg/dL and a population mean blood Pb level of 7.44 µg/dL (Al-Saleh *et al.*, 2001), and the second reported a population median blood Pb level of 9.7 µg/dL and a 95th percentile of 33.2 µg/dL (Lanphear *et al.*, 2005). In order to

compare slopes across all of these studies (linear and log-linear), EPA estimated, for each, the average slope of change in IQ with change in blood Pb between the 10th percentile [61] blood Pb level and 10 µg/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 µg/dL range from −0.4 to −1.8 IQ points per µg/dL blood Pb (CD, Tables 6–1 and 8–7), with a median of −0.9 IQ points per µg/dL blood Pb (CD, pp. 8–80).[62]

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 and 3.8 µg/dL, respectively, which are the lowest population mean levels among the datasets included in the table (Canfield, 2008; Bellinger, 2008). 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 Pb [63] 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) [64] and also 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 2008). Thus, from these subset analyses, the slopes range from −1.71 to −2.94 IQ points per µg/dL of concurrent blood Pb. We also note that the nonlinear C–R function in which greatest confidence is placed in estimating IQ loss in the quantitative risk assessment (described below in section II.C) has a slope that falls

diminished magnitude of long-term potentiation at low exposures, but not at higher exposures (CD, section 5.3.3); and low-level Pb exposures increase fixed-interval response rates and high-level Pb exposures decrease fixed interval response rates in learning deficit testing in rats (CD, section 5.3.5). Additional in vitro evidence includes Pb stimulation of PKC activity at picomolar concentrations and inhibition of PKC activity at nano- and micro-molar concentrations (CD, section 5.3.2).

[61] 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.

[62] Among this group of slopes (CD, Table 6–1) is that from the analysis of the IQ-blood Pb (concurrent) relationship for children whose peak blood Pb levels are below 10 µg/dL in the international pooled dataset studied by Lanphear and others (2005); these authors reported this slope along with the companion slope for blood Pb levels for the remaining children with peak blood Pb level equal to or above 10 µg/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), changes in IQ loss as a function of changes in lifetime average blood Pb level were estimated using the corresponding piecewise model for lifetime average blood Pb derived from the pooled dataset (USEPA, 2008; USEPA, 2007e). Selection of this model for the RRP economic analysis reflects consideration of the distribution of blood Pb levels in that analysis, those for children living in houses with Pb-based paint. With consideration of these blood Pb levels, the economic analysis document states that ''[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''. We note 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 distributions of blood Pb levels extending from just below 10 µg/dL and lower.

[63] This 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 text, 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 authors state 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 acuities, 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 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''.

[64] In 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).

intermediate between these two for blood Pb levels up to approximately 3.7 µg/dL (USEPA, 2007b).

The C–R functions discussed above are presented in two sets in Table 1 below.

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 (µg/dL) 5th–95th percentile]	Geometric mean BLL (µg/dL)	Form of model from which average slope derived	Average linear slope [A] (points per µg/dL)
Set of studies from which steeper slopes are drawn							
Tellez-Rojo <5 sub-group based on Lanphear *et al.* 2005,[B] Log-linear with low-exposure linearization (LLL) [B].	Mexico City, age 24 mo.	Children—BLL<5 µg/dL.	193	0.8–4.9	2.9	Linear	−1.71
	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. Slope presented here is the slope at a blood Pb level of 2 µg/dL.[C]					LLL[C]	−2.29 at 2 µg/dL[C]
Lanphear *et al.* 2005,[B] <7.5 peak subgroup.	Pooled International, age 6–10 yr.	Children—peak BLL <7.5 µg/dL.	103	[1.3–6.0]	3.24	Linear	−2.94
Set of studies with shallower slopes (Criteria Document, Table 6–1) [D]							
Canfield *et al.* 2003 [B], <10 peak subgroup.	Rochester, age 5 yr ..	Children—peak BLL <10 µg/dL.	71	Unspecified	3.32	Linear	−1.79
Bellinger and Needleman 2003[B].	Boston[A E]	Children—peak BLL <10 µg/dL.	48	1–9.3[E]	3.8[E]	Linear	−1.56
Tellez-Rojo *et al.* 2006.	Mexico City, age 24 mo.	Full dataset	294	0.8–<10	4.28	Linear	−1.04
Tellez-Rojo *et al.* 2006 full—loglinear.	Mexico City, age 24 mo.	Full dataset	294	0.8–<10	4.28	Log-linear	−0.94
Lanphear *et al.* 2005,[B] <10 peak[F] subgroup.	Pooled International, age 6–10 yr.	Children—peak BLL <10 µg/dL.	244	[1.4–8.0]	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[G] ..	7.44	Log-linear	−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[B] full—loglinear.	Pooled International, age 6–10 yr.	Full dataset	1333	[2.5–33.2]	9.7 (median)	Log-linear	−0.41
						Median value	−0.9 [D]

[A] Average slope for change in IQ from 10th percentile to 10 µg/dL 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.

[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.

[C] 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. The slope shown is that at 2 µg/dL. In estimating IQ loss with this function in the risk assessment (section II.C) and in the evidence-based considerations in section II.E.3, the nonlinear form of the model was used, with varying slope for all BLL above 1 µg/dL.

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

[E] The BLL for Bellinger and Needleman (2003) are for age 24 months.

[F] As referenced above and in section II.C.2.b, the form of this function derived for lifetime average blood Pb was used in the economic analysis for the RRP rule. The slope for that function was -0.88 IQ points per µg/dL lifetime averaged blood Pb.

[G] 69% of children in Al-Saleh *et al.* (2001) study had BLL<10 µg/dL.

3. Lead-Related Impacts on Public Health

In addition to the advances in our knowledge and understanding of Pb health effects at lower exposures (e.g., using blood Pb as the index), there has been some change with regard to the U.S. population Pb burden since the time of the last Pb NAAQS review. For example, the geometric mean blood Pb level for U.S. children aged 1–5, as estimated by the U.S. Centers for Disease Control, declined from 2.7 μg/dL (95% CI: 2.5–3.0) in the 1991–1994 survey period to 1.7 μg/dL (95% CI: 1.55–1.87) in the 2001–2002 survey period (CD, Section 4.3.1.3) and 1.8 μg/dL in the 2003–2004 survey period (Axelrad, 2008).[65] Blood Pb levels have also declined in the U.S. adult population over this time period (CD, Section 4.3.1.3).[66] As noted in the Criteria Document, ''blood-Pb levels have been declining at differential rates for various general subpopulations, as a function of income, race, and certain other demographic indicators such as age of housing'' (CD, pp. 8–21). For example, the geometric mean blood Pb level for children (aged one to five) living in poverty in the 2003–2004 survey period is 2.4 μg/dL. For black, non-Hispanic children, the geometric mean is 2.7 μg/dL, and for the subset of this group that is living in poverty, the geometric mean is 3.1 μg/dL. Further, the 95th percentile blood Pb level in the 2003–2004 NHANES for children aged 1–5 of all races and ethnic groups is 5.1 μg/dL, while the corresponding level for the subset of children living below the poverty level is 6.6 μg/dL. The 95th percentile level for black, non-Hispanic children is 8.9 μg/dL, and for the subset of that group living below the poverty level, it is 10.5 μg/dL (Axelrad, 2008).[67]

a. At-Risk Subpopulations

Potentially at-risk subpopulations include those with increased susceptibility (i.e., physiological factors contributing to a greater response for the same exposure) and those with increased exposure (including that resulting from behavior leading to increased contact with contaminated media) (USEPA 1986a, pp. 1–154). A behavioral factor of great impact on Pb exposure is the incidence of hand-to-mouth activity that is prevalent in very young children (CD, Section 4.4.3). Physiological factors include both conditions contributing to a subgroup's increased risk of effects at a given blood Pb level, and those that contribute to blood Pb levels higher than those otherwise associated with a given Pb exposure (CD, Section 8.5.3). These factors include 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).

We also considered evidence pertaining to vulnerability to pollution-related effects which additionally encompasses situations of elevated exposure, such as residing in older housing with Pb-containing paint or 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) that can contribute to increased risk of adverse health effects from Pb. With regard to elevated exposures in particular socioeconomic and minority subpopulations, we observe notably higher blood Pb levels in children in poverty and in black, non-Hispanic children compared to those for more economically well-off children and white children, in general (as recognized in section II.B.1.b above).

Three particular physiological factors contributing to increased risk of Pb effects at a given blood Pb level are recognized in the Criteria Document (e.g., CD, Section 8.5.3): age, health status, and genetic composition. With regard to age, the susceptibility of young children to the neurodevelopmental effects of Pb is well recognized (e.g., CD, Sections 5.3, 6.2, 8.4, 8.5, 8.6.2), although the specific ages of vulnerability have not been established (CD, pp. 6–60 to 6–64). Early childhood may also be a time of increased susceptibility for Pb immunotoxicity (CD, Sections 5.9.10, 6.8.3 and 8.4.6). Further early life exposures have been associated with increased risk of cardiovascular effects in humans later in life (CD, pp. 8–74). Early life exposures have also been associated with increased risk, in animals, of

neurodegenerative effects later in life (CD, pp. 8–74).[68] Health status is another physiological factor in that subpopulations with pre-existing health conditions may be more susceptible (as compared to the general population) for particular Pb-associated effects, with this being most clear for renal and cardiovascular outcomes. For example, African Americans as a group have a higher frequency of hypertension than the general population or other ethnic groups (NCHS, 2005), and as a result may face a greater risk of adverse health impact from Pb-associated cardiovascular effects. A third physiological factor relates to genetic polymorphisms. That is, subpopulations defined by particular genetic polymorphisms (e.g., presence of the δ-aminolevulinic acid dehydratase-2 [ALAD–2] allele) have also been recognized as sensitive to Pb toxicity, which may be due to increased susceptibility to the same internal dose and/or to increased internal dose associated with the same exposure (CD, pp. 8–71, Sections 6.3.5, 6.4.7.3 and 6.3.6).

Childhood is well recognized as a time of increased susceptibility, and as summarized in section II.B.2.b above and described in more detail in the Criteria Document, a large body of epidemiological evidence describes neurological effects on children at low blood Pb levels. The toxicological evidence further helps inform an understanding of specific periods of development with increased vulnerability to specific types of neurological effect (CD, Section 5.3). Additionally, the toxicological evidence of a differing sensitivity of the immune system to Pb across and within different periods of life stages indicates the potential importance of exposures of duration as short as weeks to months. For example, the animal studies suggest that, for immune effects, the gestation period is the most sensitive life stage followed by early neonatal stage, and that within these life stages, critical windows of vulnerability are likely to exist (CD, Section 5.9 and p. 5–245).

In summary, there are a variety of ways in which Pb exposed populations might be characterized and stratified for consideration of public health impacts. Age or lifestage was used to distinguish

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[65] These levels are in contrast to the geometric mean blood Pb level of 14.9 μg/dL reported for U.S. children (aged 6 months to 5 years) in 1976–1980 (CD, Section 4.3.1.3).

[66] For example, NHANES data for older adults (60 years of age and older) indicate a decline in overall population geometric mean blood Pb level from 3.4 μg/dL in 1991–1994 to 2.2 μg/dL in 1999–2002; the trend for adults between 20 and 60 years of age is similar to that for children 1 to 5 years of age (*http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5420a5.htm*).

[67] Although the 90th percentile statistic for these subgroups is not currently available for the 2003–04 survey period, the 2001–2004 90th percentile blood Pb level for children aged 1–5 of all races and ethnic groups is 4.0 μg/dL, while the corresponding level for the subset of children living below the poverty level is 5.4 μg/dL, and that level for black, non-Hispanic children living below the poverty level is 7.7 μg/dL (*http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm*—then click on ''Download a universal spreadsheet file of the Body Burdens data tables'').

[68] Specifically, among young adults who lived as children in an area heavily polluted by a smelter and whose current Pb exposure was low, higher bone Pb levels were associated with higher systolic and diastolic blood pressure (CD, pp. 8–74). In adult rats, greater early exposures to Pb are associated with increased levels of amyloid protein precursor, a marker of risk for neurodegenerative disease (CD, pp. 8–74).

potential groups on which to focus the quantitative risk assessment because of its influence on exposure and susceptibility. Young children were selected as the priority population for the risk assessment in consideration of the health effects evidence regarding endpoints of greatest public health concern. The Criteria Document recognizes, however, other population subgroups as described above may also be at risk of Pb-related health effects of public health concern.

b. Potential Public Health Impacts

As discussed in the Criteria Document, there are potential public health implications of low-level Pb exposure, indexed by blood Pb levels, associated with several health endpoints identified in the Criteria Document (CD, Section 8.6).[69] These include potential impacts on population IQ, which is the focus of the quantitative risk assessment conducted for this review, as well as heart disease and chronic kidney disease, which are not included in the quantitative risk assessment (CD, Sections 8.6, 8.6.2, 8.6.3 and 8.6.4). It is noted that there is greater uncertainty associated with effects at the lower levels of blood Pb, and that there are differing weights of evidence across the effects observed.[70] With regard to potential implications of Pb effects on IQ, the Criteria Document recognizes the ''critical'' distinction between population and individual risk, noting 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).[71] 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, pp. 8–81).[72] For an individual functioning in the low IQ

range due to the influence of developmental risk 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 handicap (CD, p. 8–77).

The magnitude of a public health impact is dependent upon the size of population affected and type or severity of the effect. As summarized above, there are several population groups that may be susceptible or vulnerable to effects associated with exposure to Pb, including young children, particularly those in families of low SES (CD, p. E–15), as well as individuals with hypertension, diabetes, and chronic renal insufficiency (CD, p. 8–72). Although comprehensive estimates of the size of these groups residing in proximity to sources of ambient Pb have not been developed, total estimates of these population subpopulations within the U.S. are substantial (as noted in Table 3–3 of the Staff Paper).[73]

With regard to estimates of the size of potentially vulnerable subpopulations living in areas of increased exposure related to ambient Pb, the information is still more limited. The limited information available on air and surface soil concentrations of Pb indicates elevated concentrations near stationary sources as compared with areas remote from such sources (CD, Sections 3.2.2 and 3.8). Air quality analyses (presented in Chapter 2 of the Staff Paper) indicate dramatically higher Pb concentrations at monitors near sources as compared with those more remote. As described in Section 2.3.2.1 of the Staff Paper, however, since the 1980s the number of Pb monitors has been significantly reduced by states (with EPA guidance that monitors well below the current NAAQS could be shut down) and a lack of monitors near some large sources may lead to underestimates of the extent of occurrences of relatively higher Pb concentrations. The significant limitations of our monitoring and emissions information constrain our efforts to characterize the size of at-risk populations in areas influenced by sources of ambient Pb. For example, the limited size and spatial coverage of the current Pb monitoring network constrains our ability to characterize current levels of airborne Pb in the U.S. Further, as noted above in section II.A.1, the Staff Paper review of the available information on emissions and locations

of sources (as described in section 2.3.2.1 of the Staff Paper) indicates that the network is inconsistent in its coverage of the largest sources identified in the 2002 National Emissions Inventory (NEI). The most recent analysis of monitors near sources greater than 1 ton per year (tpy) indicates that less than 15% of stationary sources with emissions greater than or equal to 1 tpy have a monitor within one mile. Additionally, there are various uncertainties and limitations associated with source information in the NEI (as described in section 2.2.5 of the Staff Paper; USEPA, 2007c).

In recognition of the significant limitations associated with the currently available information on Pb emissions and airborne concentrations in the U.S. and the associated exposure of potentially at-risk populations, Chapter 2 of the Staff Paper summarizes the information in several different ways. For example, analyses of the current monitoring network indicated the numbers of monitoring sites that would exceed alternate standard levels, taking into consideration different statistical forms. These analyses are also summarized with regard to population size in counties home to those monitoring sites (as presented in Appendix 5.A of the Staff Paper). Information for the monitors and from the NEI indicates a range of source sizes in proximity to monitors at which various levels of Pb are reported. Together this information suggests that there is variety in the magnitude of Pb emissions from sources that could influence air Pb concentrations. Identifying specific emissions levels of sources expected to result in air Pb concentrations of interest, however, would be informed by a comprehensive analysis using detailed source characterization information, which was not feasible within the time and data constraints of this review. Instead, we have developed a summary of the emissions and demographic information for Pb sources that includes estimates of the numbers of people residing in counties in which the aggregate Pb emissions from NEI sources is greater than or equal to 0.1 tpy or in counties in which the aggregate Pb emissions is greater than or equal to 0.1 tpy per 1000 square miles (as presented in Tables 3–4 and 3–5, respectively, in the Staff Paper).

Additionally, the potential for resuspension of recently and historically deposited Pb near roadways to contribute to increased risks of Pb exposure to populations residing nearby is suggested in the Criteria Document (e.g., CD, pp. 2–62 and 3–32).

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[69] The differing evidence and associated strength of the evidence for these different effects is described in detail in the Criteria Document.

[70] As is described in Section II.C.2.a, CASAC, in their comments on the analysis plan for the risk assessment described in this notice, placed higher priority on modeling the child IQ metric than the adult endpoints (e.g., cardiovascular effects).

[71] Similarly, ''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).

[72] 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).

[73] For example, approximately 4.8 million children live in poverty, while the estimates of numbers of adults with hypertension, diabetes or chronic kidney disease are on the order of 20 to 50 million (see Table 3–3 of Staff Paper).

4. Key Observations

The following key observations are based on the available health effects evidence and the evaluation and interpretation of that evidence in the Criteria Document.

• Lead exposures occur both by inhalation and by ingestion (CD, Chapter 3). As stated in the Criteria Document, ''given the large amount of time people spend indoors, exposure to Pb in dusts and indoor air can be significant'' (CD, p. 3–27).

• Children, in general and especially those of low SES, are at increased risk for Pb exposure and Pb-induced adverse health effects. This is due to several factors, including enhanced exposure to Pb via ingestion of soil Pb and/or dust Pb due to normal childhood hand-to-mouth activity (CD, p. E–15, Chapter 3 and Section 6.2.1).

• Once inhaled or ingested, Pb is distributed by the blood, with long-term storage accumulation in the bone. Bone Pb levels provide a strong measure of cumulative exposure which has been associated with many of the effects summarized below, although difficulty of sample collection has precluded widespread use in epidemiological studies to date (CD, Chapter 4).

• Blood levels of Pb are well accepted as an index of exposure (or exposure metric) for which associations with the key effects (see below) have been observed. In general, associations with blood Pb are most robust for those effects for which past exposure history poses less of a complicating factor, i.e., for effects during childhood (CD, Section 4.3).

• Both epidemiological and toxicologic studies have shown that environmentally relevant levels of Pb affect many different organ systems (CD, p. E–8). With regard to the most important such effects observed in children and adults, the Criteria Document states (CD, p. 8–60) that ''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 of effects are currently clearly of greatest public health concern. Other newly demonstrated immune and renal system effects among general population groups are also emerging as low-level Pb-exposure effects of potential public health concern.''

• Many associations of health effects with Pb exposure have been found at levels of blood Pb that are currently relevant for the U.S. population, with individual children having blood Pb

levels of 5–10 µg/dL and lower, being at risk for neurological effects (as described in the subsequent bullet). Supportive evidence from toxicological studies provides biological plausibility for the observed effects. (CD, Chapters 5, 6 and 8)

• Pb exposure is associated with a variety of neurological effects in children, notably intellectual attainment and school performance. Both qualitative and quantitative evidence, with further support from animal research, indicates a robust and consistent effect of Pb exposure on neurocognitive ability at mean concurrent blood Pb levels in the range of 5 to 10 µg/dL. Specific epidemiological analyses have further indicated association with neurocognitive effects in analyses restricted to children with individual blood Pb levels below 5–10 µg/dL, and for which group mean levels are lower. Further, ''[s]ome newly available analyses appear to show 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; Sections 5.3, 6.2, 8.4.2 and 6.10).

• Deficits in cognitive skills may have long-term consequences over a lifetime. Poor academic skills and achievement can have enduring and important effects on objective parameters of success in life as well as increased risk of antisocial and delinquent behavior. (CD, Sections 6.1 and 8.4.2)

• The current epidemiological evidence indicates a steeper slope of the blood Pb concentration-response relationship at lower blood Pb levels, particularly those below 10 µg/dL (CD, Sections 6.2.13 and 8.6).

• 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).

• In adults, with regard to cardiovascular outcomes, the Criteria Document included the following summary (CD, p. E–10).

Epidemiological studies have consistently demonstrated associations between Pb exposure and enhanced risk of deleterious cardiovascular outcomes, including increased blood pressure and incidence of hypertension.[74] 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. Studies have also found that cumulative past Pb exposure (e.g., bone Pb) may be as important, if not more, than present Pb exposure in assessing cardiovascular effects. The evidence for an association of Pb with cardiovascular morbidity and mortality is limited but supportive.

Studies of nationally representative U.S. samples observed associations between blood Pb levels and increased systolic blood pressure at population mean blood Pb levels less than 5 µg/dL, particularly among African Americans (CD, Section 6.5.2). With regard to gender differences, the Criteria Document states the following (CD, p. 6–154).

Although females often show lower Pb coefficients than males, and Blacks higher Pb coefficients than Whites, where these differences have been formally tested, they are usually not statistically significant. The tendencies may well arise in the differential Pb exposure in these strata, lower in women than in men, higher in Blacks than in Whites. The same sex and race differential is found with blood pressure.

Animal evidence provides confirmation of Pb effects on cardiovascular functions (CD, Sections 5.5, 6.5, 8.4.3 and 8.6.3).

• Renal effects, evidenced by reduced renal filtration, have also been associated with Pb exposures indexed by bone Pb levels and also with mean blood Pb levels in the range of 5 to 10 µg/dL in the general adult population, with the potential adverse impact of such effects being enhanced for susceptible subpopulations including those with diabetes, hypertension, and chronic renal insufficiency (CD, Sections 6.4, 8.4.5, and 8.6.4). The full significance of this effect is unclear,

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[74] The Criteria Document states that ''While several studies have demonstrated a positive correlation between blood pressure and blood Pb concentration, others have failed to show such association when controlling for confounding factors such as tobacco smoking, exercise, body weight, alcohol consumption, and socioeconomic status. Thus, the studies that have employed blood Pb level as an index of exposure have shown a relatively weak association with blood pressure. In contrast, the majority of the more recent studies employing bone Pb level have found a strong association between long-term Pb exposure and arterial pressure (Chapter 6). Since the residence time of Pb in the blood is relatively short but very long in the bone, the latter observations have provided rather compelling evidence for a positive relationship between Pb exposure and a subsequent rise in arterial pressure'' (CD, pp. 5–102 to 5–103). Further, in consideration of the meta-analysis also described here, the Criteria Document stated that ''The meta-analysis provides strong evidence for an association between increased blood Pb and increased blood pressure over a wide range of populations'' (CD, p. 6–130) and ''the meta-analyses results suggest that studies not detecting an effect may be due to small sample sizes or other factors affecting precision of estimation of the exposure effect relationship'' (CD, p. 6–133).

given that other evidence of more marked signs of renal dysfunction have not been detected at blood Pb levels below 30–40 µg/dL in large studies of occupationally exposed Pb workers (CD, pp. 6–270 and 8–50).[75]

• Other Pb associated effects in adults occurring at or just above 10 µg/dL include hematological (*e.g.*, impact on heme synthesis pathway) and neurological effects, with animal evidence providing support of Pb effects on these systems and evidence regarding mechanism of action (CD, Sections 5.2, 5.3, 6.3 and 6.9.2).

C. Human Exposure and Health Risk Assessments

This section presents a brief summary of the human exposure and health risk assessments conducted by EPA for this review. The complete full-scale assessment, which includes specific analyses conducted to address CASAC comments and advice on an earlier draft assessment, is presented in the final Risk Assessment Report (USEPA, 2007b).

The focus of this Pb NAAQS risk assessment is on characterizing risk resulting from exposure to policy-relevant Pb (i.e., exposure to Pb that has passed through ambient air on its path from source to human exposure—as described in section II.A.2). The design and implementation of this assessment needed to address significant limitations and complexity that go far beyond the situation for similar assessments typically performed for other criteria pollutants. Not only was the risk assessment constrained by the timeframe allowed for this review in the context of breadth of information to address, it was also constrained by significant limitations in data and modeling tools for the assessment, as discussed further in section II.C.2.h below. Furthermore, the multimedia and persistent nature of Pb, and the role of multiple exposure pathways (discussed in section II.A), add

significant complexity to the assessment as compared to other assessments that focus only on the inhalation pathway. The impact of this on our estimates for air-related exposure pathways is discussed in section II.C.2.e.

The remainder of this overview of the human health risk assessment is organized as follows. An overview of the human health risk assessment completed in the last review of the Pb NAAQS in 1990 (USEPA, 1990a) is presented first. Next, design aspects of the current risk assessment are presented, including: (a) CASAC advice regarding the design of the risk assessment, (b) description of health endpoints and associated risk metrics modeled, including the concentration-response functions used, (c) overview of the case study approach employed, (d) description of air quality scenarios modeled, (e) explanation of air-related versus background classification of risk results in the context of this analysis, (f) overview of analytical (modeling) steps completed for the risk assessment and (g) description of the multiple sets of risk results generated for the analysis. Then, key sources of uncertainty associated with the analysis are presented. And finally, a summary of exposure and risk estimates and key observations is presented.

1. Overview of Risk Assessment From Last Review

The risk assessment conducted in support of the last review used a case study approach to compare air quality scenarios in terms of their impact on the percentage of modeled populations that exceeded specific blood Pb levels chosen with consideration of the health effects evidence at that time (USEPA, 1990b; USEPA, 1989). The case studies in that analysis, however, focused exclusively on Pb smelters including two secondary and one primary smelter and did not consider exposures in a more general urban context. The analysis focused on children (birth through 7 years of age) and middle-aged men. The assessment evaluated impacts of alternate NAAQS on numbers of children and men with blood Pb levels above levels of concern based on health effects evidence at that time. The primary difference between the risk assessment approach used in the current analysis and the assessment completed in 1990 involves the risk metric employed. Rather than estimating the percentage of study populations with exposures above blood Pb levels of interest as was done in the last review (i.e., 10, 12 and 15 µg/dL), the current analysis estimates changes in health risk, specifically IQ loss, associated with

Pb exposure for child populations at each of the case study locations with that estimated IQ loss further differentiated between air-related and background Pb exposure categories.

2. Design Aspects of Exposure and Risk Assessments

This section provides an overview of key elements of the assessment design, inputs, and methods, and includes identification of key uncertainties and limitations.

a. CASAC Advice

The CASAC conducted a consultation on the draft analysis plan for the risk assessment (USEPA, 2006c) in June, 2006 (Henderson, 2006). Some key comments provided by CASAC members on the plan included: (1) Placing a higher priority on modeling the child IQ metric than the adult endpoints (e.g., cardiovascular effects), (2) recognizing the importance of indoor dust loading by Pb contained in outdoor air as a factor in Pb-related exposure and risk for sources considered in this analysis, and (3) concurring with use of the IEUBK biokinetic blood Pb model. Taking these comments into account, a pilot phase assessment was conducted to test the risk assessment methodology being developed for the subsequent full-scale assessment. The pilot phase assessment is described in the first draft Staff Paper and accompanying technical report (ICF 2006), which was discussed by the CASAC Pb panel on February 6–7 (Henderson, 2007a).

Results from the pilot assessment, together with comments received from CASAC and the public, informed the design of the full-scale analysis. The full-scale analysis included a substitution of a more generalized urban case study for the location-specific near-roadway case study evaluated in the pilot. In addition, a number of changes were made in the exposure and risk assessment approaches, including the development of a new indoor dust Pb model focused specifically on urban residential locations and specification of additional IQ loss concentration-response (C–R) functions to provide greater coverage for potential impacts at lower exposure levels.

The draft full-scale assessment was presented in the July 2007 draft risk assessment report (USEPA, 2007a) that was released for public comment and provided to CASAC for review. In their review of the July draft risk assessment report, the CASAC Pb Panel made several recommendations for additional exposure and health risk analyses (Henderson, 2007b). These included a recommendation that the general urban

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[75] In the general population, both cumulative and circulating Pb has been found to be associated with longitudinal decline in renal functions. In the large NHANES III study, alterations in urinary creatinine excretion rate (one indicator of possible renal dysfunction) were observed in hypertensives at a mean blood Pb of only 4.2 µg/dL. These results provide suggestive evidence that the kidney may well be a target organ for effects from Pb in adults at current U.S. environmental exposure levels. The magnitude of the effect of Pb on renal function ranged from 0.2 to −1.8 mL/min change in creatinine clearance per 1.0 µg/dL increase in blood Pb in general population studies. However, the full significance of this effect is unclear, given that other evidence of more marked signs of renal dysfunction have not been detected at blood Pb levels below 30–40 µg/dL among thousands of occupationally exposed Pb workers that have been studied (CD, p. 6–270).

case study be augmented by the inclusion of risk analyses in specific urban areas of the U.S. In this regard, they specifically stated the following (Henderson, 2007b, p. 3)

* * * the CASAC strongly believes that it is important that EPA staff make estimates of exposure that will have national implications for, and relevance to, urban areas; and that, significantly, the case studies of both primary lead (Pb) smelter sites as well as secondary smelter sites, while relevant to a few atypical locations, do not meet the needs of supporting a Lead NAAQS. The Agency should also undertake case studies of several urban areas with varying lead exposure concentrations, based on the prototypic urban risk assessment that OAQPS produced in the 2nd Draft Lead Human Exposure and Health Risk Assessments. In order to estimate the magnitude of risk, the Agency should estimate exposures and convert these exposures to estimates of blood levels and IQ loss for children living in specific urban areas.

Hence, EPA included additional case studies in the risk assessment focused on characterizing risk for residential populations in three specific urban locations. Further, CASAC recommended using a concentration-response function with a change in slope near 7.5 µg/dL. Accordingly, EPA included such an additional concentration-response function in the risk assessment. Results from the initial full-scale analyses, along with comments from CASAC, such as those described here, and the public resulted in a final version of the full-scale assessments which is briefly summarized here and presented in greater detail in the Risk Assessment Report and associated appendices (USEPA, 2007b).

In their review of the final risk assessment, CASAC expressed strong support, stating as follows (Henderson, 2008a, p. 4):

The 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.

b. Health Endpoint, Risk Metric and Concentration-Response Functions

The health endpoint on which the quantitative health risk assessment focuses is developmental neurotoxicity in children, with IQ decrement (or loss) as the risk metric. Among the wide variety of health endpoints associated with Pb exposures, there is general consensus that the developing nervous system in young children is the most

sensitive and that neurobehavioral effects (specifically neurocognitive deficits), including IQ decrements, appear to occur at lower blood levels than previously believed (i.e., at levels <10 µg/dL). 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).

Given the evidence described in detail in the Criteria Document (Chapters 6 and 8), and in consideration of CASAC recommendations (Henderson, 2006, 2007a, 2007b), the risk assessment for this review relies on the functions presented by Lanphear and others (2005) that relate absolute IQ as a function of concurrent blood Pb or of the log of concurrent blood Pb, and lifetime average blood Pb, respectively. As discussed in the Criteria Document (CD, p. 8–63 to 8–64), the slope of the concentration-response relationship described by these functions is greater at the lower blood Pb levels (e.g., less than 10 µg/dL). As discussed in the Criteria Document and summarized in section II.B.2, threshold blood Pb levels for these effects cannot be discerned from the currently available epidemiological studies, and the evidence in the animal Pb neurotoxicity literature does not define a threshold for any of the toxic mechanisms of Pb (CD, Sections 5.3.7 and 6.2).

In applying relationships observed with the international pooled analysis by Lanphear and others (2005) to the risk assessment, which includes blood Pb levels below the range represented by the pooled analysis, several alternative blood Pb concentration-response models were considered in recognition of a reduced confidence in our ability to characterize the quantitative blood Pb concentration-response relationship at the lowest blood Pb levels represented in the recent epidemiological studies. The functions considered and employed in the initial risk analyses for this review include the following.

• Log-linear function with low-exposure linearization, for both concurrent and lifetime average blood metrics, applies the nonlinear relationship down to the blood Pb concentration representing the lower bound of blood Pb levels for that blood metric in the pooled analysis and applies the slope of the tangent at that point to blood Pb concentrations estimated in the risk assessment to fall below that level.

• Log-linear function with cutpoint, for both concurrent and lifetime average blood metrics, also applies the

nonlinear relationship at blood Pb concentrations above the lower bound of blood Pb concentrations in the pooled analysis dataset for that blood metric, but then applies zero risk to all lower blood Pb concentrations estimated in the risk assessment (this cutpoint is 1 µg/dL for the concurrent blood Pb).

In the additional risk analyses performed subsequent to the August 2007 CASAC public meeting, the two functions listed above and the following two functions were employed (details on the forms of these functions as applied in this risk assessment are described in Section 5.3.1 of the Risk Assessment Report).

• Population stratified dual linear function for concurrent blood Pb, derived from the pooled dataset stratified at peak blood Pb of 10 µg/dL [76] and

• Population stratified dual linear function for concurrent blood Pb, derived from the pooled dataset stratified at 7.5 µg/dL peak blood Pb.

In interpreting risk estimates derived using the various functions, consideration should be given to the uncertainties with regard to the precision of the coefficients used for each analysis. The coefficients for the log-linear model from Lanphear *et al.* (2005) had undergone a careful development process, including sensitivity analyses, using all available data from 1,333 children. The shape of the exposure-response relationship was first assessed through tests of linearity, then by evaluating the restricted cubic spline model. After determining that the log-linear model provided a good fit to the data, covariates to adjust for potential confounding were included in the log-linear model with careful consideration of the stability of the parameter estimates. After the multiple regression models were developed, regression diagnostics were employed to ascertain whether the Pb coefficients were affected by collinearity or influential observations. To further investigate the stability of the model, a random-effects model (with sites

[76] As mentioned above (section II.B.2.b), this function (derived for lifetime average blood Pb), was used in the economic analysis for the RRP rule. This model was selected for the RRP economic analysis with consideration of advice from CASAC and of the distribution of blood Pb levels being considered in that analysis, which focused on children living in houses with lead-based paint (USEPA, 2008). With consideration of these blood Pb levels, the economic analysis document states that "[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).

random) was applied to evaluate the results and also the effect of omitting one of the seven cohorts on the Pb coefficient. In the various sensitivity analyses performed, the coefficient from the log-linear model was found to be robust and stable. The log-linear model, however, is not biologically plausible at the very lowest blood Pb concentrations as they approach zero; therefore, in the first two functions the log-linear model is applied down to a cutpoint (of 1 µg/dL for the concurrent blood Pb metric), selected based on the low end of the blood Pb levels in the pooled dataset, followed by a linearization or an assumption of zero risk at levels below that point.

In contrast, the coefficients from the two analyses using the population stratified dual linear function with stratification at 7.5 µg/dL and 10 µg/dL,[77] peak blood Pb, have not undergone as careful development. These analyses were primarily done to compare the lead-associated decrement at lower blood Pb concentrations and higher blood Pb concentrations. For these analyses, the study population was stratified at the specified peak blood Pb level and separate linear models were fitted to the concurrent blood Pb data for the children in the two study population subgroups.[78] While these analyses are quite suitable for the purpose of investigating whether the slope at lower concentration levels is greater compared to higher concentration levels, use of such coefficients as the primary C–R function in a risk analysis such as this may be inappropriate. Further, only 103 children had maximal blood Pb levels less than 7.5 µg/dL and 244 children had maximal blood Pb levels less than 10 µg/dL. While these children may better represent current blood Pb levels, not fitting a single model using all available data may lead to bias. Slob *et al.* (2005) noted that the usual argument for not considering data from the high dose range is that different biological mechanisms may play a role at higher doses compared to lower doses. However, this does not mean a single curve across the entire exposure range cannot describe the relationship. The fitted curve merely assumes that the underlying dose-response follows a smooth curve over the whole dose range. If biological mechanisms change when going from lower to higher doses, this change will result in a gradually changing slope of the dose-response.

The major strength of the Lanphear *et al.* (2005) study was the large sample size and the pooled analysis of data from seven different cohorts. In the case of the study population subgroup with peak blood Pb below 7.5 µg/dL, less than 10% of the available data is used in the analysis (103 of the 1333 subjects in the pooled dataset), with more than half of the data coming from one cohort (Rochester) and the six other cohorts contributing zero to 13 children to the analysis. Such an analysis consequently does not make full use of the strength of the pooled study by Lanphear and others (2005).

In consideration of the preceding discussion and the range of blood Pb levels assessed in this analysis,[79] greater confidence is placed in the log-linear model form compared to the dual-linear stratified models for purposes of the risk assessment described in this notice. Further, in considering risk estimates derived from the four core functions (log-linear function with low-exposure linearization, log-linear function with cutpoint, dual linear function, stratified at 7.5 µg/dL peak blood Pb, and dual linear function, stratified at 10 µg/dL peak blood Pb), greatest confidence is assigned to risk estimates derived using the log-linear function with low-exposure linearization since this function (a) is a nonlinear function that describes greater response per unit blood Pb at lower blood Pb levels consistent with multiple studies identified in the discussion above, (b) is based on fitting a function to the entire pooled dataset (and hence uses all of the data in describing response across the range of exposures), (c) is supported by sensitivity analyses showing the model coefficients to be robust, and (d) provides an approach for predicting IQ loss at the lowest exposures simulated in the assessment (consistent with the lack of evidence for a threshold). Note, however, that risk estimates generated using the other three concentration-response functions are also presented to provide perspective on the impact of uncertainty in this key modeling step. We additionally note that the CASAC Pb Panel recommended that C–R function derived from the pooled dataset stratified at 7.5 µg/dL, peak blood Pb, be given weight in this analysis (Henderson, 2008).

c. Case Study Approach

For the risk assessment described in this notice, a case study approach was

employed as described in Sections 2.2 (and subsections) and 5.1.3 of the Risk Assessment Report (USEPA, 2007b). In summarizing the assessment in this proposal, we have focused on five [80] case studies 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 level being evaluated, and (2) urban populations with a broader range of air-related exposures. These five case studies are:

• *A general urban case study:* This case study is not based on a specific geographic location and reflects several simplifying assumptions used 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. This case study characterizes risk for a localized part of an urban area at different standard levels, but based on national average estimates of the relationships between the different standard form assessed and ambient air exposure concentrations. Thus, while this 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.[81]

• *A primary Pb smelter case study:*[82] This case study estimates risk for children living in an area currently not in attainment with the current NAAQS that is impacted by Pb emissions from a primary Pb smelter. Results described

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[77] See previous footnote.

[78] Neither fit of the model nor other sensitivity analyses were conducted (or reported) for these coefficients.

[79] The median concurrent values in all case studies and air quality scenarios are below 5 µg/dL and those for air quality scenarios within the range of standard levels proposed in this notice are below 3 µg/dL (as shown in Table 1).

[80] 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, 2007b), significant limitations in the approaches employed for this case study have contributed to large uncertainties in the corresponding estimates.

[81] In representing the different forms of each standard level assessed (maximum monthly or maximum quarterly) as annual air concentrations for input to the blood Pb model for this case study, however, we relied on averages of these relationships for large urban areas nationally. As the averages are higher than the medians, localized areas near more than half the urban monitoring locations would have higher exposures and associated risks than those reported for this case study. Further, we note that exposure concentrations would be twice those used here if the 25th percentile values for these relationships had been used in place of the averages. For this reason, this case study should not be interpreted as representing a high-end scenario with regard to the characterization of ambient air Pb levels and associated risk.

[82] See Section II.C.2.a for a summary of CASAC's comment with regard to the primary and secondary Pb smelter case studies.

here are those for the area within 1.5 km of the facility (the ''subarea'') where airborne Pb concentrations are closest to the current standard. As such, this case study characterizes risk for a specific more highly exposed population and also provides insights on risk to child populations living in areas near large sources of Pb emissions.[83]

• *Three location-specific urban case studies:* These urban case studies focus on specific urban areas (Cleveland, Chicago and Los Angeles) to provide representations of the distribution of ambient air-related risk in specific densely populated urban locations. These case studies represent areas with specific population distributions and that experience a broader range of air-related exposures due both to potential spatial gradients in ambient air Pb levels and population density. A large majority of the population in these case studies resides in areas with much lower air concentrations than those in the very small subareas of these case studies with the highest concentrations. Ambient air Pb concentrations are characterized using source-oriented and other Pb-TSP monitors in these cities, while location-specific U.S. Census demographic data are used to characterize the spatial distribution of residential child populations in these study areas.

These different case studies generally represent two types of population exposures. The general urban and primary Pb smelter subarea provide estimates of risk for more highly air-pathway exposed children residing in small neighborhoods or localized residential areas with air concentrations somewhat near the standard level being evaluated. By contrast, the three location-specific urban case studies included in the analysis provide risk estimates for an urban population with a broader range of air-related exposures. In fact, for the location-specific urban case studies, the majority of the modeled populations experience ambient air Pb levels significantly lower than the standard level being evaluated, with only a small population

experiencing ambient air Pb levels at or near the standard.[84]

In considering risk results generated for the location-specific urban case studies, we note that, given the wide range of monitored Pb levels in urban areas, combined with the relatively limited monitoring network characterizing ambient levels in the urban setting, it is not possible to determine where these case studies fall within the distribution of ambient air-related risk in U.S. cities.

d. Air Quality Scenarios

Air quality scenarios assessed include (a) a current conditions scenario for the location-specific urban case studies and the general urban case study, (b) a current NAAQS scenario for the location-specific urban case studies, the general urban case study and the primary Pb smelter case study, and (c) a range of alternative NAAQS scenarios for all case studies. The alternative NAAQS scenarios include levels of 0.5, 0.2, 0.05, and 0.02 µg/m³, with a monthly averaging time, as well as a level of 0.2 µg/m³ scenario using a quarterly averaging time.[85]

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.[86] 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 III.B.2.h below), 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. When evaluating these results it is important to keep these limitations and uncertainties in mind.

Current conditions for the three location-specific urban case studies in terms of maximum quarterly average air Pb concentrations are 0.09, 0.14 and 0.36 µg/m³ for the study areas in Los Angeles, Chicago and Cleveland, respectively. In terms of maximum monthly average the values are 0.17 µg/m³, 0.31 µg/m³ and 0.56 µg/m³ for the study areas in Los Angeles, Chicago and Cleveland, respectively.

Details of the assessment scenarios, including a description of the derivation of Pb concentrations for air and other media are presented in Sections 2.3 (and subsections) and Section 5.1.1 of the Risk Assessment Report (USEPA, 2007b).

e. Categorization of Policy-Relevant Exposure Pathways

As discussed in Section IIA, this review focuses on air-related exposure pathways (i.e., those pathways where Pb passes through ambient air on its path from source to human exposure). These include both inhalation of ambient air Pb (including both Pb emitted directly into ambient air as well as resuspended Pb); and ingestion of Pb that, once airborne, has made its way into indoor dust, outdoor dust or soil, dietary items (e.g., crops and livestock), and drinking water. Because of the nonlinear response of blood Pb to exposure (simulated in the IEUBK blood Pb model) and also the nonlinearity reflected in the C-R functions for estimation of IQ loss, this assessment first estimates total blood Pb and risk (air- and nonair-related), and then separates out those estimates of blood Pb and associated risk associated with the pathways of interest in this review.

To separate out risk for the pathways of interest in this review, we split the estimates of total (all-pathway) blood Pb and IQ loss into background 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 identified in section II.A.2 as being tied most directly to ambient air, which consequently have the potential to respond relatively more quickly to changes in air Pb (inhalation and ingestion of indoor dust loaded directly from ambient air Pb) were placed into the ''recent air'' category. The other air-related Pb exposure pathways, associated with atmospheric deposition, were placed into the ''past air'' category. These include ingestion of Pb in

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[83] Result for the full study area, which extends 10 km out from the facility, are presented in the Risk Assessment Report (USEPA, 2007a), but are not presented here. Exposures in the full study area were dominated by modeled children farther from the facility where, as discussed in the ANPR (section III.B.2.), there is likely underestimation of ambient air-related Pb exposure due to increasing influence of other sources relative to that of the facility, which were not included in the dispersion modeling performed to estimate air concentrations for this case study.

[84] 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 second evidence-based framework (see Sections II.D.2.a 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 air pathway exposed to air Pb concentrations somewhat near the standard level evaluated.

[85] For further discussion of the air quality scenarios and averaging times included in the risk assessment, see section 2.3.1 of the Risk Assessment Report (USEPA, 2007b).

[86] 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.

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 described in section II.A.2 above).[87]

Thus, total blood Pb and IQ loss estimates were apportioned into the following pathways or pathway combinations:

• Inhalation of ambient air Pb (i.e., "recent air" Pb): This is derived using the blood Pb estimate resulting from Pb exposure limited to the inhalation pathway (and includes inhalation of Pb in ambient air from all sources contributing to the ambient air concentration estimate, including potentially resuspension).

• Ingestion of "recent air" indoor dust Pb: This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of the Pb in indoor dust that is predicted in this assessment from infiltration of ambient air indoors and subsequent deposition.[88]

• Ingestion of "other" indoor dust Pb (considered part of "past air" exposure): This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of the Pb in indoor dust that is not predicted from infiltration of ambient air indoors and subsequent deposition.[89] This is interpreted to represent indoor paint, outdoor soil/dust, and additional sources of Pb to indoor dust including historical air (as discussed in the Risk Assessment Report, Section 2.4.3). As the intercept in regression dust models will be inclusive of error associated with the model coefficients, this category also includes some representation of dust Pb associated with current ambient air concentrations (described in previous bullet). For the primary Pb smelter case study, estimates for this pathway are not separated from estimates for the pathway described above due to uncertainty regarding this categorization with the model used for this case study (Risk Assessment Report,

Section 3.1.4.2). This pathway is included in the "past air" category.

• Ingestion of outdoor soil/dust Pb: This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of outdoor soil/dust Pb. This pathway is included in the "past air" category (and could include contamination from historic Pb emissions from automobiles and Pb paint).

• Ingestion of drinking water Pb: This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of drinking water Pb. This pathway is included in the policy-relevant background category.

• Ingestion of dietary Pb: This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of dietary Pb. This pathway is included in the policy-relevant background category.

As noted above, significant limitations in our modeling tools and data resulted in an inability to parse risk estimates for specific pathways, such that we approximated estimates for the air-related and background categories. Of note in this regard is the apportionment of background (nonair) pathways. For example, while conceptually indoor Pb paint 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, ultimately, 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 lead Pb as a component of "other" indoor air (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. Further, 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). But 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.

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). These exposures were held constant across all air quality scenarios. 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. Interpretation of risk estimates is discussed more fully in section II.C.3.b.

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.

f. Analytical Steps

The risk assessment includes four analytical steps, briefly described below and presented in detail in Sections 2.4.4, 3.1, 3.2, 4.1, and 5.1 of the Risk Assessment Report (USEPA, 2007b).

• *Characterization of Pb in ambient air:* The characterization of outdoor ambient air Pb levels uses different approaches depending on the case study (as explained in more detail below): (a) source-oriented and non-source oriented monitors are assumed to represent different exposure zones in the city-specific case studies, (b) a single exposure level is assumed for the entire

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[87] As discussed below, due to technical limitations related to indoor dust Pb modeling, dust from Pb paint may be included to some extent in the "past air" category of exposure pathways.

[88] Recent air indoor dust Pb was estimated using the mechanistic component of the hybrid blood Pb model (see Section 3.1.4 of the Risk Assessment Report). For the primary Pb smelter case study, estimates for this pathway are not separated from estimates for the pathway described in the subsequent bullet due to uncertainty regarding this categorization with the model used for this case study (Section 3.1.4.2 of the Risk Assessment Report).

[89] "Other" indoor dust Pb is estimated using the intercept in the dust models plus that predicted by the outdoor soil concentration coefficient (for models that include soil Pb as a predictor of indoor dust Pb) (Section 3.1.4 of the Risk Assessment Report).

population in the general urban case study, and (c) ambient levels are estimated using air dispersion modeling based on Pb emissions from a particular facility in the primary Pb smelter case study.

• *Characterization of outdoor soil/ dust and indoor dust Pb concentrations:* Outdoor soil Pb levels are estimated using empirical data and fate and transport modeling. Indoor dust Pb levels are predicted using a combination of (a) regression-based models that relate indoor dust to ambient air Pb and outdoor soil Pb, and (b) mechanistic models.[90]

• *Characterization of blood Pb levels:* Blood Pb levels for each exposure zone are derived from central-tendency blood Pb concentrations estimated using the Integrated Exposure and Uptake Biokinetic (IEUBK) model, and concurrent or lifetime average blood Pb is estimated from these outputs as described in Section 3.2.1.1 of the Risk Assessment Report (USEPA, 2007b). For the point source and location-specific urban case studies, a probabilistic exposure model is used to generate population distributions of blood Pb concentrations based on: (a) The central tendency blood Pb levels for each exposure zone, (b) demographic data for the distribution of children (less than 7 years of age) across exposure zones in a study area, and (c) a geometric standard deviation (GSD) intended to characterize interindividual variability in blood Pb (e.g., reflecting differences in behavior and biokinetics related to Pb). For the general urban case study, as demographic data for a specific location are not considered, the GSD is applied directly to the central tendency blood Pb level to estimate a population distribution of blood Pb levels.

Additional detail on the methods used to model population blood Pb levels is presented in Sections 3.2.2 and 5.2.2.3 of the Risk Assessment Report (USEPA, 2007b).

• *Risk characterization (estimating IQ loss):* Concurrent or lifetime average blood Pb estimates for each simulated child in each case study population are converted into total Pb-related IQ loss estimates using the concentration-response functions described above in section II.C.2.b.[91]

We have also used the results of exposure modeling to estimate air-to-blood ratios for two of the case studies (the general urban and primary Pb smelter case studies). Specifically, we compared the change in ambient air Pb between adjacent NAAQS levels with the associated reduction in concurrent blood Pb levels (for the median population percentile) to derive air-to-blood ratios. As they relate air concentrations[92] input to the first analytical step to blood Pb estimates output from the third analytical step, they may be viewed as a collapsed alternate to the three steps for the exposure pathways directly linked to air concentrations in this assessment. The values for these ratios are affected by design aspects of the risk assessment, most notably those identified here:

• Because they are derived from differences in blood Pb estimates between air quality scenarios and the only pathways varied with air quality scenarios are ambient air and indoor dust (as described in section II.C.2.e above), the exposure pathways reflected in the ratios are generally the ''recent air'' pathways (described in section II.C.2.e above), which include inhalation of ambient air and ingestion of indoor dust loaded by infiltration of ambient air. Ratios for the primary Pb smelter case study subarea may additionally reflect some contributions to indoor dust from other ambient air-related pathways (e.g., ''tracking in'' of soil containing ambient air Pb), yet still not all air-related pathways. Thus, the air-to-blood ratios derived for both case studies (described in section II.C.3.a) are lower than they would be if they reflected all air-related pathways.

• The blood Pb estimates used in this calculation are for the ''concurrent'' metric (i.e., concentrations during the 7th year of life). Accordingly, the resultant air-to-blood ratios are lower than they would be if based on blood Pb estimates for the 2nd year of life (e.g., peak) or estimates averaged over the exposure period.

Key limitations and uncertainties associated with the application of these specific analytical steps are summarized in Section III.B.2.k below.

g. Generating Multiple Sets of Risk Results

In the initial analyses for the full-scale assessment (USEPA, 2007a), EPA implemented multiple modeling approaches for each case study scenario in an effort to characterize the potential impact on exposure and risk estimates of uncertainty associated with the limitations in the tools, data and methods available for this risk assessment and with key analytical steps in the modeling approach. These multiple modeling approaches are described in Section 2.4.6.2 of the final Risk Assessment Report (USEPA, 2007b). In consideration of comments provided by CASAC (Henderson, 2007b) on these analyses regarding which modeling approach they felt had greater scientific support, a pared down set of modeling combinations was identified as the core approach for the subsequent analyses. The core modeling approach includes the following key elements:

• Ambient air Pb estimates (based on monitors or modeling and proportional rollbacks, as described below),

• Background exposure from food and water (as described above),

• The hybrid indoor dust model specifically developed for urban residential applications (which predicts Pb in indoor dust as a function of ambient air Pb and nonair contribution),

• The IEUBK blood Pb model (which predicts blood Pb in young children exposed to Pb from multiple exposure pathways),

• The concurrent blood Pb metric,

• A GSD for concurrent blood Pb of 2.1 to characterize interindividual variability in blood Pb levels for a given ambient level for the urban case studies,[93] and

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[90] Indoor dust Pb modeling for the urban case studies is based on a hybrid mechanistic-empirical model which considers the direct impact of Pb in ambient air on indoor dust Pb (i.e., which models the infiltration of ambient air indoors and subsequent deposition of Pb to indoor surfaces). This modeling does not consider other ambient air-related contributions to indoor dust, such as ''tracking in'' of outdoor soil Pb. By contrast, indoor dust Pb modeling for the primary Pb smelter case study subarea uses a site-specific regression model which relates average dust Pb values (based on a recent multi-year dataset) to annual average air Pb concentrations (based on air dispersion modeling). In this way, modeling for the primary Pb smelter subarea may reflect some contributions to indoor dust Pb that relate to longer term impacts of ambient air (e.g., ''tracking in'' of outdoor soil), as well as contributions from infiltration of ambient air. Additional detail on the methods used in characterizing Pb concentrations in outdoor soil and indoor dust are presented in Sections 3.1.3 and 3.1.4 of the Risk Assessment, respectively. Data, methods and assumptions here used in characterizing Pb concentrations in these exposure media may differ from those in other analyses that serve different purposes.

[91] The four C–R functions applied in the risk assessment, which are based on analyses presented in Lanphear *et al.* (2005) include a log-linear function with low-exposure linearization, a log-linear function with a cutpoint, and two dual linear functions (based on population stratification at peak blood Pb levels of 7.5 and 10 µg/dL) (see section II.C.2.b).

[92] Because the IEUBK blood Pb model runs with an annual time step, the air concentrations input to the ''recent air'' pathways modeling steps were in terms of annual average air concentration.

[93] In the economic analysis for the RRP rule, a GSD of 1.6 was used in its probabilistic simulations, reflecting the fact that the simulated exposures focus on a subset of Pb exposure pathways (exposure to dust and airborne Pb resulting from renovation activity) and a CASAC recommendation to use the IEUBK-recommended GSD with the Leggett model, where no GSD is provided. In addition, the accompanying sensitivity analysis used a GSD of 2.1 to consider the impact on IQ change estiamtes of using a larger GSD, which

• Four different functions relating concurrent blood Pb to IQ loss (described in section II.C.2.b), including two log-linear models (one with a cutpoint and one with low-exposure linearization) and two dual-linear models with stratification, one stratified at 7.5 µg/dL peak blood Pb and the other at 10 µg/dL peak blood Pb.

For each case study, the core modeling approach employs a single set of modeling elements to estimate exposure and the four different concentration-response functions referenced above to derive four sets of risk results from the single set of exposure estimates. The spread of estimates resulting from application of all four functions captures much of the uncertainty associated model choice in this analytical step. Among these four functions, EPA has greater confidence in estimates derived using the log-linear with low-exposure linearization concentration-response function as discussed above.

In addition to employing multiple concentration-response functions, the assessment includes various sensitivity analyses to characterize the potential impact of uncertainty in other key analysis steps on exposure and risk estimates. The sensitivity analyses and uncertainty characterization completed for the risk analysis are described in Sections 3.5, 4.3, 5.2.5 and 5.3.3 of the Risk Assessment Report (USEPA, 2007b).

h. Key Limitations and Uncertainties

As recognized above, EPA has made simplifying assumptions in several areas of this assessment due to the limited data, models, and time available. These assumptions and related limitations and uncertainties are described in the Risk Assessment Report (USEPA, 2007b). Key assumptions, limitations and uncertainties are briefly identified below, with emphasis on those sources of uncertainty considered most critical in interpreting risk results. In the presentation below, limitations (and associated uncertainty) are listed, beginning with those regarding design of the assessment or case studies, followed by those regarding estimation of Pb concentrations in ambient air indoor dust, outdoor soil/dust, and blood, and lastly regarding estimation of Pb-related IQ loss.

• *Temporal aspects:* Exposure modeling uses a 7 year exposure period for each simulated child, during which time, media concentrations remain fixed

would reflect greater heterogeneity in the study population with regard to Pb exposure and blood Pb response.

(at levels associated with the ambient air Pb level being modeled) and the child remains at the same residence, while exposure factors and physiological parameters are adjusted to match the age of the child. These aspects are a simplification of population exposures that contributes some uncertainty to our exposure and risk estimates.

• *General urban case study:* As described in section II.C.2.c, this case study is not based on a specific location and is instead intended to represent a smaller neighborhood experiencing ambient air Pb levels at or near the standard of interest. Consequently, it assumes (a) a single exposure zone within which all media concentrations of Pb are assumed to be spatially uniform and (b) a uniformly distributed population of unspecified size. While these assumptions are reasonable in the context of evaluating risk for a smaller subpopulation located close to a monitor reporting values at or near the standard of interest, there is significant uncertainty associated with extrapolating these risks to a specific urban location, particularly if that urban location is relatively large, given that larger urban areas are expected to have increasingly varied patterns of ambient air Pb levels and population density. 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:* The Pb-TSP monitoring network is currently quite limited and consequently, the number of monitors available to represent air concentrations in these case studies is limited, ranged from six for Cleveland to 11 for Chicago. Accordingly, our estimates of the magnitude of and spatial variation of air Pb concentrations are subject to uncertainty associated with the limited monitoring data and method used in extrapolating from those data to characterize an ambient air Pb level surface for these modeled urban areas. Details on the approach used to derive ambient air Pb surfaces for the urban case studies based on monitoring data are presented in Section 5.1.3 of the Risk Assessment Report (USEPA, 2007b). As recognized in Section, III.B.2.a, the analyses for these case studies were developed in response to CASAC recommendations on the July 2007 draft Risk Assessment (Henderson, 2007b). Subsequently, the CASAC has reviewed the approach used in conducting the final draft of the full-

scale risk assessment, including the inclusion of the location-specific urban case studies and expressed broad support for the technical approach used (Henderson, 2008).

• *Current NAAQS air quality scenarios:* For the location-specific urban case studies, proportional roll-up procedures were used to adjust ambient air Pb concentrations up to just meet the current NAAQS (a detailed discussion is provided in Sections 2.3.1 and 5.2.2.1 of the Risk Assessment Report, USEPA, 2007b). This procedure was used to provide insights into the degree of risk which could be associated with ambient air Pb levels at or near the current standard in urban areas. 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. For the primary Pb smelter case study, where current conditions exceed the current NAAQS, attainment of the current NAAQS was simulated using air quality modeling, emissions and source parameters used in developing the 2007 proposed revision to the State Implementation Plan for the area (described in Section 3.1.1.2 of the Risk Assessment Report (USEPA, 2007b)).

• *Alternative NAAQS air quality scenarios:* In all case studies, proportional roll-down procedures were used to adjust ambient air Pb concentrations downward to attain alternative NAAQS (described in Sections 2.3.1 and 5.2.2.1 of the Risk Assessment Report, USEPA, 2007b). There is significant uncertainty in simulating conditions associated with the implementation of emissions reduction actions to meet a lower standard.

• *Estimates of outdoor soil/dust Pb concentrations:* Outdoor soil Pb concentration for both the urban case studies and the primary Pb smelter case study are based on empirical data (as described in Section 3.1.3 of the Risk Assessment). To the extent that these data are from areas containing older structures, the impact of Pb paint weathered from older structures on soil Pb levels will be reflected in these empirical estimates. In the case of the urban case studies, a mean value from a sample of houses built between 1940 and 1998 was used to represent soil Pb levels (as described in Section 3.1.3.1 of the Risk Assessment). In the case of the primary Pb smelter case study subarea, site-specific data are used. As there has been remediation of soil in this subarea, the measurements do not reflect historical air quality. Additionally,

studies since remediation have reported increasing soil Pb levels indicating that soil concentrations are still responding to current air quality, and consequently underestimate eventual steady state conditions for the current air quality. In all case studies, the same outdoor soil/dust Pb concentrations (based on these datasets) are used for all air quality scenarios (i.e., the potential longer-term impact of reductions in ambient air Pb on outdoor soil/dust Pb levels and associated impacts on indoor dust Pb have not be simulated). In areas where air concentrations have been greater in the past, however, implementation of a reduced NAAQS might be expected to yield reduced soil Pb levels over the long term. As described in Section 2.3.3 of the Risk Assessment Report (USEPA, 2007b), however, there is potentially significant uncertainty associated with this conclusion, particularly with regard to implications for areas in which a Pb source may locate where one of comparable size had not been previously. Additionally, it is possible that control measures implemented to meet alternative NAAQS may result in changes to soil Pb concentrations; these are not reflected in the assessment.

• *Estimates of indoor dust Pb concentrations for the urban case studies (application of the hybrid model)*: The hybrid mechanistic-empirical model for estimating indoor dust Pb for the urban case studies (as described in Section 3.1.4.1 of the Risk Assessment Report, USEPA, 2007b) utilizes a mechanistic model to simulate the exchange of outdoor ambient air Pb indoors and subsequent deposition (and buildup) of Pb on indoor surfaces, which relies on a number of empirical measurements for parameterization (e.g., infiltration rates, deposition velocities, cleaning frequencies and efficiencies). There is considerable uncertainty associated with these parameter estimates. In addition, there is uncertainty associated with the partitioning of total indoor dust Pb estimates between the infiltration-related ("recent air") component and other contributions ("other" as described in section II.C.2.e).

• *Estimates of indoor dust Pb concentrations for the primary Pb smelter case study (application of the site-specific regression model)*: There is uncertainty associated with the site-specific regression model applied in the remediation zone (as described in Section 3.1.4.2 of the Risk Assessment Report), and relatively greater uncertainty associated with its application to air quality scenarios that simulate notably lower air Pb levels (as is typically the case when applying

regression-based models beyond the bounds of the datasets used in their derivation). The log-log form of the regression model prevents the ready identification of an intercept term handicapping us in partitioning estimates of air-related indoor dust (and consequently exposure and risk estimates) between "recent air" and "other" components. In addition, limitations in the model-derived air estimates used in deriving the regression model prevented effective consideration for the role of ambient air Pb related to resuspension in influencing indoor dust Pb levels. A public commenter suggested that indoor dust Pb levels using this model may be overestimated due to factors associated with the model's derivation. Factors identified by the commenter, however, may contribute to a potential for either over- or underestimation, and as noted by the commenter, additional research might reduce this uncertainty.

• *Characterizing interindividual variability using a GSD:* There is uncertainty associated with the GSD specified for each case study (as described in Sections 3.2.3 and 5.2.2.3 of the Risk Assessment Report). Two factors are described here as contributors to that uncertainty. Interindividual variability in blood Pb levels for any study population (as described by the GSD) will reflect, to a certain extent, spatial variation in media concentrations, including outdoor ambient air Pb levels and indoor dust Pb levels, as well as differences in physiological response to Pb exposure. For each case study, there is significant uncertainty in the specification of spatial variability in ambient air Pb levels and associated indoor dust Pb levels, as noted above. In addition, there are a limited number of datasets for different types of residential child populations from which a GSD can be derived (e.g., NHANES datasets [94] for more heterogeneous populations and individual study datasets for likely more homogeneous populations near specific industrial Pb sources). This uncertainty associated with the GSDs introduces significant uncertainty in exposure and risk estimates for the 95th population percentile.

• *Exposure pathway apportionment for higher percentile blood Pb level and IQ loss estimates:* Apportionment of blood Pb levels for higher population percentiles is assumed to be the same as that estimated using the central tendency estimate of blood Pb in an

exposure zone. This introduces significant uncertainty into projections of pathway apportionment for higher population percentiles of blood Pb and IQ loss. In reality, pathway apportionment may differ in higher exposure percentiles. For example, paint and/or drinking water exposures may increase in importance, with air-related contributions decreasing as an overall percentage of blood Pb levels and associated risk. Because of this uncertainty related to pathway apportionment, as mentioned earlier, greater confidence is placed in estimates of total Pb exposure and risk in evaluating the impact of the current NAAQS and alternative NAAQS relative to current conditions.

• *Relating blood Pb levels to IQ loss:* 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). As discussed earlier, there are limitations in the datasets and concentration-response analyses available for characterizing the concentration-response relationship at these lower blood Pb levels. For example, the pooled international dataset analyzed by Lanphear and others (2005) includes relatively few children with blood Pb levels below 5 μg/dL and no children with levels below 1 μg/dL. In recognition of the uncertainty in specifying a quantitative concentration-response relationship at such levels, our core modeling approach involves the application of four different functions to generate a range of risk estimates (as described in Section 4.2.6 and Section 5.3.1 of the Risk Assessment Report, USEPA, 2007b). The difference in absolute IQ loss estimates for the four concentration-response functions for a given case study/air quality scenario combination is typically close to a factor of 3. Estimates of differences in IQ loss between air quality scenarios (in terms of percent), however, are more similar across the four functions, although the function producing higher overall risk estimates (the dual linear function, stratified at 7.5 μg/dL, peak blood Pb) also produces larger absolute reductions in IQ loss compared with the other three functions.

3. Summary of Estimates and Key Observations

This section presents blood Pb and IQ loss estimates generated in the exposure and risk assessments. Blood Pb estimates (and air-to-blood Pb ratios) are presented first, followed by IQ loss estimates.

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[94] The GSD for the urban case studies, in the risk assessment described in this notice, was derived using NHANES data for the years 1999–2000.

a. Blood Pb Estimates

This section presents a summary of blood Pb modeling results for concurrent blood Pb drawn from the more detailed presentation in the Staff Paper and the Risk Assessment Report (USEPA, 2007a, 2007b, 2007c).

Blood Pb level estimates for the current conditions air quality scenarios for these case studies differ somewhat from the national values associated with recent NHANES information. For example, median blood Pb levels for the current conditions scenario for the urban case studies are somewhat larger than the national median from the NHANES data for 2003–2004. Specifically, values for the three location-specific urban case studies range from 1.7 to 1.8 µg/dL with the general urban case study having a value of 1.9 µg/dL (current-conditions mean) (presented in Risk Assessment Report, Volume I, Table 5–5), while the median value from NHANES (2003–2004) is 1.6 µg/dL (*http://www.epa.gov/envirohealth/children/body_burdens/ b1-table.htm*). Additionally, NHANES values for the 90th percentile (for 2003–2004) were identified and these values can be compared against 90th percentile estimates generated for the urban case studies (see Risk Assessment Report, Appendix O, Section O.3.2 for the location-specific urban case study and Appendix N, Section N.2.1.2 for the general urban case study). The 90th percentile blood Pb levels for the current conditions scenario, for the three location-specific urban case studies range from 4.5 to 4.6 µg/dL, while the estimate for the general urban case study is 5.0 µg/dL. These 90th percentile values for the case study populations are larger than the 90th percentile value of 3.9 µg/dL reported by NHANES for all children in 2003–2004. It is noted that ambient air levels reflected in the urban case studies are likely to differ from those underlying the NHANES data.[95]

Table 2 presents total blood Pb estimates for alternative standards, focusing on the median in the assessed population, and associated estimates for the air-related percentage of total blood Pb (i.e., bounded on the low end by the ''recent air'' contributions and on the high end by the ''recent'' plus ''past air'' contribution to total Pb exposure).

Generally, 95th percentile blood Pb estimates across air quality scenarios for all case studies (not shown here) are 2–3 times higher than the median estimates in Table 2. For example, 95th percentile estimates of total blood Pb for the current NAAQS scenario are 10.6 µg/dL for the general urban case study, 12.3 µg/dL for the primary Pb smelter subarea, and 7.4 to 10.2 µg/dL for the three location-specific urban case studies (Staff Paper, Table 4–2). While the estimates indicate similar fractions of total blood Pb that is air-related between the 95th percentile and median, there is greater uncertainty in pathway apportionment among air-related and other sources for higher percentiles, including the 95th percentile.

TABLE 2.—SUMMARY OF MEDIAN BLOOD PB ESTIMATES FOR CONCURRENT BLOOD PB

[Total]

NAAQS Level simulated (µg/m³ max monthly, except as noted below)	Total blood Pb (µg/dL) (air-related percentage) A				
	General urban case study	Primary Pb smelter (subarea) case study[B][C]	Location-specific urban case studies		
			Cleveland (0.56 µg/m³)	Chicago (0.31 µg/m³)	Los Angeles (0.17 µg/m³)
1.5 max quarterly[D]	3.1 (61 to 84%)	4.6 (up to 87%)	2.1[D] (57 to 86%)	3.0[E] (63 to 83%)	2.6[E] (50 to 81%).
0.50	2.2 (41 to 73%)	3.2 (up to 81%)	1.8 (39 to 72%)	([F])	([F])
0.20	1.9 (26 to 74%)	2.3 (up to 78%)	1.7 (6 to 65%)	1.8 (17 to 67%)	1.7 ([G]) (18 to 71%).
0.05	1.7 (12 to 65%)	1.7 (up to 65%)	1.6 (1 to 63%)	1.6 (6 to 69%)	1.6 (13 to 69%).
0.02	1.6 (6 to 69%)	1.6 (up to 69%)	1.6 (1 to 63%)	1.6 (1 to 63%)	1.6 (6 to 63%).

A—Blood Pb estimates are rounded to one decimal place. Air-related percentage is bracketed by ''recent air'' (lower bound of presented range) and ''recent'' plus ''past air'' (upper bound of presented range). 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).

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

C—Median blood Pb levels for the primary smelter (full study area) are estimated at 1.5 µg/dL (for the 1.5 µg/m³ max quarterly level) and 1.4 µg/dL for the remaining NAAQS levels simulated. The air-related percentages for these standard levels range from 36% to 79%.

D—This corresponds to roughly 0.7–1.0 µg/m³ 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.

As described in section II.C.2.f, the risk assessment also developed estimates for air-to-blood ratios, which are described in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b). These ratios reflect a subset of air-related pathways related to inhalation and ingestion of indoor dust; inclusion of the remaining pathways would be expected to yield higher ratios. Additionally, these ratios are based on blood Pb estimates for the 7th year of exposure (concurrent blood Pb) which are lower than blood Pb estimates at younger ages (and than the lifetime-averaged blood Pb metric). Ratios based on other blood Pb estimates (e.g., lifetime-averaged or peak blood Pb) would be higher.

• For the general urban case study, estimates of air-to-blood ratios, presented in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b) ranged from 1:2 to 1:9, with the majority of the estimates ranging from 1:4 to 1:6.[96] As noted in Section II.C.2.f,

[95] The maximum quarterly mean Pb concentrations in the location-specific case studies ranged from 0.09–0.36 µg/m³, which are higher levels than the maximum quarterly mean values in most monitoring sites in the U.S. The median of the maximum quarterly mean values across all sites in the 2003–05 national dataset is 0.03 µg/m³ (USEPA, 2007a, appendix A).

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

because the risk assessment only reflects the impact of reductions on recent air-related pathways in predicting changes in indoor dust Pb for urban case studies, these ratios are lower than they would be if they had also reflected potential reductions in other air-related pathways (e.g., changes in outdoor surface soil/ dust Pb levels and diet with changes in ambient air Pb levels). We also note that the median blood Pb levels associated with exposure pathways that were not varied in this assessment (and consequently are not reflected in these ratios) generally range from 1.3 to 1.5 µg/dL for this case study.

• For the primary Pb smelter subarea, estimates of air-to-blood ratios, presented in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b) ranged from 1:10 and higher.[97][98] One reason for these estimates being higher than those for the urban case study is that the dust Pb model used may reflect somewhat ambient air-related pathways other than that of ambient air infiltrating

a home (as described in Section II.C.2.f above).[99]

b. IQ Loss Estimates

The risk assessment estimated IQ loss associated with both total Pb exposure and air-related Pb exposure. This section focuses on findings in relation to air-related Pb exposure, since this is the category of risk results 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 (additional categories of risk results, including IQ loss estimates based on total Pb exposure and population incidence results, are presented at the end of the section).[100]

In considering air-related risk results, we note that IQ loss associated with air-related exposure for each NAAQS scenario is bounded by *recent-air* on the low-end and *recent plus past air* on the high-end (as described in section II.C.2.e above). In considering differences in these risk estimates (or in the total risk estimates presented in the final Risk Assessment Report) for alternative NAAQS, we note that these comparisons underestimate the true impacts of the alternate NAAQS and accordingly, the benefit to public health

that would result from lower NAAQS levels. This is due to our inability to simulate in this assessment reductions in several outdoor air deposition-related pathways (e.g., diet, ingestion of outdoor surface soil). The magnitude of this underestimation is unknown.

As with the discussion of blood Pb results, the IQ loss estimates are summarized here according to air quality scenario and case study category (Table 3). In presenting these results, we have focused this presentation on estimates for the median in each case study population of children because of the greater confidence associated with estimates for the median as compared to those for 95th percentile.[101] Generally, 95th percentile IQ loss estimates for all case studies are 80 to 100% higher than the median results in Table 3. The fraction of total IQ loss that is air-related for the 95th percentile is generally similar to that for the median (for a particular combination of case study and air quality scenario).

The risk estimates presented in boldface in Table 3 are those derived using the log-linear with low-exposure linearization concentration-response function, while the range of estimates associated with all four concentration-response functions is presented in parentheses. These functions are discussed above in section II.C.2.b.

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[97] As with such estimates for the urban case study, ratios are higher at lower ambient air Pb levels, reflecting the nonlinearity of the dust Pb response with air concentration.

[98] For the primary Pb smelter (full study area), for which limitations are noted above in section II.C.2.c, 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.

[99] Also, as noted above (Section II.C.2.h), there is increased uncertainty with application of this regression-based model in air quality scenarios of notably lower air Pb levels than the data set used in its derivation.

[100] The detailed results are provided in the Risk Assessment Report (USEPA, 2007b).

[101] A complete presentation of risk estimates is available in the final Risk Assessment Report, including a presentation of estimates for the 95th percentile in Table 5–10 of that report.

TABLE 3.—SUMMARY OF RISK ATTRIBUTABLE TO AIR-RELATED PB EXPOSURE

NAAQS level simulated (µg/m³ 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/m³)	Chicago (0.31 µg/m³)	Los Angeles (0.17 µg/m³)
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)
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). 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]—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 µg/m³ 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.

Key observations regarding the median estimates of air-related risk for the current NAAQS and alternative standards presented in Table 3 include:

• For the scenario for the current NAAQS (1.5 µg/m³, maximum quarterly average), air-related risk exceeds 2 points IQ loss at the median and the upper bound of air-related risk is near or above 4 points IQ loss in all five case studies.[102]

• Alternate standards provide substantial reduction in estimates of air-related risk across the full set of alternative NAAQS considered in this analysis (i.e., 0.5 to 0.02 µg/m³ max monthly). This is particularly the case for the lower bounds of the air-related estimates presented in Table 3, which reflect the estimates for "recent air"-related pathways, which are the pathways that were varied with changes in air concentrations (as described above in section II.C.2.e). There is less risk reduction associated with the upper bounds of these estimates as the upper bound values are inclusive of the exposure pathways categorized as "past air" which were not varied with changes in air concentrations (as described in section II.C.2.3). The upper

bound estimates for the lowest level assessed (0.02 µg/m³) are 2.6–2.9 points IQ loss.

• In the general urban case study, the lower bound of air-related risk falls below 2 points IQ loss for an alternative NAAQS of 0.5 µg/m³ max monthly, and below 1 point IQ loss somewhere between an alternative NAAQS of 0.2 and 0.05 µg/m³ max monthly.

• The upper-bound of air-related risk for the primary Pb smelter subarea is generally higher than that for the general urban case study, likely due to the difference in indoor dust models used for the two case studies. The indoor dust Pb model used for the primary Pb smelter considered more completely, the impact of outdoor ambient air Pb on indoor dust (compared to the hybrid indoor dust Pb model used in the urban case studies). Specifically, the regression model used for the primary Pb smelter included consideration for longer-term relationships between outdoor ambient air and indoor dust (e.g., changes in outdoor soil and subsequent tracking in of soil Pb).

• As noted above (section II.C.2.c), the three location-specific urban case studies provide risk estimates for populations with a broader range of air-related exposures. Accordingly, because of the population distribution in these three case studies, the air-related risk is smaller for them than for the other case

studies, particularly at the population median. Further, the majority of the population in each case study resides in areas with ambient air Pb levels well below each standard level assessed, particularly for levels above 0.05 µg/m³ max monthly. Consequently, risk estimates indicate little response to alternative standard levels above 0.05 µg/m³ max monthly.

In addition to the air-related risk results described above, we present two additional categories of risk results, including (a) estimates of median IQ loss based on total Pb exposure for each case study (Table 4) and (b) IQ loss incidence estimates for each of the location-specific case studies (Tables 4 and 5).[103] Each of these categories of risk results are described in creater detail below:

• *Estimates of IQ loss for all air quality scenarios (based on total Pb exposure):* Table 4 presents median IQ loss estimates for total Pb exposure for each of the air quality scenarios simulated for each case study (as noted earlier in this section, there is greater uncertainty associated with higher-end risk percentiles and therefore, they are

[102] As noted in Table 3 and section II.C.2.d above, and discussed further, with regard to associated limitations and uncertainties, in section II.C.2.h above, a proportional roll-up procedure was used to estimate air Pb concentrations in this scenario for the location-specific case studies.

[103] As recognized in section II.C.2.d above, to simulate air concentrations associated with the current NAAQS, a proportional roll-up of concentrations from those for current conditions was performed for the location-specific urban case studies. This was not necessary for the primary Pb smelter case study in which air concentrations currently exceed the current standard.

not presented in tabular format here— see Table 5–10 of Risk Assessment Volume 1 for 95th percentile total IQ loss estimates). As with the incremental risk results presented in Table 3 above, in order to reflect the variation in estimates derived from the four different concentration-response functions included in the analysis, three categories of estimates are presented in Table 4 including (a) IQ loss estimates generated using the low concentration-response function (the model that generated the lowest IQ loss estimates), (b) estimates generated using the log-linear with low-exposure linearization (LLL) model, and (c) IQ loss estimates generated using the high concentration-response function (the model that generated the highest IQ loss estimates). It is important to emphasize, that, as noted in Section II.C.2.e, because of limitations in modeling methods, we were only able to simulate reduction in recent air-related exposures in considering alternate standard levels and could not simulate reduction in past air-related exposures. This likely results in an underestimate of the total degree of reduction in exposure and risk associated with each standard level. Therefore, in comparing total risk estimates between alternate NAAQS scenarios (i.e., considering incremental risk reductions), this aspect of the

analysis will tend to underestimate the reductions in risk associated with alternative NAAQS.

• *IQ loss incidence estimates for the three location-specific urban case studies:* Estimates of the number of children for each location-specific urban case study projected to have total Pb-related IQ loss greater than one point are summarized in Table 5, and similar estimates for IQ loss greater than 7 points are summarized in Table 6. Also presented are the changes in incidence of the current NAAQS and alternative NAAQS scenarios compared to current conditions, with emphasis placed on estimates generated using the LLL concentration-response function. Estimates are presented for each of the four concentration-response functions used in the risk analysis. This metric illustrates the overall number of children within a given urban case study location projected to experience various levels of IQ loss due to Pb exposure and how that distribution of incidence changes with alternate standard levels. These incidence estimates were only generated for the location-specific urban case studies, since these have larger enumerated study populations (additional detail on the derivation of these incidence estimates is presented in Section 5.3.1.2 of the Risk Assessment Report). The

complete set of incidence results is presented in Risk Assessment Report Appendix O, Section O.3.4.

Total IQ loss results presented in Table 4 for the primary Pb smelter case study (full study area) illustrate the reason why these results were not presented earlier in summarizing air-related IQ loss estimates for the primary Pb smelter case study in Table 3 (and instead, results for the subarea were presented). As mentioned earlier in Section II.C.2.c, the full study area for the primary Pb smelter case study incorporates a large number of simulated children with relatively low air-related impacts, which results in little differentiation between alternate standard levels in terms of total IQ loss (as well as air-related IQ loss). This can be seen by considering the results in Table 4 for the primary Pb smelter (full study area). Those results suggest that total IQ loss varies little across alternate standard levels for the full study area simulation, with the only noticeable difference in total IQ loss resulting from analysis of the current standard (when compared to alternate levels). By contrast, there are notable differences in total IQ loss between alternative standard levels for the sub-area of the primary Pb smelter case study.

TABLE 4.—SUMMARY OF RISK ESTIMATES FOR MEDIANS OF TOTAL-EXPOSURE RISK DISTRIBUTIONS

Case study and air quality scenario	Points IQ loss (total Pb exposure) [a]		
	Low C–R function estimate	LLL [b]	High C–R function estimate
Location-specific (Chicago)			
Current NAAQS (1.5 µg/m³, max quarterly)	2.4	5.6	8.8
Current conditions (0.14 µg/m³ max quarterly; 0.31 µg/m³ max monthly)	1.4	4.2	5.2
Alternative NAAQS (0.2 µg/m³, max monthly)	1.4	4.2	5.2
Alternative NAAQS (0.05 µg/m³, max monthly)	1.3	4.0	4.8
Alternative NAAQS (0.02 µg/m³, max monthly)	1.3	4.0	4.7
Location-specific (Cleveland)			
Current NAAQS (1.5 µg/m³, max quarterly)	1.7	4.7	6.3
Current conditions (0.36 µg/m³ max quarterly; 0.56 µg/m³ max monthly)	1.4	4.2	5.2
Alternative NAAQS (0.5 µg/m³, max monthly)	1.4	4.2	5.2
Alternative NAAQS (0.2 µg/m³, max quarterly)	1.4	4.1	5.0
Alternative NAAQS (0.2 µg/m³, max monthly)	1.3	4.1	4.9
Alternative NAAQS (0.05 µg/m³, max monthly)	1.3	4.0	4.7
Alternative NAAQS (0.02 µg/m³, max monthly)	1.2	3.9	4.6
Location-specific (Los Angeles)			
Current NAAQS (1.5 µg/m³, max quarterly)	2.1	5.3	7.7
Current conditions (0.09 µg/m³ max quarterly; 0.17 µg/m³ max monthly)	1.4	4.2	5.1
Alternative NAAQS (0.05 µg/m³, max monthly)	1.3	4.0	4.8
Alternative NAAQS (0.02 µg/m³, max monthly)	1.3	4.0	4.7
General Urban			
Current NAAQS (1.5 µg/m³, max quarterly)	2.5	5.8	9.2

TABLE 4.—SUMMARY OF RISK ESTIMATES FOR MEDIANS OF TOTAL-EXPOSURE RISK DISTRIBUTIONS—Continued

Case study and air quality scenario	Points IQ loss (total Pb exposure) [a]		
	Low C–R function estimate	LLL [b]	High C–R function estimate
Alternative NAAQS (0.5 µg/m³, max monthly)	1.7	4.8	6.4
Current conditions—high-end (0.87 µg/m³ max quarterly)	1.7	4.7	6.3
Alternative NAAQS (0.2 µg/m³, max quarterly)	1.6	4.6	5.9
Current conditions—mean (0.14 µg/m³ max quarterly)	1.5	4.5	5.6
Alternative NAAQS (0.2 µg/m³, max monthly)	1.5	4.4	5.6
Alternative NAAQS (0.05 µg/m³, max monthly)	1.3	4.1	5.0
Alternative NAAQS (0.02 µg/m³, max monthly)	1.3	4.0	4.8
Primary Pb smelter—full study area			
Current NAAQS (1.5 µg/m³, max quarterly)	1.2	3.8	4.4
Alternative NAAQS (0.5 µg/m³, max monthly)	1.0	3.7	4.2
Alternative NAAQS (0.2 µg/m³, max quarterly)	0.9	3.6	4.2
Alternative NAAQS (0.2 µg/m³, max monthly)	0.9	3.6	4.1
Alternative NAAQS (0.05 µg/m³, max monthly)	0.9	3.6	4.0
Alternative NAAQS (0.02 µg/m³, max monthly)	0.9	3.6	4.1
Primary Pb smelter—1.5km subarea			
Current NAAQS (1.5 µg/m³, max quarterly)	3.7	6.8	11.2
Alternative NAAQS (0.5 µg/m³, max monthly)	2.6	5.8	9.4
Alternative NAAQS (0.2 µg/m³, max quarterly)	2.0	5.2	7.4
Alternative NAAQS (0.2 µg/m³, max monthly)	1.9	5.0	6.9
Alternative NAAQS (0.05 µg/m³, max monthly)	1.4	4.2	5.1
Alternative NAAQS (0.02 µg/m³, max monthly)	1.3	4.0	4.8

[a]—These columns present the estimates of total IQ loss resulting from total Pb exposure (policy-relevant plus background). Estimates below 1.0 are rounded to one decimal place, all values below 0.05 are presented as <0.1 and values between 0.05 and 0.1 as 0.1. All values above 1.0 are rounded to the nearest whole number.

[b]—Log-linear with low-exposure linearization concentration-response function.

TABLE 5.—INCIDENCE OF CHILDREN WITH >1 POINT PB-RELATED IQ LOSS

Air quality scenario (for location-specific urban case studies)	Dual linear—stratified at 7.5 µg/dl peak blood Pb		Log-linear with linearization		Dual linear—stratified at 10 µ/dL peak blood Pb		Log-linear with cutpoint	
	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)
Chicago (total modeled child population: 396,511):								
Chicago Current Conditions	391,602	....	389,754	....	271,031	....	236,257	
Current NAAQS (1.5 µg/m³ Maximum Quarterly)	395,797	4,195	395,528	5,773	347,415	76,384	314,053	77,795
Alternative NAAQS (0.2 µg/m³ Maximum Monthly)	391,158	−444	389,461	−293	271,444	412	235,559	−698
Alternative NAAQS (0.05 µg/m³ Maximum Monthly)	389,572	−2,030	387,407	−2,347	253,775	−17,256	224,394	−11,864
Alternative NAAQS (0.02 µg/m³ Maximum Monthly)	389,176	−2,427	386,630	−3,125	249,865	−21,166	219,294	−16,963
Cleveland (total modeled child population: 13,990):								
Cleveland Current Conditions	13,809	....	13,745	....	9,526	....	8,515	
Current NAAQS (1.5 µg/m³ Maximum Quarterly)	13,893	84	13,857	112	10,664	1,137	9,769	1,254
Alternative NAAQS (0.2 µg/m³ Maximum Quarterly)	13,770	−38	13,703	−42	9,221	−305	8,160	−354
Alternative NAAQS (0.5 µg/m³ Maximum Monthly)	13,789	−20	13,720	−25	9,497	−29	8,464	−51
Alternative NAAQS (0.2 µg/m³ Maximum Monthly)	13,759	−50	13,694	−51	9,083	−443	8,010	−505
Alternative NAAQS (0.05 µg/m³ Maximum Monthly)	13,729	−80	13,642	−103	8,785	−741	7,720	−795
Alternative NAAQS (0.02 µg/m³ Maximum Monthly)	13,720	−88	13,628	−117	8,736	−790	7,668	−846
Los Angeles (total modeled child population: 372,252):								
Los Angeles Current Conditions	282,216	....	280,711	....	191,675	....	170,474	....
Current NAAQS (1.5 µg/m³ Maximum, Quarterly)	285,272	3,056	284,945	4,234	240,988	49,313	226,608	56,134

TABLE 5.—INCIDENCE OF CHILDREN WITH >1 POINT Pb-RELATED IQ LOSS—Continued

Air quality scenario (for location-specific urban case studies)	Dual linear—stratified at 7.5 µg/dl peak blood Pb		Log-linear with linearization		Dual linear—stratified at 10 µ/dL peak blood Pb		Log-linear with cutpoint	
	Incidence of >1 point IQ loss	Delta (change inincidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)
Alternative NAAQS (0.05 µg/m³ Maximum Monthly)	281,112	−1,104	279,658	−1,053	183,395	−8,280	161,914	−8,560
Alternative NAAQS (0.02 µg/m³ Maximum Monthly)	280,740	−1,476	279,057	−1,654	180,745	−10,929	158,234	−12,240

TABLE 6.—INCIDENCE OF CHILDREN WITH >7 POINTS Pb-RELATED IQ LOSS

Air quality scenario (location-specific urban case studies)	Dual linear—stratified at 7.5 ug/dL peak blood Pb		Log-linear with linearization		Dual linear—stratified at 10 ug/dL peak blood Pb		Log-linear with cutpoint	
	Incidence of > 7 points IQ loss	Delta (change in incidence compared to current conditions)	Incidence of > 7 points IQ loss	Delta (change in incidence compared to current conditions)	Incidence of > 7 points IQ loss	Delta (change in incidence compared to current conditions)	Incidence of > 7 points IQ loss	Delta (change in incidence compared to current conditions)
Chicago (total modeled child population: 396,511):								
Chicago Current Conditions	136,709	....	33,664	....	63	....	1,015	....
Current NAAQS (1.5 µg/m3 Maximum Quarterly)	244,401	107,692	100,159	66,495	555	492	5,226	4,211
Alternative NAAQS (0.2 µg/³ Maximum Monthly)	136,067	−642	32,546	−1,118	48	−16	1,007	−8
Alternative NAAQS (0.05 µg/³ Maximum Monthly)	120,706	−16,003	27,367	−6,297	16	−48	864	−151
Alternative NAAQS (0.02 µg/³ Maximum Monthly)	117,819	−18,890	26,027	−7,637	8	−56	690	−325
Cleveland (total modeled child population: 13,990):								
Cleveland Current Conditions	4,834	....	1,212	....	3	....	46	....
Current NAAQS (1.5 µg/m3 Maximum Quarterly)	6,139	1,305	1,858	647	4	2	105	59
Alternative NAAQS (0.2 µg/m3 Maximum Quarterly)	4,525	−309	1,073	−139	1	−2	40	−6
Alternative NAAQS (0.5 µg/m3 Maximum Monthly)	4,806	−28	1,180	−31	1	−2	43	−3
Alternative NAAQS (0.2 µg/m3 Maximum Monthly)	4,424	−410	1,026	−186	1	−2	43	−3
Alternative NAAQS (0.05 µg/m3 Maximum Monthly)	4,106	−728	886	−326	0	−3	24	−22
Alternative NAAQS (0.02 µg/m3 Maximum Monthly)	4,051	−783	866	−345	0	−3	27	−18
Los Angeles (total modeled child population: 372,252):								
Los Angeles Current Conditions	94,684	....	22,665	....	23	....	732	....
Current NAAQS (1.5 µg/m3 Maximum, Quarterly)	158,171	63,487	57,834	35,168	183	160	3,771	3,038
Alternative NAAQS (0.05 µg/m3 Maximum, Monthly)	87,303	−7,382	19,781	−2,884	11	−11	624	−109
Alternative NAAQS (0.02 µg/m3 Maximum, Monthly)	83,909	−10,775	17,939	−4,726	17	−6	498	−235

D. Conclusions on Adequacy 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 and additional information, the existing standard should be retained or revised. In evaluating whether it is appropriate to retain or 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 [104] and quantitative exposure- and risk-based considerations in developing conclusions on the adequacy of the current primary Pb standard. Evidence-based considerations include the assessment of evidence for a variety of

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[104] 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.

Pb-related health endpoints from epidemiological, and animal toxicological studies. Consideration of quantitative exposure- and risk-based information draws from the results of the exposure and risk assessments described above. More specifically, estimates of the magnitude of Pb-related exposures and risks associated with air quality levels associated with just meeting the current primary Pb NAAQS have been considered.[105]

In this review, a series of general questions frames the approach to reaching a decision on the adequacy of the current standard, such as the following: (1) To what extent does newly available information reinforce or call into question evidence of associations of Pb exposures with effects identified when the standard was set?; (2) to what extent has evidence of new effects or at-risk populations become available since the time the standard was set?; (3) to what extent have important uncertainties identified when the standard was set been reduced and have new uncertainties emerged?; and (4) to what extent does newly available information reinforce or call into question any of the basic elements of the current standard?

The question of whether the available evidence supports consideration of a standard that is more protective than the current standard includes consideration of: (1) Whether there is evidence that associations with blood Pb in epidemiological studies extend to ambient Pb concentration levels that are as low as or lower than had previously been observed, and the important uncertainties associated with that evidence; (2) the extent to which exposures of potential concern and health risks are estimated to occur in areas upon meeting the current standard and the important uncertainties associated with the estimated exposures and risks; and (3) the extent to which the Pb-related health effects indicated by the evidence and the exposure and risk assessments are considered important from a public health perspective, taking into account the nature and severity of the health effects, the size of the at-risk populations, and the kind and degree of the uncertainties associated with these considerations.

This approach is consistent with the requirements of the NAAQS provisions of the Act and with how EPA and the courts have historically interpreted the

Act. These provisions require the Administrator to establish primary standards that, in the Administrator's judgment, are requisite to protect public health with an adequate margin of safety. 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 primary standards be set at a zero-risk level but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.

The following discussion starts with background information on the current standard (section II.D.1), including both the basis for derivation of the current standard and considerations and conclusions from the 1990 Staff Paper (USEPA, 1990b). This is followed by a discussion of the Agency's approach in this review for evaluating the adequacy of the current standard, in section II.D.2, including both evidence-based and exposure/risk-based considerations (sections II.D.2.a and b, respectively). CASAC advice and recommendations concerning adequacy of the current standard are summarized in section II.D.3. Lastly, the Administrator's proposed conclusions with regard to the adequacy of the current standard are presented in section II.D.4.

1. Background

a. The Current Standard

The current primary standard is set at a level of 1.5 μg/m³, measured as Pb-TSP, not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. The 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). In setting the standard, EPA relied on conclusions regarding sources of exposure, air-related exposure pathways, variability and susceptibility of young children, the most sensitive health endpoints, blood Pb level thresholds for various health effects and the stability and distributional characteristics of Pb (both in the human body and in the environment) (43 FR 46247). The specific basis for selecting each of the elements of the standard is described below.

i. Level

EPA's objective in selecting the level of the current standard was "to estimate the concentration of Pb in the air to which all groups within the general population can be exposed for protracted periods without an

unacceptable risk to health'' (43 FR 46252). As stated in the notice of final rulemaking, ''This estimate was based on EPA's judgment in four key areas:

(1) Determining the 'sensitive population' as that group within the general population which has the lowest threshold for adverse effects or greatest potential for exposure. EPA concludes that young children, aged 1 to 5, are the sensitive population.

(2) Determining the safe level of total lead exposure for the sensitive population, indicated by the concentration of lead in the blood. EPA concludes that the maximum safe level of blood lead for an individual child is 30 μg Pb/dl and that population blood lead, measured as the geometric mean, must be 15 μg Pb/dl in order to place 99.5 percent of children in the United States below 30 μg Pb/dl.

(3) Attributing the contribution to blood lead from nonair pollution sources. EPA concludes that 12 μg Pb/dl of population blood lead for children should be attributed to nonair exposure.

(4) Determining the air lead level which is consistent with maintaining the mean population blood lead level at 15 μg Pb/dl [the maximum safe mean level]. Taking into account exposure from other sources (12 μg Pb/dl), EPA has designed the standard to limit air contribution after achieving the standard to 3 μg Pb/dl. On the basis of an estimated relationship of air lead to blood lead of 1 to 2, EPA concludes that the ambient air standard should be 1.5 μg Pb/m³.'' (43 FR 46252)

EPA's judgments in these key areas, as well as margin of safety considerations, are discussed below.

The assessment of the science that was presented in the 1977 Criteria Document (USEPA, 1977), indicated young children, aged 1 to 5, as the population group at particular risk from Pb exposure. Children were recognized to have a greater physiological sensitivity than adults to the effects of Pb and a greater exposure. In identifying young children as the sensitive population, EPA also recognized the occurrence of subgroups with enhanced risk due to genetic factors, dietary deficiencies or residence in urban areas. Yet information was not available to estimate a threshold for adverse effects for these subgroups separate from that of all young children. Additionally, EPA recognized both a concern regarding potential risk to pregnant women and fetuses, and a lack of information to establish that these subgroups are more at risk than young children. Accordingly, young children, aged 1 to 5, were identified as the group which has the lowest threshold for adverse

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[105] As described in seciton II.C.2.d above, levels in the location-specific urban case studies were increased from current conditions such that the portion of each case study with highest concentrations would just meet the current NAAQS.

effects of greatest potential for exposure (*i.e.,* the sensitive population) (43 FR 46252).

In identifying the maximum safe exposure, EPA relied upon the measurement of Pb in blood (43 FR 46252–46253). The physiological effect of Pb that had been identified as occurring at the lowest blood Pb level was inhibition of an enzyme integral to the pathway by which heme (the oxygen carrying protein of human blood) is synthesized, *i.e.,* delta-aminolevulinic acid dehydratase (δ-ALAD). The 1977 Criteria Document reported a threshold for inhibition of this enzyme in children at 10 μg Pb/dL. The 1977 Criteria Document also reported a threshold of 15–20 μg/dL for elevation of erythrocyte protoporphyrin (EP), which is an indication of some disruption of the heme synthesis pathway. EPA concluded that this effect on the heme synthesis pathway (indicated by EP) was potentially adverse. EPA further described a range of blood levels associated with a progression in detrimental impact on the heme synthesis pathway. At the low end of the range (15–20 μg/dL), the initial detection of EP associated with blood Pb was not concluded to be associated with a significant risk to health. The upper end of the range (40 μg/dL), the threshold associated with clear evidence of heme synthesis impairment and other effects contributing to clinical symptoms of anemia, was regarded by EPA as clearly adverse to health. EPA also noted that for some children with blood Pb levels just above those for these effects (*e.g.,* 50 μg/dL), there was risk for additional adverse effects (*e.g.,* nervous system deficits). Additionally, in the Agency's statement of factors on which the conclusion as to the maximum safe blood Pb level for an individual child was based, EPA stated that the maximum safe blood level should be "no higher than the blood Pb range characterized as undue exposure by the Center for Disease Control of the Public Health Service, as endorsed by the American Academy of Pediatrics, because of elevation of erythrocyte protoporphyrin (above 30 μg Pb/dL)".[106]

Having identified the maximum safe blood level in individual children, EPA next made a public health policy judgment regarding the target mean blood level for the U.S. population of young children (43 FR 46252–46253). With this judgment, EPA identified a target of 99.5 percent of this population to be brought below the maximum safe blood Pb level. This judgment was based on consideration of the size of the sensitive subpopulation, and the recognition that there are special high-risk groups of children within the general population. The population statistics available at the time (the 1970 U.S. Census) indicated a total of 20 million children younger than 5 years of age, with 15 million residing in urban areas and 5 million in center cities where Pb exposure was thought likely to be "high". Concern about these high-risk groups influenced EPA's determination of 99.5 percent, deterring EPA from selecting a population percentage lower than 99.5 (43 FR 46253). EPA then used standard statistical techniques to calculate the population mean blood Pb level that would place 99.5 percent of the population below the maximum safe level. Based on the then available data, EPA concluded that blood Pb levels in the population of U.S. children were normally distributed with a GSD of 1.3. Based on standard statistical techniques, EPA determined that a thus described population in which 99.5 percent of the population has blood Pb levels below 30 μg/dL would have a geometric mean blood level of 15 μg/dL. EPA described 15 μg/dL as "the maximum safe blood lead level (geometric mean) for a population of young children" (43 FR 46247).

When setting the current NAAQS, EPA recognized that the air standard needed to take into account the contribution to blood Pb levels from Pb sources unrelated to air pollution. Consequently, the calculation of the current NAAQS included the subtraction of Pb contributed to blood Pb from nonair sources, from the estimate of a safe mean population blood Pb level. Without this subtraction, EPA recognized that the combined exposure to Pb from air and nonair sources would result in a blood Pb concentration exceeding the safe level (43 FR 46253). In developing an estimate of this nonair contribution, EPA recognized the lack of detailed or widespread information about the

relative contribution of various sources to children's blood Pb levels, such that an estimate could only be made by inference from other empirical or theoretical studies, often involving adults. Additionally, EPA recognized the expectation that the contribution to blood Pb levels from nonair sources would vary widely, was probably not in constant proportion to air Pb contribution, and in some cases may alone exceed the target mean population blood Pb level (43 FR 46253–46254). The amount of blood Pb attributed to nonair sources was selected based primarily on findings in studies of blood Pb levels in areas where air Pb levels were low relative to other locations in U.S. The air Pb levels in these areas ranged from 0.1 to 0.7 μg/m³. The average of the reported blood Pb levels for children of various ages in these areas was on the order of 12 μg/dL. Thus, 12 μg/dL was identified as the nonair contribution, and subtracted from the population mean target level of 15 μg/dL to yield a value of 3 μg/dL as the limit on the air contribution to blood Pb.

In determining the air Pb level consistent with an air contribution of 3 μg Pb/dL, EPA reviewed studies assessed in the 1977 Criteria Document that reported changes in blood Pb with different air Pb levels. These studies included a study of children exposed to Pb from a primary Pb smelter, controlled exposures of adult men to Pb in fine particulate matter, and a personal exposure study involving several male cohorts exposed to Pb in a large urban area in the early 1970s (43 FR 46254).[107] Using all three studies, EPA calculated an average slope or ratio over the entire range of data. That value was 1.95 (rounded to 2 μg/dL blood Pb concentration to 1 μg/m³ air Pb concentration), and is recognized to fall within the range of values reported in the 1977 Criteria Document. On the basis of this 2-to-1 relationship, EPA concluded that the ambient air standard should be 1.5 μg Pb/m³ (43 FR 46254).

In consideration of the appropriate margin of safety during the development of the current NAAQS, EPA identified the following factors: (1) The 1977 Criteria Document reported multiple biological effects of Pb in practically all cell types, tissues and organ systems, of which the significance for health had not yet been fully studied; (2) no beneficial effects of Pb at then current environmental levels were recognized;

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[106] The CDC subsequently revised their advisory level for children's blood Pb to 25 μg/dL in 1985, and to 10 μg/dL in 1991. In 2005, with consideration of a review of the evidence by their advisory committee, CDC revised their statement on Preventing Lead Poisoning in Young Children, specifically recognizing the evidence of adverse health effects in children with blood Pb levels below 10 μg/dL and the data demonstrating that no "safe" threshold for blood Pb in children had been identified, and emphasizing the importance of preventative measures (CDC, 2005a). Recently, CDC's Advisory Committee on Childhood Lead Poisoning Prevention noted the 2005 CDC

statements and reported on a review of the clinical interpretation and management of blood Pb levels below 10 μg/dL (ACCLPP, 2007). More details on this level are provided in Section II.B.1.

[107] Mean blood Pb levels in the adult study groups ranged from 10 μg/dL to approximately 30 μg/dL and in the child groups they ranged from approximately 20 μg/dL up to 65 μg/dL (USEPA, 1986a, section 11.4.1).

(3) data were incomplete as to the extent to which children are indirectly exposed to air Pb that has moved to other environmental media, such as water, soil and dirt, and food; (4) Pb is chemically persistent and with continued uncontrolled emissions would continue to accumulate in human tissue and the environment; and (5) the possibility that exposure associated with blood Pb levels previously considered safe might influence neurological development and learning abilities of the young child (43 FR 46255). Recognizing that estimating an appropriate margin of safety for the air Pb standard was complicated by the multiple sources and media involved in Pb exposure, EPA chose to use margin of safety considerations principally in establishing a maximum safe blood Pb level for individual children (30 μg Pb/dL) and in determining the percentage of children to be placed below this maximum level (about 99.5 percent). Additionally, in establishing other factors used in calculating the standard, EPA used margin of safety considerations in the sense of making careful judgment based on available data, but these judgments were not considered to be at the precautionary extreme of the range of data available at the time (43 FR 46251).

EPA further recognized that, because of the variability between individuals in a population experiencing a given level of Pb exposure, it was considered impossible to provide the same margin of safety for all members in the sensitive population or to define the margin of safety in the standard as a simple percentage. EPA believed that the factors it used in designing the standards provided an adequate margin of safety for a large proportion of the sensitive population. The Agency did not believe that the margin was excessively large or on the other hand that the air standard could protect everyone from elevated blood Pb levels (43 FR 46251).

ii. Averaging Time, Form, and Indicator

The averaging time for the current standard is a calendar quarter. In the decision for this aspect of the standard, the Agency also considered a monthly averaging period, but concluded that "a requirement for the averaging of air quality data over calendar quarter will improve the validity of air quality data gathered without a significant reduction in the protectiveness of the standards." As described in the notice for this decision (43 FR 46250), this conclusion was based on several points, including the following:

• An analysis of ambient measurements available at the time indicated that the distribution of air Pb levels was such that there was little possibility that there could be sustained periods greatly above the average value in situations where the quarterly standard was achieved.

• A recognition that the monitoring network may not actually represent the exposure situation for young children, such that it seemed likely that elevated air Pb levels when occurring would be close to Pb air pollution sources where young children would typically not encounter them for the full 24-hour period reported by the monitor.

• Medical evidence available at the time indicated that blood Pb levels re-equilibrate slowly to changes in air exposure, a finding that would serve to dampen the impact of short-term period of exposure to elevated air Pb.

• Direct exposure to air is only one of several routes of total exposure, thus lessening the impact of a change in air Pb on blood Pb levels.

The statistical form of the current standard is a not-to-be-exceeded or maximum value. EPA set the standard as a ceiling value with the conclusion that this air level would be safe for indefinite exposure for young children (43 FR 46250).

The indicator is total airborne Pb collected by a high volume sampler (43 FR 46258). EPA's selection of Pb-TSP as the indicator for the standard was based on explicit recognition both of the significance of ingestion as an exposure pathway for Pb that had deposited from the air and of the potential for Pb deposited from the air to become re-suspended in respirable size particles in the air and available for human inhalation exposure. As stated in the final rule, "a significant component of exposure can be ingestion of materials contaminated by deposition of lead from the air," and that, "in addition to the indirect route of ingestion and absorption from the gastrointestinal tract, non-respirable Pb in the environment may, at some point become respirable through weathering or mechanical action" (43 FR 46251).

b. Policy Options Considered in the Last Review

During the 1980s, EPA initiated a review of the air quality criteria and NAAQS for Pb. CASAC and the public were fully involved in this review, which led to the publication of a criteria document with associated addendum and a supplement (USEPA, 1986a, 1986b, 1990a), an exposure analysis methods document (USEPA, 1989), and a staff paper (USEPA, 1990b).

Total emissions to air were estimated to have dropped by 94 percent between 1978 and 1987, with the vast majority of it attributed to the reduction of Pb in gasoline. Accordingly, the focus of the last review was on areas near stationary sources of Pb emissions. Although such sources were not considered to have made a significant contribution (as compared to Pb in gasoline) to the overall Pb pollution across large-urban or regional areas, Pb emissions from such sources were considered to have the potential for a significant impact on a local scale. Air Pb concentrations, and especially soil and dust Pb concentrations, had been associated with elevated levels of Pb absorption in children and adults in numerous Pb point source community studies. Exceedances of the current NAAQS were found at that time only in the vicinity of nonferrous smelters or other point sources of Pb.

In summarizing and interpreting the health evidence presented in the 1986 Criteria Document and associated documents, the 1990 Staff Paper described the collective impact on children of the effects at blood Pb levels above 15 μg/dL as representing a clear pattern of adverse effects worthy of avoiding. This is in contrast to EPA's identification of 30 μg/dL as a safe blood Pb level for individual children when the NAAQS was set in 1978. The Staff Paper further stated that at blood Pb levels of 10–15 μg/dL, there was a convergence of evidence of Pb-induced interference with a diverse set of physiological functions and processes, particularly evident in several independent studies showing impaired neurobehavioral function and development. Further, the available data did not indicate a clear threshold in this blood Pb range. Rather, it suggested a continuum of health risks down to the lowest levels measured.[108]

For the purposes of comparing the relative protectiveness of alternative Pb NAAQS, the staff conducted analyses to estimate the percentages of children with blood Pb levels above 10 μg/dL and above 15 μg/dL for several air quality scenarios developed for a small set of stationary source exposure case studies. The results of the analyses of child populations living near two Pb smelters indicated that substantial reductions in Pb exposure could be achieved through just meeting the current Pb NAAQS. According to the best estimate analyses, over 99.5% of children living in areas significantly affected by the smelters would have blood Pb levels below 15

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[108] In 1991, the CDC reduced their advisory level for children's blood Pb from 25 μg/dL to 10 μg/dL.

µg/dL if the current standard was achieved. Progressive changes in this number were estimated for the alternative monthly Pb NAAQS levels evaluated in those analyses, which ranged from 1.5 µg/m³ to 0.5 µg/m³.

In light of the health effects evidence available at the time, the 1990 Staff Paper presented air quality, exposure, and risk analyses, and other policy considerations, as well as the following staff conclusions with regard to the primary Pb NAAQS (USEPA, 1990b, pp. xii to xiv):

(1) "The range of standards * * * should be from 0.5 to 1.5 µg/m³."

(2) "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."

(3) "The most appropriate form of the standard appears to be the second highest monthly averages {sic} 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."

(4) "With a revision to a monthly averaging time more frequent sampling is needed, except in areas, like roadways remote from lead point sources, where the standard is not expected to be violated. In those situations, the current 1-in-6 day sampling schedule would sufficiently reflect air quality and trends."

(5) "Because exposure to atmospheric lead particles occurs not only via direct inhalation, but via ingestion of deposited particles as well, especially among young children, the hi-volume sampler provides a reasonable indicator for determining compliance with a monthly standard and should be retained as the instrument to monitor compliance with the lead NAAQS until more refined instruments can be developed."

Based on its review of a draft Staff Paper, which contained the above recommendations, the CASAC strongly recommended to the Administrator that EPA should actively pursue a public health goal of minimizing the Pb content of blood to the extent possible, and that the Pb NAAQS is an important component of a multimedia strategy for achieving that goal (CASAC, 1990, p. 4). In noting the range of levels recommended by staff, CASAC recommended consideration of a revised standard that incorporates a "wide margin of safety, because of the risk posed by Pb exposures, particularly to the very young whose developing nervous system may be compromised by

even low level exposures" (id., p. 3). More specifically, CASAC judged that a standard within the range of 1.0 to 1.5 µg/m³ would have "relatively little, if any, margin of safety;" that greater consideration should be given to a standard set below 1.0 µg/m³; and, to provide perspective in setting the standard, it would be appropriate to consider the distribution of blood Pb levels associated with meeting a monthly standard of 0.25 µg/m³, a level below the range considered by staff (id.).

After consideration of the documents developed during the review, EPA chose not to propose revision of the NAAQS for Pb. During the same time period, the Agency published and embarked on the implementation of a broad, multi-program, multi-media, integrated national strategy to reduce Pb exposures (USEPA, 1991). As discussed above in section I.C., as part of implementing this integrated Pb 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, particularly near stationary sources.[109]

2. Considerations in the Current Review

a. Evidence-Based Considerations

In considering the broad array of health effects evidence assessed in the Criteria Document with respect to the adequacy of the current standard, the discussion here, like that in the Staff Paper and ANPR, focuses on those health endpoints associated with the Pb exposure and blood levels most pertinent to ambient exposures. In so doing, EPA gives particular weight to evidence available today that differs from that available at the time the standard was set with regard to its support of the current standard.

First, with regard to the sensitive population, the susceptibility of young children to the effects of Pb is well recognized, in addition to more recent recognition of effects of chronic or cumulative Pb exposure with advancing age (CD, Sections 5.3.7 and pp. 8–73 to 8–75). The prenatal period and early childhood are periods of increased susceptibility to Pb exposures, with evidence of adverse effects on the developing nervous system that generally appear to persist into later childhood and adolescence (CD, Section

6.2).[110] Thus, while the sensitivity of the elderly and other particular subgroups is recognized, as at the time the 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 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, at which time the Agency identified 30 µg/dL as the maximum safe blood Pb level for individual children and 15 µg/dL as the maximum safe geometric mean blood Pb level for a population of children (as described in section II.D.1.a above). This change in the evidence since the time the standard was set is reflected in changes made by the CDC in their advisory level for Pb in children's blood, and changes they have made in their characterization of that level (as described in section II.B.1.b). Although CDC recognized a level of 30 µg/dL blood Pb as warranting individual intervention in 1978 when the Pb NAAQS was set, in 2005 they recognized the evidence of adverse health effects in children with blood Pb levels below 10 µg/dL and the data demonstrating that no "safe" threshold for blood Pb had been identified (CDC, 1991; CDC, 2005).

As summarized in section II.B above, the Criteria Document describes current evidence regarding 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).[111] As stated

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[109] A description of the various programs implemented since 1990 to reduce Pb exposures, including the recent RRP rule, is provided in section I.C.

[110] For example, the following statement is made in the Criteria Document "Negative Pb impacts on neurocognitive ability and other neurobehavioral outcomes are robust in most recent studies even after adjustment for numerous potentially confounding factors (including quality of care giving, parental intelligence, and socioeconomic status). These effects generally appear to persist into adolescence and young adulthood." (CD, p.E–9)

[111] For context, it is noted that the 2001–2004 median blood level for children aged 1–5 of all races and ethnic groups is 1.6 µg/dL, the median for the subset living below the poverty level is 2.3 µg/dL and 90th percentile values for these two groups are 4.0 µg/dL and 5.4 µg/dL, respectively. Similarly, the 2001–2004 median blood level for black, non-hispanic children aged 1–5 is 2.5 µg/dL, while the median level for the subset of that group living below the poverty level is 2.9 µg/dL and the median level for the subset living in a household with income more than 200% of the poverty level is 1.9 µg/dL. Associated 90th percentile values for 2001–2004 are 6.4 µg/dL (for black, non-hispanic children aged 1–5), 7.7 µg/dL (for the subset of that group living below the poverty level) and 4.1 µg/dL (for the subset living in a household with income more than 200% of the poverty level). (http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm—then click on

in the Criteria Document, ''The overall weight of the available evidence provides clear substantiation of neurocognitive decrements being associated in young children with blood-Pb concentrations in the range of 5–10 µg/dL, and possibly somewhat lower. Some newly available analyses appear to show 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). With regard to the evidence of neurological effects at these low levels, EPA notes, in particular (and discusses more completely in section II.B.2.b above), the international pooled analysis by Lanphear and others (2005), studies of individual cohorts such as the Rochester, Boston, and Mexico City cohorts (Canfield *et al.*, 2003a; Canfield *et al.*, 2003b; Bellinger and Needleman, 2003; Tellez-Rojo *et al.*, 2006), the study of African-American inner-city children from Detroit (Chiodo *et al.*, 2004), the cross-sectional study of young children in three German cities (Walkowiak *et al.*, 1998) and the cross-sectional analysis of a nationally representative sample from the NHANES III (collected from 1988–1994) (Lanphear *et al.*, 2000). In the study by Lanphear *et al* (2000), the mean blood Pb for the full study group was 1.9 µg/dL and the mean blood Pb level in the lowest blood Pb subgroup with which a statistically significant association with neurocognitive effects was found (individual blood Pb values <5 µg/dL) was 1.7 µg/dL (CD, pp. 6–31 to 6–32; Lanphear *et al.*, 2000; Auinger, 2008).[112] These studies and associated limitations are discussed above in section II.B.2.b.

As stated in the Criteria Document with regard to the neurocognitive effects in children, the ''weight of overall evidence strongly substantiates likely occurrence of type of effect in association with blood-Pb concentrations in range of 5–10 µg/dL, or possibly lower, as implied by (???) [in associated Table 8–5 of Criteria Document]. 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).

i. Evidence-Based Framework Considered in the Staff Paper

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 described in section II.D.1.a, 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.

As when the standard was set in 1978, there remain today contributions to blood Pb levels from nonair sources. In 1978, the Agency estimated the average blood Pb level for young children associated with nonair sources to be 12 µg/dL (as described in section II.D.1.a). However, consistent with reductions since that time in air Pb concentrations[113] which contribute to blood Pb, nonair contributions have also been reduced (as described in section II.A.4 above). The Staff Paper noted that the current evidence is limited with regard to estimates of the aggregate reduction since 1978 of all nonair sources to blood Pb and with regard to an estimate of current nonair blood Pb levels (discussed in sections II.A.4). In recognition of temporal reductions in nonair sources discussed in section II.A.4 and in the context of estimates pertinent to an application of the 1978 framework, the CASAC Pb Panel recommended consideration of 1.0–1.4 µg/dL or lower as an estimate of the nonair component of blood Pb pertinent to average blood Pb levels (as more fully

described in section II.A.4 above; Henderson, 2007b).

As in 1978, the evidence demonstrates that Pb in ambient air contributes to Pb in blood, with the pertinent exposure routes including both inhalation and ingestion (CD, Sections 3.1, 3.2, 4.2 and 4.4). In 1978, the evidence indicated a quantitative relationship between ambient air Pb and blood Pb in terms of an air-to-blood ratio that ranged from 1:1 to 1:2 (USEPA, 1977). In setting the standard, the Agency relied on a ratio of 1:2, i.e., 2 µg/dL blood Pb per 1 µg/m³ air Pb (as described in section II.D.1.a above). The Staff Paper observed that ''[W]hile there is uncertainty and variability in the absolute value of an air-to-blood relationship, the current evidence indicates a notably greater ratio * * * e.g., on the order of 1:3 to 1:10'' (USEPA, 2007c).

Based on the information described above, the Staff Paper concluded that young children remain the sensitive population of primary focus in this review, ''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).

ii. Air-Related IQ Loss Evidence-Based Framework

Since completion of the Staff Paper and ANPR, the Agency has 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-based 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,

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''Download a universal spreadsheet file of the Body Burdens data tables'').

[112] These findings include significant associations in some of the study sample subsets of children, namely those with blood Pb levels less than 10 µg/dL, less than 7.5 µg/dL, and less than 5 µg/dL. The mean blood Pb level in the third subset was 1.7 µg/dL (Auinger, 2008). A positive, but not statistically significant association, was observed in the less than 2.5 µg/dL subset (mean blood Pb of 1.2 µg/dL [Auinger, 2008]), although the effect estimate for this subset was largest among all the subsets (Lanphear *et al.*, 2000). The lack of statistical significance for this subset may be due to the smaller sample size of this subset which would lead to lower statistical power.

[113] Air Pb concentrations nationally are estimated to have declined more than 90% since the early 1980s, in locations not known to be directly influenced by stationary sources (Staff Paper, pp. 2–22 to 2–23).

and is discussed in more detail below in section II.E.3.a, concerning the level of the standard.

In this air-related IQ loss framework, we have drawn 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.[114] We have also drawn 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, and it also draws from estimates for air-to-blood ratios.

While we note the evidence of steeper slope for the C-R relationship for blood Pb concentration and IQ loss at lower blood Pb levels (described in sections II.B.2.b and II.E.3.a), for purposes of consideration of the adequacy of the current standard we are 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 have focused on a median linear estimate of the slope of the C-R function for blood Pb levels up to, but no higher than, 10 μg/dL (described in section II.B.2.b above). The median slope estimate is -0.9 IQ points per μg/dL blood Pb [115] (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 above, a population of children exposed at the current level of the standard might be expected to result in an average air-related blood Pb level above 4 μg/dL.[116]

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.

b. Exposure- and Risk-Based Considerations

As discussed above in section II.C, we have estimated exposures and health risks associated with air quality that just meets the current standard 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 and more fully in the Risk Assessment Report).

As discussed above, children are the sensitive population of primary focus in this review. The exposure and risk assessment estimates Pb exposure for children (less than 7 years of age), and associated risk of neurocognitive effects in terms of IQ loss. In addition to the risks (IQ loss) that were quantitatively estimated, EPA recognizes that there may be long-term adverse consequences of such deficits over a lifetime, and there are other, unquantified adverse neurocognitive effects that may occur at similarly low exposures which might additionally contribute to reduced academic performance, which may have adverse consequences over a lifetime (CD, pp. 8–29 to 8–30).[117] Other impacts at low levels of childhood exposure that were not quantified in the risk assessment include: other neurological effects (sensory, motor, cognitive and behavioral), immune system effects (including some related to allergic responses and asthma), and early effects related to anemia. Additionally, as noted in section II.B.2, other health effects evidence demonstrates associations between Pb exposure and adverse health effects in adults (e.g., cardiovascular and renal effects).[118]

As noted in the Criteria Document, a modest change in the population mean of a health index, that is quantified for each individual, can have substantial implications at the population level (CD, p. 8–77, Sections 8.6.1 and 8.6.2;

Bellinger, 2004; Needleman *et al.*, 1982; Weiss, 1988; Weiss, 1990)). For example, for an individual functioning in the low range of IQ due to the influence of risk factors other than Pb, a Pb-associated IQ loss of a few points might be sufficient to drop that individual into the range associated with increased risk of educational, vocational, and social handicap (CD, p. 8–77), while such a decline might create less significant impacts for the individual near the mean of the population. Further, given a uniform manifestation of Pb-related decrements across the range of IQ scores in a population, a downward shift in the mean IQ value is associated not only with a substantial increase in the percentage of individuals achieving very low scores, but also with substantial decreases in percentages achieving very high scores (CD, p. 8–81). The CASAC Pb Panel has advised on this point that "a population loss of 1–2 IQ points is highly significant from a public health perspective" (Henderson, 2007a, p. 6).

In considering exposure and risk estimates with regard to adequacy of the current standard, EPA has focused on IQ loss for air-related exposure pathways. As described in section II.C.2.e above, limitations in our data and modeling tools have resulted in an inability to develop specific estimates such that we have approximated estimates for the air-related pathways, bounded on the low end by exposure/risk estimated for the "recent air" category and on the upper end by the exposure/risk estimated for the "recent air" plus "past air" categories. Thus, the following discussion presents air-related IQ loss estimates in terms of upper and lower bounds. In addition, as noted above (section II.C.3.b), this discussion focuses predominantly on risk estimates derived using the log-linear with low-exposure linearization (LLL) C–R function, with the range associated with the other three functions used in the assessment also being noted. Further, air-related risk estimates are presented for the median and for an upper percentile (i.e., the 95th percentile of the population assessed).

EPA and CASAC recognize uncertainties in the risk estimates in the tails of the distribution and consequently the 95th percentile is reported as the estimate of the high end of the risk distribution (Henderson, 2007b, p. 3). In so doing, however, EPA notes that it is important to consider that there are individuals in the population expected to have higher risk, particularly in light of the risk management objectives for the current standard which was set in 1978 to

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[114] 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)

[115] As noted above (in section II.B.2.b), this slope is similar to the slope for the below 10 μg/dL piece of the piecewise model used in the RRP rule economic analysis.

[116] 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 estimate 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.

[117] For example, the Criteria Document notes particular findings with regard to academic achievement as "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).

[118] The weight of the evidence differs for the different endpoints.

protect the 99.5th percentile. Further, we note an increased uncertainty in our estimates of air-related risk for the upper percentiles, such as the 95th percentile, due to limitations in the data and tools available to us to estimate pathway contributions to blood Pb and associated risk for individuals at the upper ends of the distribution.

In order to consider exposure and risk associated with the current standard, EPA developed estimates for a case study based on air quality projected to just meet the standard in a location of the country where air concentrations currently do not meet the current standard (the primary Pb smelter case study). Estimates of median air-related IQ loss associated with just meeting the current NAAQS in the primary Pb smelter case study subarea had a lower bound estimate of <3.2 points IQ loss (''recent air'' category of Pb exposures) and an upper bound estimate of <9.4 points IQ loss (''recent air'' plus ''past air'' category) for the range of C–R functions (Table 3). This estimate (recent air plus past air) for the subarea based on the LLL C–R function is 6.0 points IQ loss for the median and 8.0 points IQ loss for the 95th percentile, with which we note a greater uncertainty than for the median estimate (as discussed above).[119] Modeling limitations have affected our ability to derive lower bound estimates for this case study (as described above in section II.C.2.c).

Additionally, we developed estimates of blood Pb and associated IQ loss associated with the current standard for the urban case studies. We note that we consider it extremely unlikely that air concentrations in urban areas across the U.S. that are currently well below the current standard would increase to just meet the standard. However, we recognize the potential, although not the likelihood, for air Pb concentrations in some limited areas currently well below the standard to increase to just meet the standard by way of, for example, expansion of existing sources (e.g., facilities operating as secondary smelters may exercise previously used capabilities as primary smelters) or by

the congregation of multiple Pb sources in adjacent locations. We have simulated this scenario (increased Pb concentrations to just meet the current standard) in a general urban case study and three location-specific urban case studies. For the location-specific urban case studies, we note substantial uncertainty in simulating how the profile of Pb concentrations might change in the hypothetical case where concentrations increase to just meet the current standard.

Turning first to the exposure/risk estimates for the current NAAQS scenario simulated for the general urban case study, which is a simplified representation of a location within an urban area (described in section II.C.2.h above), median estimates of air-related IQ loss range from 1.5 to 7.7 points (across all four C–R functions), with an estimate based on the LLL function bounded at the low end by 3.4 points and at the high end by 4.8 points (Table 3). At the 95th percentile for total IQ loss (LLL estimate), IQ loss associated with air-related Pb is estimated to fall somewhere between 5.5 and 7.6 points (Staff Paper, Table 4–6).

In considering the estimates for the three location-specific urban case studies, we first note the extent to which exposures associated with increased air Pb concentrations that simulate just meeting the current standard are estimated to increase blood Pb levels in young children. The magnitude of this for the median total blood Pb ranges from 0.3 µg/dL (an increase of 20 percent) in the case of the Cleveland study area (where the highest monitor is estimated to be approximately one fourth of the current NAAQS), up to approximately 1 µg/dL (an increase of 50 to 70%) for the Chicago and Los Angeles study areas, where the highest monitor is estimated to be at or below one tenth of the current NAAQS (Table 1). Median estimates of air-related risk for these case studies range from 0.6 points IQ loss (recent air estimate using low-end C–R function) to 7.4 points IQ loss (recent plus past air estimate using the high-end C–R function). The corresponding estimates based on the LLL C–R function range from 2.7 points (lowest location-specific recent air estimate) to 4.7 points IQ loss (highest location-specific recent plus past air estimate). The comparable estimates of air-related risk for children at the 95th percentile in these three case studies range from 2.6 to 7.6 points IQ loss for the LLL C–R function (Staff paper, Table 4–6), although we note increased uncertainty in the magnitude of these 95th percentile air-related estimates.

Another way in which the risk assessment results might be considered is by comparing current NAAQS scenario estimates to current conditions, although in so doing, it is important to recognize that, as stated below and described in section II.C., this will underestimate air-related impacts associated with the current NAAQS. In making such a comparison of estimates for the three location-specific urban case studies, the estimated difference in total Pb-related IQ loss for the median child is about 0.5 to 1.4 points using the LLL C–R function and a similar magnitude of difference is estimated for the 95th percentile. The corresponding comparison for the general urban case study indicates the current NAAQS scenario median total Pb-related IQ loss is 1.1 to 1.3 points higher than the two current conditions scenarios. As described in section II.C, such comparisons are underestimates of air-related impacts brought about as a result of increased air Pb concentrations, and consequently they are inherently underestimates of the true impact of an increased NAAQS level on public health.

In considering the exposure/risk information with regard to adequacy of the current standard, the Staff Paper first considered the estimates described above, particularly those associated with air-related risk.[120] The Staff Paper described 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).

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. For example, estimates of the additional number of children with IQ loss greater than one point (based on the LLL C–R function) in these three study areas, for the current NAAQS scenario as compared to current conditions, range from 100 to 6,000 across the three locations (as shown above in Table 5). The corresponding estimates for the additional number of children with IQ

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[119] We note that while we have termed risk estimates derived for the sum of ''recent air'' plus ''past air'' exposure pathways as ''upper bound'' estimates of air-related risk, the primary Pb smelter subarea is an area where soil has been remediated and thus does not reflect any historical deposition. Further, soil Pb concentrations in this area are not stable and may be increasing, seeming to indicate ongoing response to current atmospheric deposition in the area. Thus, for this case study, the ''recent air'' plus ''past air'' estimates are less of an ''upper bound'' for air-related risk than in other case studies where historical Pb deposition may have some representation in the ''past air'' soil ingestion pathway.

[120] As recognized in section III.B.2.d above, to simulate air concentrations associated with the current NAAQS, a proportional roll-up of concentrations from those for current conditions was performed for the location-specific urban case studies. This was not necessary for the primary Pb smelter case study in which air concentrations currently exceed the current standard, nor for the general urban case study.

loss greater than seven points, for the current NAAQS as compared to current conditions, range from 600 to 66,000 (as shown above in Table 6). These latter values for the change in incidence of children with greater than seven points Pb-related IQ loss represent 5 to 17 percent of the children (aged less than 7 years of age) in these study areas. This increase corresponds to approximately a doubling in the number of children with this magnitude of Pb-related IQ loss in the study area most affected. The Staff Paper concluded that these estimates indicate the potential for significant numbers of children to be negatively affected if air Pb concentrations increased to levels just meeting the current standard.

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. 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).

3. CASAC Advice and Recommendations and Public Comment

CASAC's recommendations in this review builds upon the CASAC recommendations during the 1990 review, which also advised on consideration of more health protective NAAQS. In CASAC's review of the 1990 Staff Paper, as discussed in Section II.D.1.b, they generally recommended consideration of levels below 1.0 µg/m³, specifically recommended analyses of a standard set at 0.25 µg/m³, and also recommended a revision to a monthly averaging time (CASAC, 1990).

In its letter to the Administrator subsequent to consideration of the ANPR, the final Staff Paper and the final Risk Assessment Report, the CASAC Pb Panel 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 µg/m³ with a monthly averaging time'' (Henderson, 2008, p. 1). This recommendation is consistent with their recommendations conveyed in two earlier letters in the course of this review (Henderson, 2007a, 2007b). Further, in their advice to the Agency over the course of this review, CASAC has provided rationale for their conclusions that has included

their statement 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 stated that ''Consequently, 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.

The Agency has also received comments from the public on drafts of the Staff Paper and related technical support document, as well as on the ANPR.[121] Public comments received to date that have addressed adequacy of the current standard overwhelmingly concluded that the current standard is inadequate and should be substantially revised, in many cases suggesting specific reductions to a level at or below 0.2 µg/m³. Two comments were received from specific industries expressing the view that the current standard might need little or no adjustment. One comment received early in the review stated that current conditions justified revocation of the standard.

4. Administrator's Proposed Conclusions Concerning Adequacy

Based on the large body of evidence 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, the Administrator proposes that the current standard does not protect public health with an adequate margin of safety and should be revised to provide additional public health protection.

In considering the adequacy of the current standard, the Administrator has 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.

The Administrator notes that the body of available evidence, summarized above in section III.B 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. Subsequent to the setting of the standard, the Pb NAAQS criteria review during the 1980s and the current review have provided (a) expanded and strengthened evidence of still lower Pb exposure levels associated with slowed physical and neurobehavioral development, lower IQ, impaired learning, and other indicators of adverse neurological impacts; and (b) other effects of Pb on cardiovascular function, immune system components, calcium and vitamin D metabolism and other health endpoints (discussed fully in the Criteria Document).

The Administrator notes particularly 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 III.B), 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

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[121] All written comments submitted to the Agency are available in the docket for this rulemaking, are transcripts of the public meetings held in conjunction with CASAC's review of the Staff Paper, the Risk Assessment Report, the Criteria Document and the ANPR.

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.

Based on evidence discussed above, the Administrator first considered the 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 above, however, the 1978 framework was premised on an evidentiary basis that clearly identified an adverse health effect and a health-based policy judgment that identified a level that would be safe for an individual child with respect to this adverse health effect. The adaptation to the 1978 framework applies this framework to a situation where there is no longer an evidentiary basis to determine a safe level for individual children. In addition, this approach does not address explicitly what magnitude of effect should be considered adverse. Given these two limitations, the Administrator has focused primarily instead on the air-related IQ loss evidence-based framework described above in considering the adequacy of the current standard.

In considering the application the air-related IQ loss framework to the current evidence as discussed above in section II.D.2.a, the Administrator notes that this framework suggests an average air-related IQ loss for a population of children exposed at the level of the current standard on the order of 4 or more IQ points. The Administrator judges that an air-related IQ loss of this magnitude 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 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.

The Administrator has also considered the results of the exposure and risk assessments conducted for this review, which provides some further perspective on the potential magnitude

of air-related IQ loss. However, taking into consideration the uncertainties and limitations in the assessments, notably including questions as to whether the assessment scenarios that roll up current air quality to simulate just meeting the current standard are realistic in wide areas across the U.S., the Administrator has not placed primary reliance on the exposure and risk assessments. Nonetheless, the Administrator observes that in areas projected to just meet the current standard, the quantitative estimates of IQ loss associated with air-related Pb, as summarized above in section II.D.2.b, 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 the potential that the prevalence of such levels of Pb concentrations may be underestimated by currently available data.

The Administrator believes that the air-related blood Pb and IQ loss estimates discussed in the Staff Paper and Risk Assessment Report, summarized above, as well as the estimates of air-related IQ loss suggested by this evidence-based framework, are important from a public health perspective and are indicative of potential risks to susceptible and vulnerable groups. In reaching this proposed judgment, the Administrator considered the following factors: (1) The estimates of blood Pb and IQ loss for children from air-related Pb exposures associated with the current standard, (2) the estimates of numbers of children with different amounts of increased Pb-related IQ loss associated with the current standard, (3) the variability within and among areas in both the exposure and risk estimates, (4) the uncertainties in these estimates, and (5) the recognition that there is a broader array of Pb-related adverse health outcomes for which risk estimates could not be quantified and that the scope of the assessment was limited to a sample of case studies and to some but not all at-risk populations, leading to an incomplete estimation of public health impacts associated with Pb exposures across the country.[122] In addition to the

evidence-based and risk-based conclusions described above, the Administrator also notes that it was the unanimous conclusion of the CASAC Panel that EPA needed to "substantially lower" the level of the primary Pb NAAQS to fully protect the health of children and adult populations (Henderson, 2007a, 2007b, 2008).

Based on all of these considerations, the Administrator proposes 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.

E. 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 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. Considerations and proposed conclusions on indicator are discussed in section II.E.1, and on averaging time and form in section II.E.2. Considerations and proposed conclusions on a level for a Pb NAAQS with a Pb-TSP indicator are discussed in section II.E.3, and considerations on a level for a Pb NAAQS with a Pb-PM$_{10}$ indicator are discussed in section II.E.4.

1. Indicator

The indicator for the current standard is Pb-TSP (as described in section II.D.1.a above).[123] When the standard was set in 1978, the Agency proposed Pb-TSP as the indicator, but considered identifying Pb in particulate matter less than or equal to 10 μm in diameter (Pb-PM$_{10}$) as the indicator. EPA had received comments expressing concern

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[122] While recognizing that there are significant uncertainties associated with the risk estimates from the case studies, EPA places an appropriate weight on the risk assessment results for purposes of evaluating the adequacy of the current standard, given the strength of the evidence of the existence of effects at blood Pb levels associated with exposures at the level of the current standard, the

magnitude of the IQ losses that are estimated, and the consistency of these IQ losses with the estimates of IQ loss derived from the alternative evidence-based framework. The weight to place on the risk assessment results for purposes of evaluating alternative levels of the standard is discussed later in the discussion on the level of the standard.

[123] The 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.

that because only a fraction of airborne particulate matter is respirable, an air standard based on total air Pb would be unnecessarily stringent. The Agency responded that while it agreed that some Pb particles are too small or too large to be deposited in the respiratory system, a significant component of exposures can be ingestion of materials contaminated by deposition of Pb from the air. In addition to the route of ingestion and absorption from the gastrointestinal tract, nonrespirable Pb in the environment may, at some point, become respirable through weathering or mechanical action. 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 FRM sampler for TSP.

In the 1990 Staff Paper, this issue was reconsidered in light of information regarding limitations of the high-volume sampler used for the Pb-TSP measurements, and the continued use of Pb-TSP as the indicator was recommended in the Staff Paper (USEPA, 1990):

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 * * *

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-PM$_{10}$ (collected by low-volume sampler) 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 equivalence method (FEM) in terms of PM$_{10}$ 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-PM$_{10}$ 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-PM$_{10}$ data for judging attainment or nonattainment with a Pb-TSP NAAQS. These issues included the impact of controlling Pb-PM$_{10}$ for sources predominantly emitting Pb in particles larger than those captured by PM$_{10}$ monitors [124] (i.e., ultra-coarse), [125] and the options included potential application of Pb-PM$_{10}$ FRM/FEMs at sites with established relationships between Pb-TSP and Pb-PM$_{10}$, and use of Pb-PM$_{10}$ data, with adjustment, as a surrogate for Pb-TSP data. The ANPR broadly solicited comment in these areas.

In the current review, both the CASAC Pb Panel and members of the CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee have recommended that EPA consider a change in the indicator to PM$_{10}$, utilizing low-volume PM$_{10}$ sampling (Henderson, 2007a, 2007b, 2008; Russell, 2008). [126] In their January 2008 letter, the CASAC Lead Panel

[124] For simplicity, the discussion here and below speaks as if PM$_{10}$ 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 PM$_{10}$ 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, which is broad enough to include virtually all particles capable of being transported any significant distance from their source except under extreme wind events. As explained below, the capture efficiency of a high-volume TSP sampler for any given size particle is affected by wind speed and wind direction.

[125] In this notice, we use "ultra-coarse" to refer to particles collected by a TSP sampler but not by a PM$_{10}$ sampler (we note that CASAC has variously also referred to these particles as "very coarse" or "larger coarse-mode" particles), "fine" to refer to particles collected by a PM$_{2.5}$ sampler, and "coarse" to refer to particles collected by a PM$_{10}$ 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.

[126] "Low-volume PM$_{10}$ 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 PM$_{10}$ in which the monitor draws 1500 liters/minute (90 m³/hour). All commercial TSP FRM samplers at this time are high-volume samplers; both high-volume and low-volume PM$_{10}$ FRM samplers are available. Low-volume sampling is the more recently introduced method. Low-volume and high-volume samplers differ in many other ways also, including filter size, accuracy of the flow control, and degree of computerization.

unanimously recommended that EPA revise the Pb NAAQS indicator to rely on low-volume PM$_{10}$ sampling (Henderson, 2008). They indicated support for their recommendation in a range of areas. First, they noted poor precision in high-volume TSP sampling, wide variation in the upper particle size-cut as a function of wind speed and direction, and greater difficulties in capturing the spatial non-homogeneity of ultra-coarse particles with a national monitoring network. They stated that the low-volume PM$_{10}$ collection method is a much more accurate and precise collection method, and would provide a more representative characterization on a large spatial scale of monitored particles which remain airborne longer, thus providing a characterization that is more broadly representative of ambient exposures over large spatial scales. They also noted the automated sequential sampling capability of low-volume PM$_{10}$ monitors which would be particularly useful if the averaging time is revised (i.e., to a monthly averaging time, as recommended by CASAC), which, in CASAC's view would necessitate an increased monitoring frequency. Further, they noted the potential for utilization of the more widespread PM$_{10}$ sampling network (Henderson, 2007a, 2007b, 2008). [127] In their advice, 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 PM$_{10}$ 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-PM$_{10}$ and Pb-TSP sampling data [128] (Henderson, 2007a, 2007b, 2008).

The Agency received comments on the discussion of the indicator in the ANPR from several state and local agencies and national/regional air pollution control organizations, as well as a national environmental organization. These public comments

[127] EPA notes that costs, including those of operating a monitoring network, may not be considered in establishing or revising the NAAQS.

[128] In their advice, CASAC recognized the potential for site-to-site variability in the relationship between Pb-TSP and Pb-PM$_{10}$ (Henderson, 2007a, 2007b). They also stated in their September 2007 letter, "The Panel urges that PM$_{10}$ 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 a PM$_{10}$ Pb/TSP Pb 'equivalency ratio' could be determined on a regional or site-specific basis."

were somewhat mixed. Most of these commenters recommended maintaining Pb-TSP as the indicator to ensure that Pb emitted in larger particles is not overlooked by the Pb NAAQS. Some of those comments and others suggested keeping TSP as the indicator but revising the FRM to a low-volume TSP method [129] and considering tighter sampling height criteria to reduce variability.[130] Others, in considering a potential PM_{10}-based indicator or the use of PM_{10} data as a surrogate for Pb-TSP, noted the need for characterization of the relationship between Pb-PM_{10} and Pb-TSP, which varies with proximity to some sources. One state agency and a national organization of regulatory air agencies expressed clear support for revising the indicator to Pb-PM_{10}, predominantly citing advantages associated with improved technology and efficiency in data collection.

In considering these issues concerning the appropriate indicator, EPA takes note of previous Agency conclusions that the health evidence indicates that Pb in all particle size fractions, not just respirable Pb, 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. As recognized by the Agency in setting the standard, and as noted by CASAC in their advice during this review, these particles include ultra-coarse particles. Thus, choosing the appropriate indicator requires consideration of the impact of the indicator on protection from both the inhalation and ingestion pathways of exposure and Pb in all particle sizes, including ultra-coarse particles.

As discussed in section 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. For example, the measured values from a high-volume TSP sampler may differ substantially, depending on wind speed and direction, for the same actual ambient concentration of Pb-TSP.[131] 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. The result is a clear risk of error from underestimating the ambient level of total Pb in the air, especially in areas near sources of ultra-coarse particles, by underestimating the amount of the ultra-coarse particles. There is also the potential for overestimation of individual sampling period measurements associated with high wind events.[132]

The low-volume PM_{10} sampling methodology does not exhibit such variability [133] due both to increased precision of the monitor and decreased spatial variation of Pb-PM_{10}

concentrations. As a result, greater precision is associated with sample measurements for Pb collected using the PM_{10} sampling methodology. The result is a lower risk of error in measuring the ambient Pb in the PM_{10} size class than there is risk of error in measuring the ambient Pb in the TSP size class using Pb TSP samplers. On the other hand, PM_{10} samplers do not include the Pb in particles greater than PM_{10} that also contributes to the health risks posed by air-related Pb, especially in areas influenced by sources of ultra-coarse particles. There are also concerns over whether control strategies put in place to meet a NAAQS with a Pb-PM_{10} indicator will be effective in controlling ultra-coarse Pb-containing particles. In evaluating these two indicators, the differences in the nature and degree of these sources of error between Pb-TSP and Pb-PM_{10} need to be considered and weighed, to determine the appropriate way to protect the public from exposure to air-related Pb.

As noted above, EPA is concerned about the total mass of all Pb particles emitted into the air and subsequently inhaled or ingested. Measurements of Pb-TSP address a greater fraction of the particles of concern from a public health perspective than measurements of Pb-PM_{10}, but limitations with regard to the sampler mean that these data are less precise. EPA recognizes substantial variability in the high-volume Pb-TSP method, meaning there is a risk of not consistently identifying sites that fail to achieve the standard, both across sites and across time periods for the same site.

Alternatively, using low-volume Pb-PM_{10} as the indicator would allow the use of a technology that has better precision in measuring PM_{10}. In addition, since Pb-PM_{10} concentrations have less spatial variability, such monitoring data may be representative of Pb-PM_{10} air quality conditions over a larger geographic area (and larger populations) than would Pb-TSP measurements. The larger scale of representation for Pb-PM_{10} 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.[134] However, there would be a different source of error, in that larger Pb particles not captured by PM_{10} samplers would not be measured.

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[129] The Pb-TSP FRM specification, 40 CFR 50 appendix G, currently explicitly requires the use of the high-volume TSP FRM sampler which is required by appendix B for the mass of TSP. Therefore it would require amendments to 40 CFR 50 appendix B and/or G (or a new dedicated appendix) to establish a low-volume TSP sampler as the only FRM, or as an alternative FRM, for TSP and/or Pb-TSP measurement. A number of researchers have utilized both self-built and commercially available low-volume TSP samplers in ambient air studies. Typically, these samplers are identical to low-volume PM_{10} FRM samplers with the exception that their inlets and other size separation devices (or lack thereof) are aimed at collecting TSP. EPA is not aware of any rigorous evaluation of the performance of these available, non-designated low-volume TSP samplers or their equivalence to the TSP FRM. No one has applied to date for designation of a low-volume TSP sampler as a FEM, either for TSP measurement per se or for purposes of Pb-TSP measurement.

[130] Currently, probe heights for Pb-TSP and PM_{10} sampling are allowed to be between 2 and 15 meters above ground level for neighborhood-scale monitoring sites (those intended to represent concentrations over a relatively large area around the site) and between 2 and 7 meters for microscale sites. Near very low-height sources of TSP, including fugitive dust sources at ground level, concentrations of TSP, especially the concentrations of particles larger than 10 microns, can vary substantially across this height range with higher concentrations closer to the ground; near-ground concentrations can also vary more in time than concentrations higher up.

[131] As noted in section V, the collection efficiency (over the 24-hour collection period) of particles larger than approximately 10 microns in a high-volume TSP FRM sampler varies with wind speed due to aerodynamic effects, with a lower collection efficiency under high winds. The collection efficiency also varies with wind direction due to the non-cylindrical shape of the TSP sampler inlet. These characteristics tend to result in reporting less than the true TSP concentration over the 24-hour collection period.

[132] We note that it is possible for high winds to blow Pb particles onto a high-volume TSP sampler's filter after the end of its 24-hour collection period before the filter is retrieved, causing the reported concentration for the 24-hour period to be higher than the actual 24-hour concentration.

[133] Low-volume PM_{10} 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.

[134] The larger scale would also make comparisons between two or more monitoring sites more indicative of the true comparison between the areas surrounding the monitoring sites, with regard to the Pb captured by Pb-PM_{10} monitors, which could be informative in studies of Pb uptake and health effects in populations.

The fraction of Pb collected with a TSP sampler that would not be collected by a PM_{10} 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). This means that this error is of most concern in locations in closer proximity to such sources, which may also be locations with some of the higher ambient air levels. As discussed below, such variability would be a consideration in determining the appropriate level for a standard based on a $Pb-PM_{10}$ indicator.

Accordingly, we believe it is reasonable to consider continued use of a Pb-TSP indicator, focusing on the fact that it specifically includes the ultra-coarse Pb particles in the air that are of concern and need to be addressed in protecting public health from air-related exposures. In considering the option of retaining Pb-TSP as the indicator, EPA recognizes that high-volume FRM TSP samplers would continue to be used at many monitoring sites operated by State and local agencies. In addition, it is possible that one or more low-volume TSP monitors would be approved as FEM, under the provisions of 40 CFR 53, Ambient Air Monitoring Reference and Equivalent Methods. EPA believes, along with some commenters as noted above, that low-volume Pb-TSP sampling would have important advantages over high-volume Pb-TSP sampling.[135] To facilitate the ability of monitor vendors and monitoring agencies to gain FEM status for low-volume Pb-TSP monitors, EPA is proposing certain revisions to the side-by-side equivalence testing requirements in 40 CFR 53 regarding the ambient Pb concentrations required during testing so that testing is more practical for a monitor vendor to conduct, as described in more detail in section V below. We note that 40 CFR 53.7, Testing of Methods at the Initiative of the Administrator, allows EPA itself

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[135] Low-volume Pb-TSP samplers could be assembled by making low-cost parts substitution to either low-volume PM_{10} or low-volume $PM_{2.5}$ samplers; some models would have the same sequential sampling ability as CASAC has noted for low-volume $Pb-PM_{10}$ samplers; sensitivity to wind direction would be eliminated; and their flow control and data processing and reporting abilities would be substantially better than high-volume Pb-TSP samplers. Low-volume Pb-TSP sampling data would have the same geographic variability as high-volume Pb-TSP sampling data, however. The size-specific capture efficiency curves of currently available commercial low-volume sampling systems are not well characterized, nor their sensitivity to wind speed. EPA therefore recognizes some uncertainty about their equivalence to high-volume samplers in terms of the capture of ultra-coarse particles.

to conduct the required equivalence testing for a method and then determine whether the requirements for equivalence are met. It would also be possible for EPA to promulgate amendments to 40 CFR 50 establishing one or more particular designs of a low-volume sampler as a Pb-TSP FRM, or to establish performance specifications that would facilitate the approval of low-volume samplers as FRM on a performance basis rather than a design basis; this could be done as a replacement for the high-volume TSP and Pb-TSP FRM or as an alternative TSP and/or Pb-TSP FRM. Either path to FRM status would avoid the need for the side-by-side testing, prescribed by 40 CFR 53, of low-volume samplers to demonstrate equivalence to the high-volume FRM sampler, although some amount and type of new testing in the field or in a wind tunnel may be appropriate before such changes should be made. EPA invites comments on the low-volume TSP sampler concept.

Within the option of continued use of a Pb-TSP indicator, EPA recognizes that some State, local, or tribal monitoring agencies, or other organizations, for the sake of the advantages noted above, may wish to deploy low-volume $Pb-PM_{10}$ samplers rather than Pb-TSP samplers. In anticipation of this, we have also considered an approach within the option of retaining Pb-TSP as the indicator that would allow the use of $Pb-PM_{10}$ data (when and if low-volume $Pb-PM_{10}$ samplers have been approved by EPA as either FRM or FEM), with adjustment(s), for monitoring for compliance with the Pb-TSP NAAQS. This approach would have five components: (1) The establishment of a FRM specification for low-volume $Pb-PM_{10}$ monitoring including both a PM_{10} sampler specification and a reference chemical analysis method for determination of Pb in the collected particulate matter; (2) the establishment of a path to FEM designation for $Pb-PM_{10}$ monitoring methods that differ from the FRM in either the sampler or the analytical method; (3) flexibility for monitoring agencies to deploy low-volume $Pb-PM_{10}$ monitors anywhere that Pb monitoring is required by the revised Pb monitoring requirements to help implement the revised NAAQS; (4) specific steps for applying an adjustment to low-volume $Pb-PM_{10}$ data for purposes of making comparisons to the level of the NAAQS specified in terms of Pb-TSP, and (5) a provision in the data interpretation guidelines that, whenever and wherever Pb-TSP data from a monitoring site is available and sufficient for determining whether or

not the Pb-TSP standard has been exceeded, any collocated $Pb-PM_{10}$ data from that site for the associated time period will not be considered. The first three and the last components are discussed in depth in sections IV and V below. Because the issue of adjustment to low-volume $Pb-PM_{10}$ data is linked closely to considerations of the advantages of one indicator option versus another, it is discussed here.

In considering how to identify the appropriate adjustment(s) to be made to $Pb-PM_{10}$ data for purposes of making comparisons to the level of the NAAQS specified in terms of Pb-TSP, we recognize the importance to protecting public health of taking into account the ultra-coarse particles that are not included in $Pb-PM_{10}$ measurement. As discussed below, one approach to doing so would be to adjust or scale $Pb-PM_{10}$ data upwards before comparison to a Pb-TSP NAAQS level where the data are collected in an area that can be expected to have ultra-coarse particles present.

$Pb-PM_{10}$/Pb-TSP relationships vary from site to site and time to time. These $Pb-PM_{10}$/Pb-TSP relationships have a systematic variation with distance from emissions sources emitting particles larger than would be captured by $Pb-PM_{10}$ samplers, such that generally there are larger differences between $Pb-PM_{10}$ and Pb-TSP near sources. This is due to the faster deposition of the ultra-coarse particles (as described in section II.A.1). The exact size mix of particles at the point(s) of emissions release and the height of the release point(s) also affect the relationship. Accordingly, EPA is proposing to require the one-time development and the continued use of site-specific adjustments for $Pb-PM_{10}$ data, for those sites for which a State prefers to conduct $Pb-PM_{10}$ monitoring rather than Pb-TSP monitoring. Site-specific studies to establish the relationships between Pb-TSP and $Pb-PM_{10}$, conducted using side-by-side paired samplers, would allow $Pb-PM_{10}$ monitoring using locally determined factors based on local study data to determine compliance with a NAAQS based on Pb-TSP.

In addition, EPA invites comment on also providing in the final rule default scaling factor(s) for use of $Pb-PM_{10}$ data in conjunction with a Pb-TSP indicator, as an alternative for States which wish to conduct $Pb-PM_{10}$ monitoring rather than Pb-TSP monitoring near Pb sources but prefer not to conduct a site-specific scaling factor study. EPA has identified and analyzed available collocated $Pb-PM_{10}$ and Pb-TSP data from 23 monitoring sites in seven States. (Schmidt and Cavender, 2008). This analysis considered both source-

oriented and nonsource-oriented sites. In this analysis, EPA identified only three of the 23 monitoring sites with collocated data as being source-oriented. One of these sites was near an operating Pb smelter at the time of the collocated monitoring; Pb emissions from smelters typically contain both ultra-coarse particles from materials handling and resuspension of contaminated dust, and fine and coarse particles from the high temperature smelting operation itself. However, since this study was conducted, EPA has promulgated a Maximum Achievable Control Technology (MACT) standard for primary lead smelting that controls process and fugitive dust emissions. (64 FR 30194, June 4, 1999). The other two source-oriented sites include one located near a battery manufacturer, and one located near an automobile plant. The data for the smelter site was collected in 1988 and indicate an average Pb-TSP concentration of about 2.5 µg/m³. The data for the battery manufacturer site were collected in the mid-1990s and indicate an average Pb-TSP concentration of about 0.09 µg/m³; data for the third site, located near an automotive plant, collected within the past 5 years, indicate an average Pb-TSP concentration at that site of about 0.03 µg/m³. As discussed in Schmidt and Cavender (2008), ratios between Pb-TSP and Pb-PM_{10} concentrations varied somewhat within the data for each site, but the ratios between the Pb-TSP and Pb-PM_{10} concentration averages were 2.0 for the smelter site (based on 20 data pairs), 1.6 at the site near the battery manufacturer (based on 107 data pairs), and 1.1 at the site located near an automotive plant (based on 167 data pairs).

Collectively, these three monitoring sites suggest that site-specific scaling factors for source-oriented monitoring sites may vary between 1.1 and 2.0; the range may also be greater. EPA notes that in selecting a default factor for source-oriented monitoring sites, if that approach is taken in the final rule, it may be appropriate to consider default adjustment factors from within the mid to upper part of this range rather than the lower end to avoid the possibility of underestimating the appropriate scaling factor for a large proportion of the source-oriented sites for which States might choose the default factor rather than conduct a local study. On this basis, EPA invites comment on the possibility of providing a default factor(s) for source-oriented sites and on the selection of a value(s) from within this range for all source-oriented monitoring sites, as an option to the

proposed requirement for development a site-specific factor through analysis of paired monitoring data. EPA invites comment on the selection of a single or multiple default factors for source-oriented sites from within this range. While the selection of the scaling factor in concept could depend on a characterization of the particle size mix emitted by the Pb source, we note that reliable information on the mix of coarse and ultra-coarse particles may often be unavailable. For example, EPA could select a default factor that is at or near the upper end of the range, 2.0, to avoid the risk of underprotection in situations in which there is as high or nearly as high a proportion of ultra-coarse Pb as at the smelter site. Alternatively, EPA could discount the smelter data set on the basis that the 1988 data set does not reasonably represent any likely current or future smelter situation. Similarly, EPA could rely on the data taken near the automotive plant since it is the most recent and largest dataset. EPA also invites comment on other sets of paired data from near Pb sources of which we may be unaware, and comment on other approaches of selecting a default factor for the final rule based on paired data, including approaches that might use more than one default factor for source-oriented monitoring sites with the selection of the factor for a given monitoring site depending on the characteristics of the nearby sources, the ambient concentration of Pb-PM_{10}, or other factors.

EPA also invites comment on whether and what default scaling factor(s) should be established for monitoring sites which, as far as is known, are not influenced by nearby emission sources. We have reviewed paired data from the 20 monitoring sites that appear to fit this description (Schmidt and Cavender, 2008). Average Pb-TSP concentrations at nearly all these sites were near to or below the lowest concentration on which comments are invited as to the NAAQS level. Judging from ratios at these 20 sites, it appears that site-specific factors generally range from 1.0 to 1.4 (with the factors for three sites ranging from 1.8 to 1.9), and the ratios may be influenced by measurement variability in both samplers as well as by actual air concentrations. Given the relatively low ambient concentrations that we believe currently prevail at nonsource-oriented sites, the value of a default scaling factor selected within the range of 1.0 to 1.4 would have little effect on the NAAQS compliance determination at such sites. EPA invites comment on the approach of requiring

use of a default factor(s) for adjusting Pb-PM_{10} data at nonsource-oriented sites and on the selection of a value(s) from within the range of 1.0 to 1.4 and also solicits comment on selection of a default scaling factor from within the broader range of 1.0 to 1.9. We note that allowing the use of a default scaling factor of 1.0 for nonsource-oriented sites would in effect allow a State the option of comparing Pb-PM_{10} data directly to the level of the Pb-TSP standard at nonsource-oriented monitoring sites, without conducting a site-specific study. Below, and in section II.E.4, EPA discusses the possibility of revising the indicator to Pb-PM_{10}, which would result in such unadjusted comparisons of Pb-PM_{10} data to the standard at all monitoring sites.

EPA recognizes that the available data from collocated monitoring of Pb-TSP and Pb-PM_{10}, described above, have limitations which make their interpretation and use in selecting default scaling factors subject to considerable uncertainty. All of the Pb-PM_{10} measurements at these sites were made with high-volume PM_{10} samplers, which are more variable than the low-volume samplers for which scaling factors would actually be applied after the final rule; this greater variability no doubt has added to the variation in ratios discussed above. Only three source-oriented sites have collocated data; with such a small sample of sites both the range of ratios and the distribution of ratios among all current and future source-oriented sites remains uncertain. There were many more nonsource-oriented sites which tended to show notably lower ratios, implying lower scaling factors, but all had relatively low concentrations; these ratios may or may not be representative of monitoring sites near well controlled Pb sources. In many cases, the period of collocated testing was only a few months; ratios observed in such a short period may not be representative of ratios that occur at other times of the year that may be more critical to attainment status. Also, EPA has not yet had the benefit of CASAC review of the detailed compilation of these data, as (Schmidt and Cavender, 2008) was prepared subsequent to the most recent consultation with CASAC's AAMM Subcommittee. Because of these uncertainties, EPA is proposing to require States that wish to use Pb-PM_{10} data for a Pb-TSP standard to develop site-specific scaling factors based on their own collocated monitoring using paired Pb-TSP and low-volume Pb-PM_{10} samplers over at least a one-year period, as described in section IV. EPA intends

to encourage States to consider conducting local studies, even if the final rule allows the use of default factors. Also, EPA invites comment on whether to provide for the use of default scaling factors, and the values of those factors.

As a possible second option, taking into consideration the advice of the CASAC Pb Panel and members of the CASAC AAMM Subcommittee, EPA has also considered potential revision of the indicator to $Pb-PM_{10}$. In so doing, we recognize several potential important benefits of such a revision, as well as the need to reflect such a revision in the selection of level of the standard.[136] We recognize that the low volume PM_{10} sampler provides better precision and size selection characteristics which would make the associated data more comparable across sites.

In considering a potential revision of the indicator to $Pb-PM_{10}$, we recognize that an important issue is whether regulating concentrations of $Pb-PM_{10}$ will lead to appropriate controls on all particle size Pb emissions from sources. For example, it would be of concern if a NAAQS based on a $Pb-PM_{10}$ indicator resulted in different emissions control decisions at sources with a large percentage of Pb in the size range not substantially captured by PM_{10} sampling (e.g., fugitive dust emissions from Pb smelters) than the emission control decisions that would be made if the NAAQS was based on Pb-TSP. In that case, a PM_{10}-based NAAQS might not yield emissions changes by some Pb sources which under a Pb-TSP indicator would have contributed to NAAQS exceedances and subsequent emissions changes. Alternatively, while collocated Pb-TSP and $Pb-PM_{10}$ data are lacking for a broad range of source types, there are likely many sources (e.g., high temperature combustion processes) for which virtually all of the emitted particles represented in a Pb-TSP measurement would be captured by a $Pb-PM_{10}$ measurement. Further, there are likely other source types with a range of particle sizes extending beyond $Pb-PM_{10}$, for which controls adopted to meet a $Pb-PM_{10}$ requirement would also achieve a proportional reduction in ultra-coarse particles. In these situations, one might not expect any difference in emissions control

decisions whether the NAAQS is $Pb-PM_{10}$-based or Pb-TSP-based.

If the indicator were to be revised to $Pb-PM_{10}$, low-volume $Pb-PM_{10}$ samplers would become the required approach to Pb monitoring at required monitoring sites and would be a logical choice wherever else NAAQS-oriented Pb monitoring is undertaken. Nonetheless EPA notes that retaining Pb-TSP monitors at some relatively small subset of the $Pb-PM_{10}$ monitoring sites would be beneficial for purposes of scientific understanding of both ambient conditions and the performance of the two types of measurement systems.

For reasons discussed here, 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 to date, the Administrator proposes 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, but with expansion of the measurements accepted for determining attainment or nonattainment of the Pb NAAQS to provide an allowance for use of $Pb-PM_{10}$ data, measured by the new low-volume $Pb-PM_{10}$ 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 as described above and more specifically below in section IV. The Administrator invites comment on also 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. In consideration of all of the issues discussed above, the Administrator also invites comment on a second option, a revision of the current indicator to $Pb-PM_{10}$. (Considerations related to the level of a standard based on a PM_{10} indicator are discussed below in section II.E.4.) The Administrator solicits comment on all of the issues discussed above, and specifically with regard to the potential for a $Pb-PM_{10}$ indicator to influence implementation of controls in ways that would lead to less control associated with larger particles than might be achieved with a Pb-TSP-based NAAQS, taking into account the variability noted above for TSP sampling.

2. Averaging Time and Form

The statistical form of the current standard is a not-to-be-exceeded or maximum value, averaged over a calendar quarter. This might also be described as requiring that no average

air Pb concentration representing a time period of duration as long as calendar quarter (or longer) may exceed the level of the standard. As noted in section II.D.1.a, EPA set the standard in 1978 as a ceiling value with the conclusion that this air level would be safe for indefinite exposure for young children (43 FR 46250).

The basis for selection of the current standard's averaging time of calendar quarter 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 $\mu g/m^3$, 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 $\mu g/dL$ was the maximum safe level of blood Pb for an individual child.

With regard to averaging time, after consideration 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.B above and discussed in detail in the Criteria Document, the currently available health effects evidence [137] 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

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[136] EPA recognizes and has specifically considered that such a decision would affect the selection of the level of the standard, recognizing that it is the combination of indicator and level (with averaging and time and form) that determine the degree of protection afforded by the standard. Section II.E.4 further considers the impact of adoption of a $Pb-PM_{10}$ indicator on the selection of a level for the standard.

[137] The differing evidence and associated strength of the evidence for these different effects is described in detail in the Criteria Document.

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.[138] In consideration of averaging time for the Pb NAAQS, we note the following aspects of the current health effects evidence.

• Children are exposed to ambient Pb via inhalation and ingestion, with Pb that is taken into the body absorbed through the lungs and through the gastrointestinal tract. Studies on Pb uptake, elimination, and distribution show that Pb is absorbed into peripheral tissues in adults within a few days (USEPA 1986a; USEPA 1990b, p. IV–2). Absorption of Pb from the gastrointestinal tract appears to be greater and faster in children as compared to adults (CD, Section 4.2.1). Once absorbed, it is quickly distributed from plasma to red blood cells and throughout the body.

• 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).

• Blood Pb levels, including levels of the toxicologically active fraction, respond quickly to increased Pb exposure, such that an abrupt increase in Pb uptake rapidly changes blood Pb levels. The associated time to reach a new quasi-steady state with the total body burden after such an occurrence is projected to be approximately 75 to 100 days (CD, p. 4–27).

• The elimination half-life, which describes the time for blood Pb levels to stabilize after a reduction in exposure, for the dominant phase for blood Pb responses to changes in exposure is on the order of 20 to 30 days for adults (CD, p. 4–25). Blood elimination half-lives are influenced by contributions from bone. Given the tighter coupling in children of bone stores with blood levels, children's blood Pb is expected to respond more quickly than adults (CD, pp. 4–20 and 4–27).

• Data from NHANES II and an analysis of the temporal relationship between gasoline consumption data and blood lead data generally support the inference of a prompt response of children's blood Pb levels to changes in exposure. Children's blood Pb levels and the number of children with elevated blood Pb levels appear to respond to monthly variations in Pb emissions from Pb in gasoline (EPA,

1986a, p. 11–39; Rabinowitz and Needleman, 1983; Schwartz and Pitcher, 1989; USEPA, 1990b).

• The evidence with regard to sensitive neurological effects is limited in what it indicates regarding the specific duration of exposure associated with effect, although it indicates both the sensitivity of the first 3 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). The animal evidence supports our understanding of periods of development with increased vulnerability to specific types of effect (CD, Section 5.3), and indicates a potential importance of exposures on the order of months.

• Evidence of a differing sensitivity of the immune system to Pb across and within different periods of life stages indicates a potential importance of exposures as short as weeks to months duration. For example, the animal evidence suggests that the gestation period is the most sensitive life stage followed by early neonatal stage, and within these life stages, critical windows of vulnerability are likely to exist (CD, Section 5.9 and p. 5–245).

Evidence described in the Criteria Document and the risk assessment indicate that ingestion of dust can be a predominant exposure pathway for young children to air-related Pb, and that there is a strong association between indoor dust Pb levels and children's blood Pb levels. As stated in the Criteria Document, "given the large amount of time people spend indoors, exposure to Pb in dusts and indoor air can be significant" (CD, p. 3–27). The Criteria Document further describes studies that evaluated the influence of dust Pb exposure on children's blood Pb: "Using a structural equation model, Lanphear and Roghmann (1997) also found the exposure pathway most influential on blood Pb was interior dust Pb loading, directly or through its influence on hand Pb. Both soil and paint Pb influenced interior dust Pb; with the influence of paint Pb greater than that of soil Pb. Interior dust Pb loading also showed the strongest influence on blood Pb in a pooled multivariate regression analysis (Lanphear *et al.*, 1998)." (CD, p. 4–134). Further, a recent study of dustfall near an open window in New York City indicates the potential for a relatively rapid response of indoor dust Pb loading to ambient airborne Pb, on the order of weeks (CD, p. 3–28; Caravanos *et al.*, 2006a).

We note that the health effects evidence identifies varying length

durations in exposure that may be relevant and important. In light of uncertainties in aspects such as response times of children's exposure to airborne Pb, we recognize, as in the past, that this evidence provides a basis for consideration of both calendar quarter and calendar month as averaging times.

In considering averaging time and form, EPA has combined the current quarterly averaging time with the current not-to-be exceeded (maximum) form and has 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 afford. We also note that, as discussed below, the second maximum monthly form provides a roughly comparable degree of protection on a broad national scale.

In this consideration of averaging time and form, EPA has taken into account analyses using air quality data for 2003–2005 that are presented in the Staff Paper (chapter 2). These analyses consider both a period of three calendar years and a period of one calendar year (with the form of the current standard being the maximum quarterly mean). These analyses indicate that, with regard to either single-year or 3-year statistics for the 2003–2005 dataset, a second maximum monthly mean yields very similar, although just slightly greater, numbers of sites exceeding various alternative levels as a maximum quarterly mean, with both yielding fewer exceedances than a maximum monthly mean.[139] That is, these two averaging time and form combinations resulted in roughly the same number of areas that would not attain a standard at any given level on a broad national scale, suggesting roughly comparable public health protection. However, the relative protection provided by these two forms may differ from area to area. For example, some of the areas meeting a maximum quarterly mean standard over the 2003–2005 period at a given level did not meet a second maximum monthly mean standard at the same level because there were at least two months with high monthly concentrations which were averaged with a lower concentration month in the same quarter. On the other hand,

[138] 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).

[139] For example, 49 sites (of 189) exceed a standard level of 0.10 μg/m³ based on a form of maximum quarterly mean while 54 sites exceed based on a form of second maximum monthly mean. Further, 25 sites exceed a standard level of 0.30 μg/m³ based on a form of maximum quarterly mean while 29 sites exceed based on a form of second maximum monthly mean (Staff Paper, Table 2–6).

theoretically it is possible for an area to meet a given standard level with a second maximum monthly mean averaging time and form and not meet it for a maximum quarterly mean (e.g., the second highest monthly average may be below the standard level while the quarterly average may exceed it). Moreover, control programs to reduce quarterly mean concentrations may not have the same protective effect as control programs aimed at reducing concentrations in every individual month. 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, it is difficult to more quantitatively compare the protectiveness of the quarterly mean versus the second maximum monthly mean approaches.

In their advice to the Agency in this review, CASAC has recommended that consideration be given to changing from a calendar quarter to a monthly averaging time (Henderson, 2007a, 2007b, 2008). In making that recommendation, CASAC emphasizes support from studies that suggest that blood Pb concentrations respond at shorter time scales than would be captured completely by quarterly values, as indicated by their description of their recommendation for adoption of a monthly averaging time as ''more protective of human health in light of the response of blood lead concentrations that occur at sub-quarterly time scales'' (Henderson, 2007a). 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 and form in the ANPR, the majority concurred with the CASAC recommendation for a revision of the averaging time to a calendar month.

The 1990 Staff Paper and the Staff Paper for this review both recommended that the Administrator consider specifying, in the form of the NAAQS, that compliance with the NAAQS will be evaluated over a 3-year period. The Administrator has considered this recommendation and is proposing to adopt it. In the 3-year approach, a monitor would be considered to be in violation of the NAAQS as of a certain date if in any of the three previous calendar years with

sufficiently complete data (as explained in detail in section IV below), the value of the selected form of the indicator (e.g., second maximum monthly average or maximum quarterly average) exceeded the level of the NAAQS. 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 form and level of the standard being violated. Many types of Pb sources have variable emissions from day-to-day and year-to-year due to market conditions for their products and/or weather variations that can affect the generation of fugitive dust from contaminated roadways and grounds. In addition, variations in wind patterns from year to year can cause a near-source Pb monitor to be exposed to high concentrations on more days in one year than in another, even if source emissions are constant, especially if it operates on only some days. Thus, it is possible for a monitor to indicate a violation of a hypothetical form and level in one period but not in another, even if no permanent controls have been applied at nearby source(s). Analysis of historical Pb air concentration data has confirmed that this pattern of fluctuating monitoring results can happen at the levels and forms being proposed. It would potentially reduce the public health protection afforded by the standard if areas fluctuated in and out of formal 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. 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/maintenance.

In considering averaging time and form for the standard, the Administrator has 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. The Administrator recognizes that there is support in the evidence for a monthly averaging time 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.[140] The Administrator also recognizes 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 concludes that this information provides support for an averaging time no longer than a calendar quarter. Further, the Administrator recognizes that if substantial weight is given to the evidence of even shorter times for response of dust Pb, blood Pb, and associated effects to airborne Pb, a monthly averaging time may be appropriate. Accordingly, the Administrator is proposing two options with regard to the form and averaging time for the standard, and with both he proposes making the time period evaluated in considering attainment be 3 years. One option is to retain the current not-to-be-exceeded form with an averaging time of a calendar quarter, such that the form would be maximum quarterly average across a 3-year span. The second option is to revise the averaging time to a calendar month and the form to be the second highest monthly average across a 3-year span. Based on the considerations discussed above, EPA requests comment on whether a level for a NAAQS with a monthly averaging time and a second-highest monthly average form should be based on an adjustment to a higher level than the level for a NAAQS with a quarterly averaging time and a not-to-be-exceeded form, and, if so, on the magnitude of the adjustment that would be appropriate.

3. Level for a Pb NAAQS With a Pb-TSP Indicator

With regard to level of the standard, for a standard using a Pb-TSP indicator, we first discuss evidence-based and exposure/risk-based considerations, including considerations and

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[140] The 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 Neurobehavioral 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)

conclusions of the Staff Paper, in sections II.E.3.a and II.E.3.b below. This is followed by a summary of CASAC advice and recommendations and public comments (section II.E.3.c) and the Administrator's proposed conclusions (section II.E.3.d). In addition, we discuss considerations and solicit comment with regard to a level of a standard using a Pb-PM$_{10}$ indicator in section II.E.4 below.

a. Evidence-Based Considerations

As a general matter, 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.[141] In addition, exposure to Pb comes from various media, only some of which are air-related. This presents a more complex situation than does evidence of associations between occurrences of health effects and ambient air concentrations of an air pollutant, such as is the case for particulate matter and ozone. 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 of blood Pb with neurocognitive decrement, with greater risk of decrement-associated changes in blood Pb at the lower levels of blood Pb in the exposed population (Section 3.3.7; 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 this large body of epidemiological studies. Unlike the recent review of the NAAQS for ozone, there are no clinical studies useful for informing a determination of the appropriate level for a standard.[142] The discussion 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.

In considering the evidence with regard to selection of the level of the standard, the Agency has considered the same evidence-based frameworks discussed above in section II.D.2.a on the adequacy of the current standard. That is, the Staff Paper considered how to apply an adapted 1978 framework to the much expanded body of evidence that is now available, and the Agency has further considered this evidence in the context of the air-related IQ loss evidence-based framework that builds on a recommendation by the CASAC Pb Panel. These evidence-based approaches are discussed below in considering the appropriate standard levels to propose.

As noted in section II.D.2.a above, this review focuses on young children as a key sensitive population for Pb exposures. In this sensitive population, the current evidence demonstrates the occurrence of health effects, including neurological effects, associated with blood Pb levels extending well below 10 µg/dL (CD, sections 6.2, 8.4 and 8.5). As further described in section II.D.2.a above, some studies indicate Pb effects on intellectual attainment of children for which population mean blood Pb levels in the analysis ranged from approximately 2 to 8 µg/dL (CD, Sections 6.2, 8.4.2 and 8.4.2.6). Further, as noted above, the current evidence does not indicate a threshold for the more sensitive health endpoints such as neurological effects in children (CD, pp. 5–71 to 5–74 and Section 6.2.13).[143]

As when the standard was set in 1978, there remain today contributions to blood Pb levels from nonair sources. As discussed above (section II.D.2), current evidence is limited with regard to estimates of the aggregate reduction since 1978 of all nonair sources to blood Pb and with regard to an estimate of current nonair blood Pb levels (discussed more fully in sections II.A.4) In recognition of temporal reductions in nonair sources discussed in section II.A.4 and in the context of estimates pertinent to an application of the 1978 framework, the CASAC Pb Panel recommended consideration of 1.0 to 1.4 µg/dL or lower as an estimate of the nonair component of blood Pb pertinent to average blood Pb levels in children (as described in section II.A.4 above;

Henderson, 2007a). The Staff Paper considered this range of 1.0 to 1.4 µg/dL for the nonair component of blood Pb in its application of the adapted 1978 evidence-based framework.

As discussed in section II.B.1.c, the current evidence in conjunction with the results and observations drawn from the exposure assessment support a focus on air-to-blood ratios for children in the range of 1:3 to 1:7, based on consideration of both inhalation and ingestion exposure pathways and on the lower air and blood Pb levels pertinent to this review. In considerations here, we have described the value of 1:5 as falling somewhat central within the range supported by the evidence.

i. Evidence-Based Framework Considered in the Staff Paper

Recommendations in the Staff Paper on standard levels were based upon an approach that built upon and adapted the general approach used by EPA in setting the standard in 1978. In adapting this approach to the currently available information, the Staff Paper recognized the more extensive and stronger body of evidence now available on a broader range of health effects associated with exposure to Pb. For example, EPA recognizes that today ''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). This is in contrast to the situation in 1978 when the Agency judged that the maximum safe individual and geometric mean blood Pb levels for a population of young children were 30 µg/dL and 15 µg/dL, respectively.[144]

In the Staff Paper application of an adapted 1978 framework, the focus shifted away from identifying a safe blood Pb level for an individual child (and then determining an ambient air level that would keep a very high percentage of children at or below that safe level), because information was no longer available to identify such a level. Rather, the Staff Paper approach focused on identifying an appropriate population mean blood Pb level, and then identifying an ambient air level that would keep the mean blood Pb levels of children exposed at that air level below the target population mean blood Pb level. Based on the review of

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[141] 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).

[142] See, e.g., 72 FR 37878–9 (July 11, 2007) (Ozone NAAQS Notice of Proposed Rulemaking).

[143] This differs from the Agency's recognition in the 1978 rulemaking of a threshold of 40 µg/dL blood Pb for an individual child for effects of Pb considered clearly adverse to health at that time, i.e., impairment of heme synthesis and other effects which result in anemia.

[144] More specifically, when the standard was set in 1978, the Agency stated that the population mean, measured as the geometric mean, must be 15 µg/dL in order to ensure that 99.5 percent of children in the United States would have a blood Pb level below 30 µg/dL, which was identified as the maximum safe blood Pb level for individual children based on the information available at that time (43 FR 46247–46252).

the evidence, the Staff Paper approach substituted a level of 2 µg/dL for the target population geometric mean blood Pb of 15 µg/dL used in 1978. In the absence of a demonstrated safe level, at either an individual or a population level, the Staff Paper used 2 µg/dL as representative of the lowest population mean level for which there is evidence of a statistically significant association between blood lead levels and health effects (e.g., CD, p. E–9; Lanphear *et al.*, 2000).

This approach does not evaluate the magnitude or degree of health effects occurring across the population at that mean blood lead level. In this adaptation of the 1978 approach the focus is solely on the existence of a relationship between blood lead levels and neurocognitive effects. The approach takes as the public health goal the identification of an ambient air lead level that can be expected to keep the mean blood lead level of an exposed population of children at or below the lowest level at which a statistically significant association has been demonstrated between blood lead level and neurocognitive effects.[145]

Starting with a target population geometric mean blood lead level of 2 µg/dL for the population of exposed children, then subtracting 1 to 1.4 µg/dL for the nonair component of blood Pb, yields 0.6 to 1 µg/dL as a target for the geometric mean air contribution to blood Pb. The adapted 1978 approach divides the air-related target by 5, an air-to-blood ratio somewhat central within the range of air Pb to blood Pb ratios generally supported by the currently available evidence. This resulted in a potential standard level of 0.1 to 0.2 µg/m³.

[145] There are some similarities between this approach and the approach employed in determining the levels for the daily and annual PM standards in the latest PM review, where EPA determined an ambient PM level based on the ambient levels in the epidemiology studies that found statistically significant associations between changes in ambient PM levels and changes in occurrences of health effects. See 71 FR 61144 (October 17, 2006). However, there are several important differences in this adaptation to the 1978 approach for lead. For example, the health effects evaluated in the PM epidemiological studies were clearly adverse health effects, ranging from hospital admissions to premature mortality. In addition, the studies looked directly at the association between ambient level and occurrences of health effects. Here the epidemiology studies look at the association between blood lead level and neurocognitive effect, and there is an additional step to link the blood lead level to air-related lead. In addition, at a population level there is a less clear delineation of when the neurocognitive effect is adverse to public health. This is discussed below in this section with respect to the impact on public health of a shift in the mean IQ of a population of children.

The Staff Paper conclusions on level for the primary Pb standard built on the staff's conclusion that the overall body of evidence clearly calls into question the adequacy of the current standard with regard to health protection afforded to at-risk populations. Based on consideration of the health effects evidence, as described above, the Staff Paper concluded that it is reasonable to consider a range for the level of the standard, for which the upper part is represented by 0.1 to 0.2 µg/m³.

ii. Air-related IQ Loss Evidence-Based Framework

As mentioned above, in analyses subsequent to the Staff Paper and ANPR, the Agency has primarily considered the evidence in the context of an alternative evidence-based framework, referred to as the air-related IQ loss framework. This framework focuses on the contribution of air-related Pb to neurocognitive effects, 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. This framework does not focus on overall blood lead levels or on nonair contribution to blood lead levels. While this avoids some of the limitations noted above with the adapted 1978 approach, EPA recognizes that looking at air-related Pb in isolation from other sources of Pb could be considered a limitation for this framework. The different limitations of each of these frameworks derive from the limitations in the underlying body of evidence available for this review.

In this air-related IQ loss evidence-based framework, we have drawn 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. We have drawn 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 air-related IQ loss framework focuses on selecting a standard 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, taking into consideration such factors as the uncertainties inherent in such estimates. In addition to this judgment by the Administrator, this framework is also based on specifying an air-to-blood ratio (also used in the

adapted 1978 framework) and a C–R function(s) for population mean IQ response associated with blood Pb level.

In considering the evidence with regard to C–R functions, and in recognition of the finding in the evidence of a steeper slope at lower blood Pb levels (i.e., the nonlinear relationship), we have identified two sets of C–R functions (discussed more fully above in section II.B.2.b). The first set focuses on C–R functions reflecting population mean concurrent blood Pb levels of approximately 3 µg/dL.[146] The second set (CD, pp. 8–78 to 8–80) considers 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 µg/dL (see Table 1).[147]

As discussed above in section II.B.2.b, the C–R functions from analyses involving the lower mean blood Pb levels, that are closer to current mean blood Pb levels in U.S. children, provide slopes of IQ loss with increasing blood Pb that range from −1.71 to −2.94 IQ points per µg/dL blood Pb. These include C–R function from Lanphear *et al.* (2005) recommended for consideration by CASAC, in light of the current blood Pb levels of U.S. children (Henderson, 2008),[148] and also the C–R function

[146] As noted above in section II.B.2.b, the log-linear C–R function with low-exposure linearization (LLL) used in the quantitative risk assessment, based on log-linear model in Lanphear *et al* 2005), has a slope that falls intermediate within this first set of functions at low blood Pb levels. The log-linear model by Lanphear *et al* (2005) is derived from the pooled International dataset for which the median blood Pb is 9.7 µg/dL.

[147] For context, it is noted that the 2001–2004 median blood level for children aged 1–5 of all races and ethnic groups is 1.6 µg/dL, the median for the subset living below the poverty level is 2.3 µg/dL and 90th percentile values for these two groups are 4.0 µg/dL and 5.4 µg/dL, respectively. Similarly, the 2001–2004 median blood level for black, non-hispanic children aged 1–5 is 2.5 µg/dL, while the median for the subset of that group living below the poverty level is 2.9 µg/dL and the median level for the subset living in a household with income more than 200% of the poverty level is 1.9 µg/dL. Associated 90th percentile values for 2001–2004 are 6.4 µg/dL (for black, non-hispanic children aged 1–5), 7.7 µg/dL (for the subset of that group living below the poverty level) and 4.1 µg/dL (for the subset living in a household with income more than 200% of the poverty level). (*http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm*—then click on ''Download a universal spreadsheet file of the Body Burdens data tables'').

[148] In their September 2007 letter, the CASAC Pb Panel ''recommends using the two-piece linear function for relating IQ alterations to current blood lead levels with a slope change or ''hinge'' point closer to 7.5 µg/dL than 10.82 µg/dL as used by EPA staff in the second draft exposure/risk assessments document. The higher value used by staff underestimates risk at lower blood Pb levels, where most of the population will be located.

given greatest weight in the risk assessment (discussed above in section II.C.2.b), the loglinear function with low-exposure linearization (the LLL function). The function yielding the lowest slope in this range is from the analysis by Tellez-Rojo and others (2006) of very young children with blood Pb levels below 5 µg/dL, with a group mean blood Pb level of 2.9 µg/dL. The function yielding the highest slope in this range is from the analysis by Lanphear and others (2005) of children whose blood Pb levels never exceeded 7.5 µg/dL, with a group mean blood Pb level of 3.24 µg/dL. The LLL function falls within the range of the other two functions at lower blood Pb levels, with an average slope of − 2.29 IQ points per µg/dL across blood Pb levels extending below 2 µg/dL.

The second set of C–R functions discussed in section II.B.2.b is drawn from a larger group of studies, although these studies include groups of children with higher blood Pb levels (CD, pp. 8– 78 to 8–80) such that the population mean levels for these studies include population mean blood Pb levels ranging from a mean of 3.3 up to a median of 9.7 µg/dL (see Table 1). This second set of C–R functions is represented by a median of − 0.9 IQ points per µg/dL blood Pb (CD, p. 8– 80).[149]

In applying the air-related IQ loss evidence-based framework, as with the adapted 1978 framework, we recognize uncertainty in our estimates for the two input parameters (air-to-blood ratio and C–R function slope). Accordingly, in associating various standard levels with the estimated magnitudes of air-related mean IQ loss that would likely be prevented by keeping exposed populations below such standard levels,

we have considered combinations of parameter estimates that are potentially supportable within this framework. With regard to the C–R functions we have drawn estimates from both sets of functions. For the first set of C–R functions, we have relied on the upper and lower-end values to provide a range at lower blood Pb levels, and have focused on the LLL function for blood Pb levels above approximately 2.5 to 3.0 µg/dL, as shown in Table 7.[150] From the second set of C–R functions, we have relied on the median estimate across the range of blood Pb levels considered. For air-to-blood ratios, we have focused on the estimate of 1:5 as above, and also provided IQ loss estimates using higher and lower estimates of air-to-blood ratio (i.e., 1:3 and 1:7) within the range supported by the evidence. These estimates are presented in Table 7 below.

TABLE 7.—ESTIMATES OF AIR-RELATED POPULATION MEAN IQ LOSS FOR CHILDREN EXPOSED AT THE LEVEL OF THE STANDARD

| Potential level for standard (µg/m³) | Air-related population mean IQ loss (points) for children exposed at level of the standard | | | | | | | | | |
| | Air-to-blood ratio of 1:3 | | Air-to-blood ratio of 1:4 | | Air-to-blood ratio of 1:5 | | Air-to-blood ratio of 1:6 | | Air-to-blood ratio of 1:7 | |
	1st group of C–R functions	2nd group of C–R functions	1st group of C–R functions	2nd group of C–R functions	1st group of C–R functions	2nd group of C–R functions	1st group of C–R functions	2nd group of C–R functions	1st group of C–R functions	2nd group of C–R functions
0.50	*2.9–3.1	1.4	*3.5–3.8	1.8	*4.1–4.3	2.3	*4.6–4.8	2.7	*5.0–5.3	3.2
0.40	*2.4–2.6	1.1	*3.0–3.2	1.4	*3.5–3.8	1.8	*4.0–4.2	2.2	*4.4–4.6	2.5
0.30	1.5–2.6	0.8	*2.4–2.6	1.1	*2.9–3.1	1.4	*3.3–3.5	1.6	*3.6–3.9	1.9
0.20	1.0–1.8	0.5	1.4–2.4	0.7	1.7–2.9	0.9	*2.4–2.6	1.1	*2.7–3.0	1.3
0.10	0.5–0.9	0.3	0.7–1.2	0.4	0.9–1.5	0.5	1.0–1.8	0.5	1.2–2.1	0.6
0.05	0.3–0.4	0.14	0.3–0.6	0.18	0.4–0.7	0.2	0.5–0.9	0.27	0.6–1.0	0.3
0.02	0.1–0.2	0.05	0.1–0.2	0.07	0.2–0.3	0.09	0.2–0.4	0.1	0.2–0.4	0.1

*These estimates were derived using only the nonlinear C–R function from the risk assessment which, given its nonlinearity, EPA considers to better assess risk across the range that includes extending into these higher standard levels (and the associated higher blood Pb levels). That is, the upper and lower values presented in the asterisked cells are both derived using the LLL function, as described in the text and associated footnote above, rather than using the two linear functions of − 1.71 from Tellez-Rojo, 2005 (<5 µg/dL subgroup) and − 2.94 from Lanphear, 2005 (<7.5 µg/dL peak blood Pb subgroup) as is the case in the cells without asterisks.

Using the air-to-blood ratio of 1:5 with the range of slopes from the first set of C–R functions indicates an air-related mean IQ loss estimate of 0.9 to 1.5 points for a population of children exposed at the standard level of 0.10 µg/ m³. Similarly, the air-related mean IQ loss estimate for a standard level of 0.20 µg/m³ is 1.7 to 2.9 points. Using the air-to-blood ratio of 1:5 and the slope from

the second set of C–R functions (from blood Pb levels extending up to 10 µg/ dL) in the calculation indicates an air-related mean IQ loss of 0.5 points for a population of children exposed at the standard level of 0.10 µg/m³; the corresponding air-related mean IQ loss estimate for a standard level of 0.20 µg/ m³ is 0.9 points. Using the 1:5 air-to-blood ratio with first set of C–R

functions indicates an air-related mean IQ loss estimate of approximately 3 points for a population of children exposed at the standard level of 0.30 µg/ m³. Using the slope from the second set of C–R functions indicates an air-related mean IQ loss estimate of 1.4 points for a population of children exposed at the standard level of 0.30 µg/m³.

Epidemiologic data indicate that the slope of the line below 7.5 µg/dL is approximately minus three (− 3) IQ decrements per 1 µg/dL blood lead and the vast majority of children in the U.S. have maximal baseline Pb blood levels below 7.5 µg/dL (Lanphear *et al.*, EHP 2005; MMWR 2005). On a population level, the mean increase in blood lead concentration from airborne lead would generally be up to, but not exceeding, a blood lead concentration of 7.5 µg/ dL. This approach should also account for sensitive subpopulations of children.'' In in their January 2008 letter, the Panel also points to several other studies ''confirming that the relationship of lead exposure is non-linear and per-sists at blood lead levels considerably lower than 5 µg/dL (Lanphear, 2000; Wasserman, 2003; Kordas, 2006; Tellez-Rojo, 2006). In particular, Tellez-Rojo and co-workers

reported that the slope of the association between 24-month blood lead and the 24-month Mental Development Index (MDI) for 294 children who had peak blood lead levels below 5 µg/dL was negative (− 1.7 points for each 1 µg/dL increase in blood lead concentration, p=0.01). Collectively, these studies indicate that there is sufficient evidence to support the use of the dose-response relationship from the pooled analysis at blood lead levels < 5 µg/dL (Lanphear, 2005), as described in the Final Lead Staff Paper and previously recommended by CASAC.''

[149] As noted above (in section II.B.2.b), this slope is similar to the slope for the below 10 µg/dL piece of the piecewise model used in the RRP rule economics analysis.

[150] We derived estimates of air-related IQ loss using the LLL (nonlinear) function giving equal weight to all contributions of Pb to total blood Pb as illustrated by the following example. For a level of 0.30 µg/m³, and an air-to-blood ratio of 1:5, the resultant estimate of air-related blood Pb is 1.5 µg/ dL. Using estimates for nonair blood Pb levels of 1 and 1.4 µg/dL, the estimates of total blood Pb are 2.5 and 2.9 µg/dL. The corresponding total Pb-related IQ loss estimates based on the LLL function are 5.2 and 5.6 points IQ loss. These estimates are then multiplied by the fraction of total Pb that is air-related (*i.e.*, 1.5/2.5 and 1.5/2.9) to derive the estimated range of air-related IQ loss (2.9–3.1 points).

As mentioned above, we recognize uncertainty in the air-to-blood values, and have accordingly also considered estimates of air-to-blood ratio that are lower and higher than the 1:5 value used above. Accordingly, we note that using a lower air-to-blood ratio, such as 1:3 (low end of range from evidence) generally results in lower air-related IQ loss estimates with either set of C–R functions (approximately 40% lower than those using a ratio of 1:5). Similarly, use of a higher air-to-blood ratio, such as 1:7, yields higher air-related mean IQ loss estimates with either set of C–R functions (approximately 40% higher than those using a ratio of 1:5).

In applying this framework, we have also considered higher standard levels, above 0.30 μg/m³ up to the highest alternative level included in the risk assessment (e.g., up to 0.50 μg/m³). Using the 1:5 air-to-blood ratio with the first set of C–R functions, the air-related mean IQ loss estimate for a standard level of 0.50 μg/m³ is approximately 4 points. Using the slope from the second set of C–R functions indicates an air-related mean IQ loss estimate of 2.3 points for a population of children exposed at the standard level of 0.50 μg/m³. Using the 1:3 air-to-blood ratio with the first set of C–R functions indicates an air-related mean IQ loss estimate of approximately 3 points for a population of children exposed at the standard level of 0.50 μg/m³. Using the 1:3 air-to-blood ratio and the slope for the second set of C–R functions indicates an air-related mean IQ loss estimate of 1.4 points for a population of children exposed at the standard level of 0.50 μg/m³.

Further, we have also considered lower standard levels, down to the lowest alternative levels included in the risk assessment (e.g., 0.05 to 0.02 μg/m³). For example, across both sets of C–R functions and the range of air-to-blood ratios considered above (1:3 to 1:7), a standard level of 0.05 μg/m³ indicates an air-related mean IQ loss of approximately 0.1 to 1 point. The estimates for either set of C–R functions are approximately 50% lower at the standard level of 0.02 μg/m³.

b. Exposure- and Risk-Based Considerations

To inform judgments about a range of levels for the standard that could provide an appropriate degree of public health protection, in addition to considering the health effects evidence, EPA also considered the quantitative estimates of exposure and health risks attributable to air-related Pb upon meeting specific alternative levels of alternative Pb standards and the uncertainties in the estimated exposures and risks, as discussed above in Section III.B. As discussed above, the risk assessment conducted by EPA is based on exposures that have been estimated for children of less than 7 years of age in several case studies. The assessment estimated the risk of adverse neurocognitive effects in terms of IQ loss associated with total and air-related Pb exposures, including incidence of different magnitudes of IQ loss in the three location-specific case studies. In so doing, EPA is mindful of the important uncertainties and limitations that are associated with the exposure and risk assessments. For example, with regard to the risk assessment important uncertainties include those related to estimation of blood Pb C–R functions, particularly for blood Pb concentrations at and below the lower end of those represented in the epidemiological studies characterized in the Criteria Document.

EPA also recognizes important limitations in the design of, and data and methods employed in, the exposure and risk analyses. For example, the available monitoring data for Pb relied upon for estimating current conditions for the urban case studies are quite limited, in that monitors are not located near many of the larger known Pb sources, which results in potential underestimation of current conditions, and there is uncertainty about the proximity of existing monitors to other Pb sources potentially influencing exposures, such as old urban roadways and areas where housing with Pb paint has been demolished or has undergone extensive exterior renovation. All of these limitations raise uncertainty as to whether these data adequately capture the magnitude of ambient Pb concentrations to which the target population is currently exposed. Additionally, EPA recognizes that there is not sufficient information available to evaluate all relevant sensitive groups (e.g., adults with chronic kidney disease) or all Pb-related health effects (e.g., neurological effects other than IQ loss, immune system effects, adult cardiovascular or renal effects), and the scope of our analyses was generally limited to estimating exposures and risks in case studies intended to illustrate a variety of Pb exposure situations across the U.S., with three of them focused on specific areas in three cities. As noted above, however, coordinated intensive efforts over the last 20 years have yielded a substantial decline in blood Pb levels in the United States. Recent NHANES data (2003–2004) yield blood lead level estimates for children age 1 to 5 years of 1.6 μg/dL (median) and 3.9 μg/dL (90th percentile). These median and 90th percentile national-level data are lower than modeled values generated for the three location-specific urban case studies current conditions scenarios (described in section II.C.3.a above). As noted in section II.C.3.a, however, the urban case studies and the NHANES study are likely to differ with regard to factors related to Pb exposure, including ambient air levels (e.g., the national median ambient air Pb concentrations are generally lower than those in the location-specific case studies).

As described in section II.C.2.e, we also recognize limitations in our ability to characterize the contribution of air-related Pb to total Pb exposure and Pb-related health risk. As a result, we have approximated estimates for the air-related pathways, bounded on the low end by exposure/risk estimated for the ''recent air'' category and on the upper end by the exposure/risk estimated for the ''recent air'' plus ''past air'' categories.[151]

We generally focus in this discussion on risk estimates derived using the LLL (log-linear with low exposure linearization) C–R function. Further, in considering the risk estimates in light of IQ loss estimates (described in section II.E.3.a) of the air-related IQ loss evidence-based framework, we focus here on risk estimates for the general urban and primary Pb smelter subarea case studies as these cases studies generally represent population exposures for more highly air-pathway exposed children residing in small neighborhoods or lozalized residential areas with air concentrations nearer the standard level being evaluated than do 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.

In considering the results of the risk assessment for the alternative standard levels assessed, we note that the risk estimates are roughly consistent with and generally supportive of the evidence-based mean air-related IQ loss estimates described above (section II.E.3.a). For example, at a standard level of 0.20 μg/m³, the evidence-based approach indicates estimates of mean air-related IQ loss ranging from less than

[151] As noted in section II.C.2.e above, the recent air category does not include a variety of air-related categories (including some associated with air deposition to outdoor surfaces and diet) and both the recent air and past categories may include some Pb in soil or dust from the historical use of Pb in paint.

1 to approximately 3 points IQ loss, while the median air-related risk estimates for this level in the general urban case study are represented by a lower bound near 1 point IQ loss and an upper bound near 3 points IQ loss. The corresponding upper bound air-related IQ loss estimate for the primary Pb smelter case study subarea is 3.7 points. Alternatively, at a standard level of 0.50 μg/m³, the evidence-based approach indicates estimates of mean air-related IQ loss ranging from approximately 1.5 points to greater than 4 points, while the median air-related risk estimates for this level for the general urban case study are represented by a lower bound near 2 points IQ loss and an upper bound just below 4 points IQ loss (section II.C.3.b). The corresponding upper bound air-related IQ loss estimate for the primary Pb smelter case study subarea is 4.5 points. Also, while the risk assessment did not specifically assess the standard levels of 0.10 and 0.30 μg/m³, we note that estimates for these levels based on interpolation from the estimates described above are also roughly consistent with and generally supportive of the evidence-based mean air-related IQ loss estimates described in section II.E.3.a above (Murphy and Pekar, 2008).

As mentioned above (section II.E.3.a), the Staff Paper conclusions on level for the primary Pb standard built on staff 's conclusion that the overall body of evidence clearly calls into question the adequacy of the current standard with regard to health protection afforded to at-risk populations. Drawing from both consideration of the evidence and consideration of the quantitative risk and exposure information (described in section II.E.3.b), staff concluded that the available information provides strong support for consideration of a range of standard levels that are appreciably below the level of the current standard in order to provide increased public health protection for these populations, with support for this conclusion. With regard to the risk estimates, the Staff Paper recognized that, to the extent one places weight on risk estimates for the lower standard levels, those estimates may suggest consideration of a range of levels that extend down to the lowest levels assessed in the risk assessment, 0.02 to 0.05 μg/m³. In summary, the Staff Paper concluded that "a level for the standard set in the upper part of [the staff] recommended range (0.1–0.2 μg/m³, particularly with a monthly averaging time) is well supported by the evidence and also supported by estimates of risk associated with policy-relevant Pb that overlap with the range

of IQ loss that may reasonably be judged to be highly significant from a public health perspective, and is judged to be so by CASAC" (USEPA, 2007c). Further, the Staff Paper concluded that "a standard set in the lower part of the range would be more precautionary and would place weight on the more highly uncertain range of estimates from the risk assessment" (USEPA, 2007c).

c. CASAC Advice and Recommendations and Public Comments

Beyond the evidence- and risk/exposure-based information discussed above, EPA's consideration of the level for the TSP-based standard also takes into account the advice and recommendations of CASAC, based on their review of the Criteria Document, the Staff Paper and the related technical support document, and the ANPR, as well as comments from the public on drafts of the Staff Paper and related technical support document and the ANPR.

In their advice to the Agency during this review CASAC has recognized the importance of both the health effects evidence and the exposure and risk information in selecting the level for the TSP-based standard (Henderson, 2007a, 2007b, 2008). In two separate letters sent prior to publication of the ANPR, CASAC stated that it is the unanimous judgment of the CASAC Lead Panel that the primary NAAQS should be "substantially lowered" to "a level of about 0.2 μg/m³ or less," reflecting their view of the health effects evidence (Henderson, 2007a,b). In their most recent letter, reflecting their review of the ANPR and Staff Paper, the Panel reiterated their earlier judgment, stating that *"[t]he Committee unanimously and fully supports 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 μg/m³ with a monthly averaging time."*

The CASAC Pb Panel also provided advice regarding how the Agency should consider IQ loss estimates derived from the risk assessment in selecting a level for the standard (Henderson, 2007a). The Panel stated that they consider a population loss of 1–2 IQ points to be "highly significant from a public health perspective".

Among the many public comments the Agency has received in this review regarding the level of the standard, the overwhelming majority recommended appreciable reductions in the level, e.g., setting it at 0.2 μg/m³ or less, while only a few recommended that the Agency

make no or only a modest adjustment. Among the comments recommending appreciable reduction, many noted the importance of considering exposures and risks to vulnerable and susceptible populations. Some recognized that blood Pb levels are disproportionately elevated among minority and low-income children, and recommended more explicit consideration of issues of environmental justice. And some comments also noted the need for the standard to provide an adequate margin of safety, indicating that such a need might provide support for consideration of much lower levels. The American Academy of Pediatrics recommended that EPA set the level at 0.2 or lower, and also recommended that EPA consider the approach developed by the State of California Environmental Protection Agency (Cal-EPA) for the purposes of school site assessment, which has at its goal prevention of a rise in blood Pb level that Cal-EPA has predicted to be associated with an incremental increase estimated to decrease IQ by 1 point.

d. Administrator's Proposed Conclusion Concerning Level

For the reasons discussed below, 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 to date, the Administrator proposes to revise the existing primary Pb standard. Specifically, the Administrator proposes 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 μg/m³, 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 discussed below.

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 also solicits comments on whether to proceed instead with alternative levels of a primary Pb-TSP standard within ranges from above 0.30 μg/m³ up to 0.50 μg/m³ and below 0.10 μg/m³. Based on the comments received and the accompanying rationales, the Administrator may adopt other standards within the range of the alternative levels identified above in lieu of the standards he is proposing today. In addition, as discussed below, the Administrator also solicits 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 builds on his proposed conclusion, discussed above in section II.D.4, 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 range from IQ loss, a health outcome that could be quantified in the risk assessment, to health outcomes that could not be directly estimated, including decrements in other neurocognitive functions, other neurological effects and immune system effects, as well as cardiovascular and renal effects in adults. In reaching a proposed decision about the level of the Pb primary standard, the Administrator has considered: the evidence-based considerations from the Criteria Document and the Staff Paper and those based on the air-related IQ loss evidence-based framework discussed above; the results of the exposure and risk assessments discussed 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 is 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 described above in section II.E.3.a.ii. As a general matter, in considering this evidence-based framework, the Administrator 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 discussed above, these complexities include evidence based on blood Pb as the dose metric, exposure pathways that are both air-related and nonair-related, and the absence of any discernible threshold levels in the health effects evidence. Further, the Administrator recognizes 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 this evidence-based framework, including C–R functions and air-to-blood ratios. In addition, 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 neurocognitive effects in sensitive populations, such as IQ loss in children.

The air-related IQ loss evidence-based framework considered by the Administrator focuses on quantitative relationships between air-related Pb and neurocognitive effects (e.g., IQ loss) in children, building on recommendations from CASAC to consider the body of evidence in a more quantitative manner. More specifically, this framework is premised on a public health goal of selecting a 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, taking into consideration uncertainties inherent in such estimates. In addition to this public health policy judgment regarding IQ loss, two other parameters are relevant to this framework—a C–R function for population IQ response associated with blood Pb level and an air-to-blood ratio. Based on the discussion of these parameters in section II.E.3.a above, the Administrator concludes that, in considering alternative standard levels below the level of the current standard, it is appropriate to take into account the same two sets of C–R functions, recognizing uncertainties in the related evidence, as was done in considering the adequacy of the current standard (as discussed above in section II.D). He notes that the first set of C–R functions

reflects the evidence indicative of steeper slopes in relationships between blood Pb and IQ in children, and that the second set of C–R functions reflects relationships with shallower slopes between blood Pb and IQ in children. In addition, the Administrator concludes that it is appropriate to consider various air-to-blood ratios, again recognizing the uncertainties in the relevant evidence. He notes that an air-to-blood ratio of 1:5 is within the reasonable range of values that EPA considers to be generally supported by the available evidence, which includes ratios of 1:3 up to 1:7.

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 notes 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 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, the Administrator proposes 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.

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 above in section II.E.3.a.ii that addresses a broad range of standard levels. In so doing, the Administrator first focused on the estimates associated with the first set of C–R functions in conjunction with the range of air-to-blood ratios considered by EPA in this framework. Specifically, using an air-to-blood ratio of 1:5, the Administrator notes that a standard level of 0.10 µg/m³ would limit the estimated degree of impact on population mean IQ loss from air-related Pb to no more than 1.5 points, the mid-point of the proposed range of protection. Using the full range of air-to-blood ratios considered in this framework (1:3 to 1:7), he notes that a standard set at this level (0.10 µg/m³) would limit the estimated degree of air-

related impact on population mean IQ loss to a range from less than 1 point to around 2 points. Again based on the first set of C–R functions, the Administrator notes that a standard level of 0.20 µg/m³ would also limit the estimated degree of air-related impact on population mean IQ loss to within the proposed range of protection based on using an air-to-blood ratio of 1:3.

In considering the use of the second set of C–R functions in conjunction with the range of air-to-blood ratios considered in this framework (1:3 to 1:7), the Administrator notes for example that a standard set within the range of 0.10 to 0.30 µg/m³ would limit the estimated degree of air-related impact on population mean IQ loss to a range from less than one-half point to just under 2 points. More specifically, based on using an air-to-blood ratio of 1:5 (the approximately central estimate) in conjunction with the second set of C–R functions, the Administrator notes that a standard level of 0.30 µg/m³ would limit the estimated degree of impact on population mean IQ loss from air-related Pb to just under 1.5 points, the mid-point of the proposed range of protection.

Taking these considerations into account, and based on the full range of information presented in Table 7 above on estimates of air-related IQ loss in children over a broad range of alternative standard levels, the Administrator concludes that it is appropriate to propose a range of standard levels, and that a range of levels from 0.10 to 0.30 µg/m³ is consistent with his target for protection from air-related IQ loss in children. In recognition of the uncertainties in these key parameters, the Administrator believes that the selection of a standard level from within this range is conditional on judgments as to the most appropriate parameter values to use in the context of this evidence-based framework. For example, he notes 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 solicits comment on the

appropriate values to use for these key parameters in the context of this evidence-based framework, reflecting that his proposal 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 µg/m³ is conditional on judgments as to the appropriate values of key parameters to use in this context.

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 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 discussed above in sections II.C and II.E.3.b, for purposes of evaluating potential new standards, the Administrator places less weight on the risk estimates than on the evidence-based assessments. Nonetheless, the Administrator finds that the risk estimates are roughly consistent with and generally supportive of the evidence-based air-related IQ loss estimates described above, as discussed above in section II.E.3.b. This lends support to the proposed range based on this evidence-based framework.

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 judgments 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 this time, as well as the recommendations of CASAC and public comments, the Administrator is proposing that a standard level within the range of 0.10 to 0.30 µg/m³ would be requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety. He also recognizes that selection of a level from within this range is 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 notes that this proposed range encompasses the specific level of 0.20 µg/m³, the upper end of the range recommended by CASAC and by many public commenters. The Administrator

provisionally concludes 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.

Because there is no bright line clearly directing the choice of level within this reasonable range, 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 solicits 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 solicit 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 solicits 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.

For the reasons discussed above, the Administrator proposes 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 µg/m³, conditional on judgments as to the appropriate C–R functions and air-to-blood ratio to use in the context of the air-related IQ loss framework.

The Administrator notes that this framework indicates that for standard levels above 0.30 µg/m³ up to 0.50 µg/m³, 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 proposes 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 µg/m³ would be greater than what is requisite to protect

public health with an adequate margin of safety.

In addition, the Administrator notes that for standard levels below 0.10 μg/m³, 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 proposes to conclude that the degree of public health protection that standards below 0.10 μg/m³ would likely afford would be greater than what is requisite to protect public health with an adequate margin of safety.

Having reached this proposed decision 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 recognizes 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 recognizes 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 solicits comment on these and other issues.

In particular, the Administrator solicits comment on alternative levels of a primary Pb-TSP standard of above 0.30 μg/m³ up to 0.50 μg/m³. In considering the air-related IQ loss framework and the case when the second set of C–R functions is used in conjunction with the lowest air-to-blood ratio considered in this framework (i.e., 1:3), a standard level as high as 0.50 μg/m³ would still limit the estimated degree of impact on population mean IQ loss from air-related Pb to no more than 1.5 points, the mid-point of the proposed range of protection. Comment is solicited on levels within this range

and the associated rationale for selecting such a level in terms of the appropriate weight to place on relevant parameter values that may extend to values outside the ranges of values considered by EPA, or in terms of alternative evidence- or risk-based frameworks that might support standard levels within this range.

In addition, the Administrator solicits comment on alternative levels below 0.10 μg/m³. In considering the evidence-based framework discussed above, a standard level within this range would likely provide a degree of protection in terms of air-related population mean IQ loss that is greater than the proposed range based on the use of any of the relevant parameter values within the ranges considered by EPA. Comment is solicited on levels within this range and the associated rationale for selecting such a level in terms of the appropriate weight to place on relevant parameter values that may extend to values outside of the ranges considered by EPA, or alternative public health policy judgments as to the degree of protection that is warranted, or the appropriate weight to place on the results of the risk assessment.

More broadly, as discussed above, the Administrator recognizes that Pb can be considered a non-threshold pollutant.[152] In recognizing that no threshold has been identified below which there is no risk of harm, EPA's views are consistent with the views of the CDC, the Federal agency that tracks children's blood Pb levels nationally and provides guidance on levels at which medical and environmental case management activities should be implemented (CDC, 2005a; ACCLPP, 2007). In 2005, CDC revised its statement on Preventing Lead Poisoning in Young Children, specifically recognizing the evidence of adverse health effects in children and the data demonstrating that no "safe" threshold for blood Pb had been identified (CDC, 2005a). EPA's views are also consistent with other organizations, including, for example, the American Academy of Pediatrics that recognized in commenting on the ANPR that "[t]here is no known "safe" level of blood lead in children" (AAP, 2008). In addition, the California Environmental Protection Agency, in a recent risk

[152] 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).

assessment report, recognizes that "no safe level has been definitively established" for effects of Pb in children (CalEPA, 2007, p. 1). Given the current state of scientific evidence, which does not resolve the question of whether or not there is a threshold, we recognize that there is no level below which we can say with scientific confidence that there is no risk of harm from exposure to ambient air related lead.

The Administrator also recognizes, as discussed in section I.A above, that 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. In setting primary standards that are "requisite" to provide the this degree of public health protection, the Supreme Court has affirmed that EPA's task is to establish standards that are neither more nor less stringent than necessary for this purpose. The question then becomes how the Agency should reconcile these scientific and legal understandings in reviewing the Pb NAAQS.

As discussed above, EPA is proposing a range of levels for the primary Pb NAAQS, with the range extending down to 0.10 μg/m³. This range reflects the Administrator's proposed conclusion that lower levels would be more than necessary to protect public health with an adequate margin of safety. This proposed conclusion is based in large part on EPA's evaluation of the evidence, recognizing important uncertainties in the scientific evidence and related assessments, and reflects the proposed public heath policy judgment of the Administrator on these issues. As discussed above, these uncertainties stem in part from the complexities of determining the health impact of air-related Pb given the multi-media exposure pathways for exposure to lead and the persistence of Pb in the environment. The major areas of uncertainty include the appropriate air-to-blood ratio; the apportionment of Pb between air-related and nonair Pb; the increasing uncertainty at lower blood Pb levels as to the existence, nature, and degree of health effects; and the uncertainty over the public health significance of smaller and smaller impacts on IQ or other similar neurocognitive metrics from exposure to air-related Pb. In recognition of such uncertainties, EPA is also soliciting comment on a lower range of standard levels below 0.10 μg/m³.

In so doing, EPA fully recognizes that a standard set at the lowest proposed level of 0.10 μg/m³, or any non-zero level, would not be a risk-free standard.

As in numerous prior NAAQS reviews, we recognize that the CAA does not require that EPA set a risk-free standard. Instead, EPA is to recognize and take risk into account, and set a standard that is requisite to protect public health with an adequate margin of safety based on the currently available information. This calls for a public health policy judgment informed by many factors, most notably the nature and severity of the health effects at issue, the size of the population(s) at risk, and the kind and degree of uncertainties involved. After considering all of these factors in this review, the Administrator's proposed judgment is that a standard set below 0.10 μg/m³ would not satisfy this statutory directive.

The Administrator recognizes that the current state of the scientific evidence clearly indicates that health effects from Pb occur at much lower blood Pb levels than we understood in the past, and that the appropriate level for ambient air Pb is much lower than we thought in the past. Further the Administrator expects that, as time goes on, future scientific studies will continue to enhance our understanding of Pb, and anticipates 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. As noted above, this has the potential to raise fundamental questions as to how the Agency can 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. Faced with scientific evidence that could reasonably be interpreted as demonstrating that any ambient Pb level above zero contributes to adverse health effects in at-risk populations, some might conclude that the only standard requisite to protect public health with an adequate margin of safety would be a standard set at zero. While EPA's proposed conclusions on the current scientific evidence and an appropriate standard based on that evidence and on its interpretation of the statute clearly differ from such a view, EPA nonetheless believes that inviting comment in this review on the views described above and the issues raised by such circumstances is appropriate.

More specifically, EPA invites comment on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero. Comments on this question might address issues such as: The level of scientific certainty that would be needed to support such a decision; the level of harm, e.g., severity

of health effect and size of affected population, that would be needed to support such a decision; and whether there are normative or quantitative criteria that could be applied in deciding whether, and if so, when it would be appropriate to set a standard at zero. EPA invites comment on how to reconcile the above issues in this and subsequent NAAQS reviews.

4. Level for a Pb NAAQS with a Pb-PM$_{10}$ Indicator

EPA is requesting comment on the option of revising the indicator for the Pb NAAQS from Pb-TSP to Pb-PM$_{10}$, based on low-volume sample collection as discussed above in section II.E.1 and below in section V.A. In this section, we discuss considerations important to selection of a level for such a Pb-PM$_{10}$-based standard (section II.E.4.a) and CASAC's advice and public comments on this issue (section II.E.4.b). Approaches for adjusting the level of a Pb NAAQS with Pb-TSP indicator for a Pb-PM$_{10}$-based standard, and a range of levels for a Pb-PM$_{10}$-based standard, under consideration and on which EPA is soliciting comment are presented in II.E.4.c.

a. Considerations With Regard to Particles Not Captured by PM$_{10}$

In the course of deciding to propose the Pb-TSP indicator approach as described in section II.E.1 above, EPA has noted the important role of both respirable and non-respirable Pb particles in air-related Pb exposure of concern and the lesser capture of these particles by PM$_{10}$ samplers compared to TSP samplers. We recognize that the health evidence indicates that Pb in all particle size fractions, not just respirable Pb, contributes to Pb in blood and to associated health effects. Further, the quantity of Pb in ambient particles with the potential to deposit (indoors and outdoors, leading to a role in ingestion pathways) is a key contributor to air-related exposure, and these particles include ultra-coarse mode particles that are not captured by PM$_{10}$ samplers (as discussed in section II.E.1 above). In recognition of these considerations, both of the indicator options discussed in this notice recognize the need to consider use of an adjustment related to the use of PM$_{10}$ measurements, either when considering the optional use of Pb-PM$_{10}$ data for comparison with a Pb-TSP-based NAAQS, or when considering a level for a NAAQS based on a Pb-PM$_{10}$ indicator.

Section II.E.1 above contains extensive discussion of the relationship between Pb-PM$_{10}$ and Pb-TSP, including the fact that Pb-PM$_{10}$/Pb-TSP

relationships vary from site to site and from time to time, but have a systematic variation with distance from emissions sources emitting particles larger than would be captured by Pb-PM$_{10}$ samplers, such that generally there are larger differences between Pb-PM$_{10}$ and Pb-TSP near sources. Section II.E.1 goes on to identify and solicit comment on two ranges from which scaling factors could be chosen that would be applied to the Pb-PM$_{10}$ measurements to derive surrogate Pb-TSP concentrations for use in making comparisons to a Pb-TSP-based NAAQS. In recognition of the influence of proximity to sources on the relationship between Pb-TSP and Pb-PM$_{10}$ measurements for source types with a high fraction of ultra-coarse particles containing Pb, different scaling factors are identified for source-oriented monitoring sites and nonsource-oriented monitoring sites (as described in section II.E.1). These ranges have been developed based on analyses of the available collocated Pb-TSP and Pb-PM$_{10}$ data (Schmidt and Cavender, 2008) and recognition of variability and uncertainty inherent in this data set.

The data supporting the range for source-oriented scaling factors, as discussed in Schmidt and Cavender (2008), indicate the potential, in areas influenced by some types of sources (e.g., Pb smelters), for PM$_{10}$ samplers to capture as little as approximately 50% of the Pb that is measured with Pb-TSP monitors. The data from 20 sites not known to be near Pb sources show a range of ratios between Pb-TSP and Pb-PM$_{10}$ that vary from day to day and between sites. When rounded to one decimal place, these ratios of the multi-day mean concentration of Pb-TSP to the same statistic for Pb-PM$_{10}$ at each site ranged from 1.0 to 1.9.[153] Eighty-five percent of the sites had ratios between 1.0 and 1.4, and slightly over one-half the sites had ratios between 1.0 and 1.2. This is consistent with the conceptual model that concentrations of ultra-coarse particles of Pb are quite low at sites not near the primary sources of such particles, such that Pb-PM$_{10}$ monitors at such sites would tend to collect the large majority, but generally not all, of total airborne Pb.

In considering the need for and magnitude of a potential adjustment to derive a standard level for a Pb-PM$_{10}$-

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[153] On individual days, the ratio between the two measures was sometimes below 1.0 or well over 2.0, which may be the result of sampler errors and data rounding particularly when concentrations of one or both measures were low. Accordingly, EPA considers the ratio of the multi-day mean concentration of Pb-TSP to the same statistic for Pb-PM$_{10}$ at each site to be a better indicator of typical monitor behavior.

based NAAQS, we note the inherent variability in the TSP sampling methodology which will contribute variability to relationships derived between Pb-PM$_{10}$ and Pb-TSP data. We also note the influence on such relationships of proximity to sources of Pb particles that would not be captured by PM$_{10}$ samplers. This latter influence is evident in the difference between the two ranges of scaling factors proposed in section II.E.1 above.

We are also aware of the limitations of the dataset available on which to base these decisions, including those related to the quantity of collocated measurements and particularly the very limited number of source-influenced monitors for which such measurements are available, and the correspondingly limited number of types of sources represented. Moreover, the available collocated measurements suggesting the above-referenced 50% figure in a source-influenced location are from conditions in which ambient concentrations were above the current standard level and well above the proposed range of levels. If the contributing emissions sources had been controlled so that local concentrations were within or near the range proposed for the revised standard, it is unclear whether the relationship between Pb-PM$_{10}$ and Pb-TSP data would have been different or not. The Pb-TSP concentrations at sites in the dataset analyzed that were not known to be source-influenced were well below the proposed range of standard levels, leaving uncertainty about typical proportions of ultra-coarse particles in nonsource areas with Pb-TSP concentrations near the proposed range of levels.

If EPA adopts a PM$_{10}$ indicator, the approach of using two adjustment factors representing source-oriented and nonsource-oriented sites, or the approach of site-specific adjustment factors, would not be used in setting a standard level.[154] Rather, the complexity of the site-to-site variability in the Pb-TSP/Pb-PM$_{10}$ relationship would have to be reflected in a decision about whether and how to adjust the level of the standard to account for the fact that a Pb-PM$_{10}$ indicator would be less inclusive of Pb particles than would a Pb-TSP indicator.

b. CASAC Advice

As noted above, CASAC has described the use of an adjustment of the NAAQS

level to accommodate the loss of the ultra-coarse Pb particles that are important contributions to Pb exposure but that are excluded by PM$_{10}$ samplers (section II.E.1). For example, in discussion of the recommendation for the Agency to revise the Pb NAAQS indicator to Pb-PM$_{10}$ (using low-volume samplers) in their February 2007 letter, the CASAC Pb Panel stated that ''Presumably a downward scaling of the level of the Lead NAAQS could accommodate the loss of very large coarse-mode lead particles * * *'' (Henderson, 2007a). With regard to the magnitude of such scaling, CASAC has recognized the usefulness of some ''short period of concurrent PM$_{10}$ and TSP lead sampling'' to ''help develop site-specific scaling factors at sites with highest concentrations'' (Henderson, 2007a) and also indicated an expectation that, in general, Pb-PM$_{10}$ will represent a large fraction of, and be highly correlated with TSP Pb (Henderson, 2007b). In their most recent letter, the Panel stated generally that ''it would be well within EPA's range of discretionary options to accept a slight loss of ultra-coarse lead at some monitoring sites by selecting an appropriately conservative level for the revised Pb NAAQS'' (Henderson, 2008). In summary, while the CASAC recognized the appropriateness of making an adjustment to the level for a Pb-PM$_{10}$-based NAAQS, they did not provide a quantitative value, but did note interest in sites with highest concentrations. Further, CASAC expressed the view that the overall health-related benefits from moving to a PM$_{10}$-based standard could outweigh a small loss in protection from exposure to ultra-coarse particles in some areas.

The Agency received few public comments with regard to a standard level for a revised indicator of Pb-PM$_{10}$. Of these, some generally agreed with CASAC that an adjustment to the level was appropriate, recognizing the difference in the two sampling methods. Some were concerned that the current data may not support the derivation of a single scaling or adjustment factor that would provide requisite protection for some communities near some large point source emitters of dust.

c. Approaches for Levels for a PM$_{10}$-Based Standard

For the reasons identified in the preceding section and in section II.E.1 above, EPA's consideration of a Pb-PM$_{10}$ indicator is accompanied by consideration of an adjustment of the proposed level for the standard, in recognition of the importance for public health of those ultra-coarse dust

contributions not captured by PM$_{10}$ samplers.

In considering the appropriate level for a standard for which the indicator is Pb-PM$_{10}$, EPA recognizes the importance of all particle size fractions and the dominant role of the ingestion pathway in contributing to human exposures to air-related Pb. We also recognize that the proportion of Pb captured by TSP monitors that is not captured by PM$_{10}$ monitors will vary, not only in reflection of the inherent greater variability of the TSP sampler (as compared to the PM$_{10}$ sampler), but also based on proximity to sources emitting ultra-coarse Pb particles. An appreciably lower proportion of the Pb captured by TSP monitors will be captured by PM$_{10}$ monitors in areas near such sources (e.g., Pb smelters).

However, we are also aware of the limitations with regard to the available Pb monitoring data on which to base a decision with regard to an adjustment that appropriately recognizes these considerations. EPA notes that at lower levels, there is increased uncertainty as to the appropriate scaling factor to use, particularly in light of the very limited data we have on which to base an analysis. Additionally, we take note of advice from CASAC and public comments with regard to considerations for a level to accompany a Pb-PM$_{10}$ indicator.

Based on these and other considerations summarized above (II.E.1 and II.E.4.a), including the data indicating the proportion of Pb-TSP that may not be captured by PM$_{10}$ samplers in some source-oriented locations, EPA requests comment on whether a level for a NAAQS with a Pb-PM$_{10}$ indicator should be based on an adjustment to a lower level than the level for a NAAQS with a Pb-TSP indicator, and, if so, on the magnitude of the adjustment that would be appropriate. Taking into consideration uncertainties in the appropriate adjustment for a Pb-PM$_{10}$ based level (due to the very limited collocated dataset with which to evaluate relationships between Pb-TSP and Pb-PM$_{10}$), and the appropriate policy responses based on the currently available information, EPA specifically solicits comment on the appropriate level for a Pb-PM$_{10}$-based primary standard within the full range of levels on which comment is being solicited for a Pb-TSP standard, i.e., levels up to 0.50 μg/m³. Based on the comments received and the accompanying rationales, EPA may adopt standards within this broad range of alternative levels.

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[154] As discussed below in sections IV and VI, however, EPA is soliciting comment on the potential use of Pb-TSP data for initial designations for Pb-PM$_{10}$ standard and whether the associated use of scaling factors would be appropriate.

F. Proposed Decision on the Primary 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 to date, the Administrator is proposing options for the revision of 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, including neurocognitive and neurobehavioral effects, in children. Specifically, with regard to the indicator and level of the standard, the Administrator proposes to revise the level of the standard to a level within the range of 0.10 to 0.30 μg/m³ in conjunction with retaining the current indicator of Pb-TSP but with allowance for the use of Pb-PM₁₀ data. The Administrator also solicits comment on alternative levels up to 0.50 μg/m³ and down below 0.10 μg/m³. With regard to the form and averaging time of the standard, the Administrator proposes two options: (1) To retain the current averaging time of a calendar quarter and the current not-to-be-exceeded form, to apply across a 3-year span, and (2) to revise the averaging time to a calendar month and the form to be the second-highest monthly average across a 3-year span.

Corresponding revisions to data handling conventions and the schedule for States to request exclusion of ambient Pb concentration data affected by exceptional events are specified in proposed 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.

In recognition of alternative views of the science and the exposure and risk assessments, the uncertainties inherent in this information, and the appropriate policy responses based on the currently available information, the Administrator also solicits comments on other options. More specifically, the Administrator solicits comment on revising the indicator to Pb-PM₁₀ and on the same broad range of levels on which EPA is soliciting comment for the proposed Pb-TSP indicator, i.e., up to 0.50 μg/m³. In

addition, the Administrator invites comment on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero. Based on the comments received and the accompanying rationales, the Administrator may adopt other standards within the range of the alternative levels identified above in lieu of the standards he is proposing today.

III. Rationale for Proposed Decision on the Secondary Standard

This section presents the rationale for the Administrator's proposed decision to revise the existing secondary NAAQS. In considering the currently available evidence on Pb-related welfare effects, the Staff Paper notes that 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 distinct secondary standard for Pb.

A. Welfare Effects Information

Welfare effects addressed by the secondary NAAQS 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. A qualitative assessment of welfare effects evidence related to ambient Pb is summarized in this section, drawing from Chapter 6 of the Staff Paper. The presentation here first recognizes 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, multipathway 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, 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. This gasoline-derived Pb was emitted predominantly in small size particles which were widely dispersed and transported across large distances. Many sites receiving Pb predominantly through such long-range transport 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, AX7.1.4.2, 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, 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, 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.

B. 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). Funding constraints 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 complete presentation of results is provided in the

pilot phase Risk Assessment Report (ICF, 2006) and summarized in Chapter 6 of the Staff Paper.

1. Design Aspects of Assessment and Associated Uncertainties

The screening level risk assessment involved several location-specific case studies and a national-scale surface water and sediment screen. The case studies included areas surrounding a primary Pb smelter and a secondary Pb smelter, as well as a location near a nonurban roadway. An additional case study for an ecologically vulnerable location was identified and described (ICF, 2006), but resource constraints have precluded risk analysis for this location.

The case study analyses were designed to estimate the potential for ecological risks associated with exposures to Pb emitted into ambient air. Soil, surface water, and/or sediment concentrations were estimated 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. Results of these comparisons are not definitive estimates of risk, but rather serve to identify those locations at which there is the greatest likelihood for adverse effect. Similarly, the national-scale screening assessment evaluated surface water and sediment monitoring locations across the United States for the potential for ecological impacts associated with atmospheric deposition of Pb. The reader is referred to the pilot phase Risk Assessment Report (ICF, 2006) for details on the use of this information and models in the screening assessment.

The measures of exposure for these analyses are total Pb concentrations in soil, dissolved Pb concentrations in fresh surface waters (water column), and total Pb concentrations in freshwater sediments. The hazard quotient (HQ) approach was then used to compare Pb media concentrations with ecological screening values. The exposure concentrations were estimated for the three case studies and the national-scale screening analyses as described below:

• For the primary Pb smelter case study, measured concentrations of total Pb in soil, dissolved Pb in surface waters, and total Pb in sediment were used to develop point estimates for sampling clusters thought to be associated with atmospheric Pb deposition, rather than Pb associated with nonair sources, such as runoff from waste storage piles.

• For the secondary Pb smelter case study, concentrations of Pb in soil were

estimated using fate and transport modeling based on EPA's MPE methodology (USEPA, 1998) and data available from similar locations.

• For the near roadway nonurban case study, measured soil concentration data collected from two interstate sampling locations, one with fairly high-density development (Corpus Christi, Texas) and another with medium-density development (Atlee, Virginia), were used to develop estimates of Pb in soils for each location.

• For the national-scale surface water and sediment screening analyses, measurements of dissolved Pb concentrations in surface water and total Pb in sediment for locations across the United States were compiled from available databases (USGS, 2004). Air emissions, surface water discharge, and land use data for the areas surrounding these locations were assessed to identify locations where atmospheric Pb deposition may be expected to contribute to potential ecological impacts. The exposure assessment focused on these locations.

The ecological screening values used in this assessment 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 more fully in section 7.1.3.3 and Appendix M of the pilot phase Risk Assessment Report (ICF, 2006).

The HQ is calculated as the ratio of the media concentration to the ecotoxicity screening value, and represented by the following equation:

HQ = (estimated Pb media concentration)/(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 dissolved Pb data were available and evaluated in the national-scale surface water and sediment screens. In identifying sites for inclusion in the assessment, 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 estimated the aquatic toxicity of Pb (CD, sections AX7.2.1.2 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).

2. Summary of Results

The following is a brief summary of key observations related to the results of

the screening-level ecological risk assessment. A more 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).

• The national-scale screen of surface water data initially identified some 42 sample locations of which 15 were then identified as unrelated to mining sites and having water column levels of dissolved Pb that were greater than hardness adjusted chronic criteria for the protection of aquatic life (with one location having a HQ of 15), 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.

• In the primary Pb smelter case study, for which measurements were used to estimate nonair media concentrations, all three of the soil sampling clusters (including the "reference areas") had HQs that exceeded 1.0 for birds. Samples from one cluster also had HQs greater than 1.0 for plants and mammals. The surface water sampling clusters all had measurements below the detection limit of 3.0 µg/L. However, three sediment sample clusters had HQs greater than 1.0. In summary, the concentrations of Pb in soil and sediments exceed screening values for these media indicating potential for adverse effects to terrestrial organisms (plants, birds and mammals) and to sediment dwelling organisms. While the contribution to these Pb concentrations from air as compared to nonair sources is not quantified, air emissions from this facility are substantial (Appendix D, USEPA 2007b; ICF 2006). Further, the contribution of air Pb under the current NAAQS to these concentrations as compared to that prior to the current NAAQS is unknown.

• In the secondary Pb smelter case study, the soil concentrations, developed from soil data for similar locations, resulted in avian HQs greater than 1.0 for all distance intervals evaluated. The soil concentrations within 1 km of the facility, scaled using a combination of measurements and modeling (as described in the Staff Paper, Chapter 6) also showed HQs greater than 1.0 for plants, birds, and mammals. These estimates indicate a potential for adverse effect to those receptor groups. We note that the contribution of nonair sources to these concentrations is unknown. Further, the contribution of air Pb under the current NAAQS to these concentrations as compared to that prior to the current NAAQS is also unknown.

• In the nonurban, near roadway case study, HQs for birds and mammals were greater than 1.0 at all but one of the distances from the road. Plant HQs were greater than 1.0 at the closest distance. In summary, HQs above one were estimated for plants, birds and mammals, indicating potential for adverse effect to these receptor groups. We note that the contribution of air Pb under the current NAAQS to these concentrations as compared to that prior to the current NAAQS is unknown.

C. The Secondary Standard

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.

The following discussion starts with background information on the current standard (section III.C.1). The general approach for this current review is summarized in section III.C.2. Considerations and conclusions with regard to the adequacy of the current standard are discussed in section III.C.3, with evidence and exposure-risk-based considerations in sections III.C.3.a and b, respectively, followed by a summary of CASAC advice and recommendations (section III.C.3.c) and the Administrator's proposed conclusions (section III.C.3.d). Considerations, conclusions and the Administrator's

proposed decision with regard to elements of the secondary standard are discussed in section III.C.4.

1. Background on the Current Standard

The current standard was set in 1978 to be identical to the primary standard (1.5 µg Pb/m³, 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 nonavailable 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, 1990). 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 µg/m³.

2. Approach for Current Review

In evaluating whether it is appropriate to retain the current secondary Pb standard, or whether revision is appropriate, the Administrator has considered the evidence and risk analyses presented in the Criteria Document, the Staff Paper, the ANPR and the associated technical support documents, [together with the associated uncertainties] and CASAC advice and public comment on these documents. The Staff Paper and ANPR recognize that the available welfare effects evidence generally reflects laboratory-based evidence of toxicological effects on specific organisms exposed to concentrations of Pb at which scientists generally agree that adverse effects are likely to occur. It is widely recognized, however, that environmental exposures are likely to be at lower concentrations and/or accompanied by significant confounding factors (e.g., other metals, acidification), which increases our uncertainty about the likelihood and magnitude of the organism and ecosystem response.

3. Conclusions on Adequacy of the Current Standard

a. Evidence-Based Considerations

In considering the welfare effects evidence with respect to the adequacy of the current standard, the Administrator considers not only the array of evidence newly assessed in the Criteria Document but also that assessed in the 1986 Criteria Document and summarized in the 1990 Staff Paper. As discussed extensively in the latter two documents, there was a significantly improved characterization of environmental effects of Pb in the ten years after the Pb NAAQS was set. And in the subsequent nearly 20 years, many additional studies on Pb effects in the environment are now available (2006 Criteria Document). Some of the more relevant aspects of the evidence available since the standard was set include the following:

• A more quantitative determination of the mobility, distribution, uptake, speciation, and fluxes of atmospherically delivered Pb in terrestrial ecosystems shows that the binding of Pb to organic materials in the soil slows its mobility through soil and may prevent uptake by plants (CD, Sections 7.1.2, 7.1.5, AX7.1.4.1, AX7.1.4.2, AX7.1.4.3 and AX7.1.2). Therefore, while atmospheric deposition of Pb has decreased, Pb may be more persistent in some ecosystems than others and may remain in the active zone of the soil, where exposure

may occur, for decades (CD, Sections 7.1.2, AX7.1.2 and AX7.1.4.3).

• Plant toxicity may occur at lower levels than previously identified as determined by data considered in development of Eco–SSLs (CD, pp. 7–11 to 7–12, AX7–16 and Section AX7.1.3.2), although the range of reported soil Pb effect levels is large (tens to thousands of mg/kg soil).

• Avian and mammalian toxicity may occur at lower levels than those previously identified, although the range of Pb effect levels is large (<1 to >1,000 mg Pb/kg bw-day) (CD, p. 7–12, Section AX7.1.3.3).

• There is an expanded understanding of the fate and effects of Pb in aquatic ecosystems and of the distribution and concentrations of Pb in surface waters throughout the United States (CD, Section AX7.2.2).

• New methods for assessing the toxicity of metals to water column and sediment-dwelling organisms and data collection efforts (CD, Sections 7.2.1, 7.2.2, AX7.2.2, and AX7.2.2.2) have improved our understanding of Pb aquatic toxicity and findings include an indication that in some estuarine systems Pb deposited during historic usage of leaded gasoline may remain in surface sediments for decades. (CD, p. 7–23).

• A larger dataset of aquatic species assessed with regard to Pb toxicity, and findings of lower effect levels for previously untested species (CD, p. AX7–176 and Section AX7.2.4.3).

• Currently available studies have also shown effects on community structure, function and primary productivity, although some confounders (such as co-occurring pollutants) have not been well addressed (CD, Section AX7.1.4.2).

• Evidence in ecological research generally indicates the value of a critical loads approach; however, current information on Pb critical loads is lacking for many processes and interactions involving Pb in the environment and work is ongoing (CD, Section 7.3).

Given the full body of current evidence, despite wide variations in Pb concentrations in soils throughout the country, Pb concentrations are likely in excess of concentrations expected from geologic or other non-anthropogenic forces. In particular, 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 (CD, Section AX7.1.4.3). 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, Section 3.2 and AX7.1.2.3).

There are several difficulties in quantifying the role of current ambient 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 very sparse 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. However, the evidence summarized above and 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.

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 AX7.2.2.2.2 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 looking to laboratory studies and current media concentrations in a wide range of areas, 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.

b. Risk-Based Considerations

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.

The screening level risk assessment involved a comparison of estimates of environmental media concentrations of Pb to ecological screening levels to assess the potential for ecological impacts from Pb that was emitted into the air. Results of these comparisons are not considered to be definite predictors of risk, but rather serve to identify those locations at which there is greatest likelihood for adverse effect. Similarly, the national-scale screening assessment evaluated the potential for ecological impacts associated with the atmospheric deposition of Pb released into ambient air at surface water and sediment monitoring locations across the United States.

The ecological screening levels employed in the screening level risk assessment for different media are drawn from different sources. Consequently there are somewhat different limitations and uncertainties associated with each. In general, their use here recognizes their strength in identifying media concentrations with the potential for adverse effect and their relative nonspecificity regarding the magnitude of risk of adverse effect.

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 primary Pb smelter case study 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 this facility are substantial (Appendix D, USEPA 2007b; ICF 2006). Additionally, estimates of Pb concentration in soils associated with the nonurban near roadway case study and the secondary Pb smelter case study were also associated with HQs above 1 for plants, birds and mammals, indicating potential for adverse effect to those receptor groups. The industrial facility in the secondary Pb smelter case study is much younger than the primary Pb smelter and apparently became active less than ten years prior to the establishment of the current standard.

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 Pb concentrations in several aquatic systems exceeded screening values. In the case of the national-scale screen of surface water data, 15 locations were identified with water column levels of dissolved Pb that were greater than hardness-adjusted chronic criteria for the protection of aquatic life (with one location having a HQ as high as 15), indicating a potential for adverse effect if concentrations were persistent over chronic periods. Further, 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 banning 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 some locations at concentrations, particularly in soil, and aquatic sediment above the screening levels, 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. Further, environmental concentrations may be related to emissions prior to establishment of the current standard and such concentrations appear to indicate a potential for harm to ecological receptors today.

c. CASAC Advice and Recommendations

In the CASAC letter transmitting advice and recommendations pertaining to the review of the ANPR and final Staff Paper and Pb Exposure and Risk Assessments, the CASAC Pb panel provided recommendations regarding the need for a Pb NAAQS, and the adequacy of the current Pb NAAQS, as well as comments on the documents. With regard to the revision of the primary and secondary NAAQS, this CASAC letter (Henderson, 2008) said:

The Committee unanimously and fully supports 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 µg/m³ with a monthly averaging time. The CASAC is also unanimous in its recommendation that the secondary (public-welfare based) standard for lead needs to be substantially lowered to a level at least as low as the recommended primary NAAQS for Lead.

In earlier comments on the December 2006 draft documents, the CASAC Pb Panel concluded they presented "compelling scientific evidence that current atmospheric Pb concentrations and deposition—combined with a large reservoir of historically deposited Pb in soils, sediments and surface waters—continue to cause adverse environmental effects in aquatic and/or terrestrial ecosystems, especially in the vicinity of large emissions sources." The Panel went on to state that "These effects persist in some cases at locations where current airborne lead concentrations are below the level of the current primary and secondary lead standards" and "Thus, from an environmental perspective, there are convincing reasons to both retain lead as a regulated criteria air pollutant and to lower the level of the current secondary standard" (Henderson, 2007a).

In making this recommendation, the CASAC Pb Panel also cites the persistence of Pb in the environment, the possibility of some of the large amount of historically deposited Pb becoming resuspended by natural events, and the expectation that humans are not uniquely sensitive among the many animal and plant species in the environment.

CASAC provided further advice and recommendations on the Agency's consideration of the secondary standard in this review in their letter of September 2007 (Henderson, 2007b). In that letter they recognized the role of the secondary standard in influencing the long-term environmental burden of Pb and a need for environmental monitoring to assess the success of the standard in this role.

Similarly, in CASAC's advice on the ANPR and final Staff Paper they concluded:

[I]t is critical that the secondary Lead NAAQS be set at a sufficiently-stringent level so as to ensure that there is no reversal of the current downward trend in lead concentrations in the environment. 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. Moreover, the Agency needs to give greater priority to the monitoring of environmental lead in the ambient air.

However, CASAC also recognized that EPA "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" (Henderson, 2007a).

d. Administrator's Proposed Conclusions on Adequacy of Current Standard

In considering the adequacy of the current 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 in Section III.A). Depending on the interpretation, the available data and evidence, primarily qualitative, suggests 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 concludes that there is potential for adverse effects occurring under the current standard, however 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, it is conclusive that deposition of Pb from air sources is occurring and that this ambient Pb is likely to be persistent in the environment. Historically deposited Pb 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).

There is only very limited information available pertinent to assessing whether groups of organisms which influence ecosystem function are subject to similar effects as those in humans. The screening-level risk information, while limited and accompanied by various uncertainties, also suggests occurrences of environmental Pb concentrations existing under the current standard that could have adverse environmental effects. 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 proposes to conclude that the current secondary standard for Pb is not requisite to protect public welfare from known or anticipated adverse effects.

4. Conclusions and Proposed Decision on the Elements of the Secondary 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 that provides protection for public welfare from exposure to Pb, 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 concerns regarding the relative advantages of TSP and PM_{10} as the basis for the indicator apply here as for the primary standard.

Lead is a cumulative pollutant with environmental effects that can last many decades. In considering the appropriate averaging time for a secondary standard for such a pollutant the concept of critical loads may be useful (CD, section 7.3). However, information is currently insufficient for such use in this review.

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). EPA concurs with CASAC's conclusion 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. The Administrator concurs with CASAC's conclusion 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 proposes 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.4 above).

IV. Proposed Appendix R— Interpretation of the NAAQS for Lead and Proposed Revisions to the Exceptional Events Rule

The EPA is proposing 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 would detail the computations necessary for determining when the proposed Pb NAAQS is met. The proposed appendix also would address data reporting; sampling frequency and data completeness considerations; the use of scaled Pb-PM_{10} data as a surrogate for Pb-TSP data (or vice versa), including associated scaling instructions; and rounding conventions. Although the Administrator is proposing one indicator and inviting comment on another, and proposing several possible combinations of different averaging times, forms, and levels, for simplicity the proposed data handling appendix text only directly addresses one combination: a Pb-TSP indicator with an option for using scaled Pb-PM_{10} data for NAAQS comparisons, an averaging time of monthly, a second maximum (over three years) form, and a level of 0.20 μg/m³. The proposed appendix text indicates in brackets, as examples, the change that would be needed if the level of the standard is set at 0.10 or 0.30 μg/m³ rather than at 0.20 μg/m³. A decision to adopt Pb-PM_{10} as the indicator, to adopt a different indicator, averaging time, and/or form, or not to make use of surrogate data would require other differences in the text of the appendix; the proposed differences in the appendix text to accommodate such difference are described below, after the explanation of the proposed version of the appendix.

The EPA is also proposing 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 now contained 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.

A. Background

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 this proposed Pb NAAQS) possibly multi-parameter (i.e., Pb-TSP and/or Pb-PM_{10}) 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), then no determination of current compliance or violation is possible.

The regulatory language for the current Pb NAAQS, originally adopted in 1977, contains no data interpretation instructions. Because of that, the EPA

has issued various guidance documents and memoranda relevant to the topic. This situation contrasts with the situations for ozone, $PM_{2.5}$, and PM_{10} for which there are detailed data interpretation appendices in 40 CFR part 50. EPA has used its experience drafting and applying these other data interpretation appendices to develop the proposed text for appendix R.

An exceptional event is an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Air quality data affected by an exceptional event in certain specified ways may be excluded from consideration when EPA makes a determination that an area is meeting or violating the associated NAAQS, subject to EPA review and concurrence. Section 50.14 contains both substantive criteria that an event and the associated air concentration data must meet in order to be excluded, and process steps and deadlines for a State to submit specified information to EPA. The key deadlines are that a State must initially notify EPA that data have been affected by an event and provide an initial description of the event by July 1 of the year after the data are collected, and that the State must submit the full justification for exclusion within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data, for example a designation action, is anticipated, the schedule is foreshortened and all information must be submitted to EPA no later than a year before the decision is to be made. This schedule presents problems when a NAAQS has been recently revised, as discussed below.

The Staff Paper did not address data interpretation details, and although the ANPR discussed data handling to a limited extent, there has been only limited comment by CASAC or the public to date (other than comments on the related issues of form and indicator for the standard, including scaling factor issues). Similarly, no comments were received on exceptional event issues.

B. Interpretation of the NAAQS for Lead

1. Interpretation of a Standard Based on Pb-TSP

The purpose of a data interpretation rule for the Pb NAAQS is to give effect to the form, level, averaging time, and indicator specified in the proposed regulatory text at 40 CFR 50.16, anticipating and resolving in advance

various future situations that could occur. The proposed Appendix R, like the existing NAAQS interpretation appendices for ozone, $PM_{2.5}$, and PM_{10}, addresses the possible situation of there being less than 100% complete data available, which is an issue in common across NAAQS pollutants. It also addresses several issues which are specific to the proposed Pb NAAQS, as described below.

With regard to data completeness, the proposed Appendix follows past EPA practice for other NAAQS pollutants by requiring that in general at least 75% of the monitoring data that should have resulted from following the planned monitoring schedule in a period must be available for the key air quality statistic from that period to be considered valid. For the combination of NAAQS parameters addressed in the proposed text, the key air quality statistic is the mean concentration in an individual month, and so the 75% requirement is applied for that time period. With the proposed required sampling schedule of one day in three under a monthly mean form for the standard (section V), typically there will be 10 required sampling days so a monthly mean would be considered valid if there were data available for at least 8 of those days.[155] EPA invites comment on this proposed 75% requirement, recognizing that for the current NAAQS based on a quarterly mean concentration form with a required one-day-in-six schedule, the current EPA policy is effectively that there be at least 11 days of data in a quarterly mean.

The proposed rule text for Pb data interpretation, like the corresponding existing rule for $PM_{2.5}$, has two provisions that help a monitoring agency guard against a month ending up with data completeness below 75%. First, there is a provision to allow data from secondary, collocated samplers to substitute for data from a primary monitor on a day when the primary monitor for some reason fails to deliver valid data. There is also a provision which would allow a monitoring agency to make up a sampling day on which no valid data were collected, and to count the make-up sampling data in the assessment of data completeness. To help insure that sampling days are well distributed across the month and that a make-up day will generally fall within the same source emissions and

meteorological regime as the missed sampling day, a number of specific restrictions are proposed on the number of make-up days per month and on how soon after the missed scheduled sampling day they must occur. These restrictions are stated in the proposed rule text, and are adapted from current practice for $PM_{2.5}$ with adaptations to fit the monthly form of the proposed Pb standard.

A monthly mean Pb concentration for Pb-TSP would be calculated from all available daily mean concentrations within that calendar month, including successfully completed sampling days, allowed make-up sampling days, and any other sampling days actually completed successfully by the primary monitor or by secondary monitors if there is no data from a primary monitor. These other sampling days would not be used in calculating data completeness, however; this follows the example of the current requirements for $PM_{2.5}$ data interpretation.

Recognizing that even allowing for make-up samples, there may be months with fewer than 75% complete data, the proposed text provides for two diagnostic tests which are intended to identify those cases with completeness less than 75% in which it nevertheless is very likely, if not virtually certain, that the monthly mean concentration would have been observed to be either above or below the level of the NAAQS if monitoring data had been complete. One test, to be applied if the mean of the incomplete data is above the NAAQS level, substitutes low hypothetical concentrations for as much of the missing data as needed to meet the 75% requirement; if the resulting mean is still above the NAAQS level, then the NAAQS level is considered to have been exceeded for the month. The hypothetical low values would be set equal to the lowest concentration observed in the same month over the 3-year period being evaluated, in effect giving the benefit of the doubt as to the actual concentrations on the days with missing data. If the monthly mean nevertheless is above the NAAQS, it is virtually certain that the mean of complete data would also have been above the NAAQS. The other test, to be applied if the mean of the incomplete data is below the NAAQS level, works similarly except that at most 50% of the scheduled data can be missing and all missing data is substituted with the highest value observed in the same month over the 3-year period, with the same rationale. If the monthly mean nevertheless is below the NAAQS, it is virtually certain that the mean of complete data would also have been

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[155] Fewer than 10 days could be required, and fewer needed for the monthly average to be valid, for February at all sites and in all months for sites approved for only one-day-in-six sampling because they have a history of recording concentrations well below the level of the NAAQS. See Section V for more detail on required sampling schedules.

below the NAAQS. Data substitution tests similar to these are currently used for ozone and PM$_{2.5}$. It should be noted that one outcome of applying the substitution tests proposed for Pb is that a month with incomplete data may still be determined to not have a valid monthly mean and to be unusable in making NAAQS exceedance determinations for that monthly time period. In turn, this may make it impossible to make a determination of compliance or violation for the 3-year period, depending on the completeness and levels of the concentration data from the other months.

EPA invites comment on also incorporating into the final rule two other possible tests that could allow a NAAQS exceedance determination to be made on the basis of monthly data that is not at least 75% complete. EPA may incorporate a version of either or both of these additional tests into the final rule. The first additional test would allow use of the monthly mean based on data that is between 50% and 75% complete if that monthly mean were below some percentage (for example, 50%) the NAAQS, on the rationale that if the available daily values (typically there would be 5 values in a month with 50% complete data) have a mean below some sufficiently low limit, day-to-day variability at the site must be small and the actual concentrations on the days with missing data are very unlikely to have been high enough to make the true monthly mean exceed the NAAQS level.

The second additional test would be more statistically rigorous, yet will allow compliance determinations to be made on some smaller data sets by considering uncertainty bounds. The test would use the available data to create a two-sided statistical confidence interval around the calculated monthly mean concentration. A reduced minimum completeness percentage such as 50% would still be applied to ensure that there are enough sampling days that they could not all be from within a very short period of time. As expected, the uncertainty range about the monthly mean would increase as the number of samples decreases, and as there is more variability in the data that were collected (more high concentrations days mixed with low concentration days). If the prescribed two-sided confidence interval is entirely above the level of the NAAQS, then the NAAQS would be deemed to have been exceeded in that month. Note that the calculated monthly mean in this situation would also have been above the NAAQS level. If the confidence interval is entirely below the level of the NAAQS, then the NAAQS would be

deemed to have not been exceeded in that month. EPA invites comment on the statistical assumptions that should be considered to create a confidence interval from the available data, for example the assumed distribution of the underlying ambient data and how the confidence intervals should be constructed. For example, the confidence interval could be constructed based on an assumption of a log-normal distribution for daily concentrations combined with the concept of a ''finite population correction factor,'' where means based on data with between 50 and 75% completeness would have an associated uncertainty range.[156] Any data that is at least 75% complete could be considered ''complete'' and would have no confidence interval. This approach would make the general completeness test and this statistical test yield the same result for a month with at least 75% completeness. EPA notes that such a statistical confidence interval approach is not presently used in data interpretation for any other NAAQS, but no other NAAQS involves the combination of an averaging period as short as a month with a sampling schedule as infrequent as one day in three.

Section V.C. contains provisions which interact with the proposed data completeness requirements described above. EPA invites comment on whether the proposed data completeness provisions taken together provide a good balance between avoiding situations in which no determination of attainment or nonattainment can be made until more data are collected during another calendar year, and avoiding erroneous determinations caused by reliance on small sample sizes affected by data variability. EPA also plans to explore this question prior to the final rule, by analyzing hypothetical cases reflecting the variability seen in historical monitoring data, and may make adjustments to the proposed provisions for the final rule.[157]

The proposed rule text would require that only a minimum of two valid

monthly means be available over the 3-year period in order to determine that a site has violated the NAAQS, since if the NAAQS has been observed to be exceeded twice the concentrations in the other months would be irrelevant to a finding of NAAQS violation. Valid monthly means would be required for all 36 possible months in the 3-year period in order to make a finding that the NAAQS has been met. An exception would be allowed if there are 35 valid monthly means and none of them exceed the NAAQS, because in that case it is irrelevant whether the one month with incomplete data experienced an exceedance or not.

The proposed text of Appendix R has provisions to implement the proposal that Pb-PM$_{10}$ data adjusted by the application of site-specific scaling factors be treated as surrogate Pb-TSP data. These provisions are somewhat complex, to be able to address various possible situations without ambiguity. These situations arise from the possibility that both Pb-TSP and Pb-PM$_{10}$ monitoring might take place at a single site, with differences from day to day within the 3-year period as to which samplers were operating and yielded valid data for the day. The proposed approach is to consider all Pb-TSP and Pb-PM$_{10}$ data that have been collected and submitted by the monitoring agency, *i.e.*, once Pb-PM$_{10}$ data have been collected and submitted the monitoring agency could not choose to have them ignored.[158] However, where and when both types of data exist, the Pb-TSP data would be given first consideration. Specifically the proposed approach is to treat as separate questions whether the Pb-TSP monitor and the Pb-PM$_{10}$ monitor have produced a valid monthly mean concentration, taking into account the provisions for make-up samples and data substitution from secondary monitors, but not mixing Pb-TSP and Pb-PM$_{10}$ data within the month. If valid monthly means for both Pb-TSP and Pb-PM$_{10}$ have been achieved, *i.e.*, the main or a supplemental data completeness test has been passed, the Pb-TSP data takes precedence and the Pb-PM$_{10}$ data for

[156] See, for example, the explanation of the finite population correction factor approach at grants.nih.gov/grants/funding/modular/eval/ Sample_MGAP.doc. Another useful reference is ''Sampling: Design and Analysis'', Lohr, Sharon L., Brooks/Cole Publishing Co., Pacific Grove, CA, 1999.

[157] This exploration will be somewhat similar to the work EPA did on data quality objectives for the PM$_{2.5}$ monitoring network, but likely will be more simplistic in light of the more limited available data. See ''Data Quality Objectives (DQOs) for PM$_{2.5}$,'' July 25, 2001, *http://www.epa.gov/ttn/ amtic/files/ambient/pm25/qa/2001Dqo.pdf.*

[158] Section 3(a) of the proposed Appendix R has a more detailed statement of what ambient data will be considered when determining compliance with the NAAQS than is given in other data interpretation appendices to 40 CFR part 50. EPA invites comment on this codification of current practice. One new feature is a provision for the use of data collected before the promulgation of the proposed changes and additions to the FRM/FEM criteria, to make it clear that these changes and additions are in effect retroactive. FRM/FEM revisions and new FRM/FEM designations have not always been treated as retroactive but in the case of the revised Pb NAAQS EPA wishes to maximize the available data for making designations.

that month are ignored. However, across the 3-year period, monthly means for Pb-TSP and scaled Pb-PM$_{10}$ can be considered together in determining whether more than one monthly mean Pb concentration has exceeded the level of the NAAQS. This allows for the possibility that a monitoring agency may have switched from one type of monitoring to the other during the 3 years, or that it has been more successful in getting complete Pb-TSP data in some months than in others.

The proposed Appendix R addresses the procedures and criteria for development and use of site-specific scaling factors for Pb-PM$_{10}$ data. The scaling factor is the number that would multiply Pb-PM$_{10}$ data to get a surrogate for Pb-TSP data. The proposal would require States to develop a site-specific scaling factor for each monitoring site at which the State wishes to use Pb-PM$_{10}$ data as a surrogate for Pb-TSP data, either to allow it to only operate a Pb-PM$_{10}$ monitor or to make a Pb-PM$_{10}$ monitor eligible as a back-up source of Pb data for greater data completeness. The site-specific scaling factor would have to be based on at least a year of measurements of both types at the site in question. EPA invites comment on the detailed criteria for developing such local scaling factors, given in section 2(b) of the proposed Appendix.

The existing FRM for Pb-TSP, Appendix G of 40 CFR part 50, contains procedures for calculating Pb concentration data in micrograms per cubic meter at standard conditions of temperature and pressure (STP). The proposed FRM for low-volume Pb-PM$_{10}$, Appendix Q of 40 CFR part 50, requires reporting of concentration data at local conditions of temperature and pressure, for reasons explained in section V. For consistency going forward, we are proposing in the proposed appendix R that for monitoring conducted on or after January 1, 2009, Pb-TSP data should be reported at local conditions of temperature and pressure also. The first deadline for such reporting will be about June 30, 2009 (to be exact, 90 days from March 31, 2009) so monitoring agencies will have ample lead time to change their reporting procedures. However, EPA believes it would be an unnecessary burden to require monitoring agencies to re-submit pre-January 1, 2009 Pb-TSP data corrected to local conditions, given that the adjustment would in most cases be small. The proposed Appendix R would provide that pre-2009 Pb-TSP data reported in STP is to be compared directly to the level of the standard with no adjustment for the difference in reporting forms, but gives the monitoring agency the option of re-submitting the data corrected to local conditions. EPA invites comment on this approach.

Both FRM rules require reporting of daily Pb concentrations with three decimal places. When monthly means are calculated, they are to be rounded to two decimal places for purposes of comparing to the level of the NAAQS, which is expressed to two decimal places.

2. Interpretation of Alternative Elements

This section addresses changes that would be made to the proposed Appendix R as printed at the end of this notice, if the Administrator decides to adopt certain features which are being proposed today in the alternative to those described above, or on which comment is invited.

If a quarterly maximum mean form is adopted for the final standard, we propose that the basic period for assessing completeness would still be the month. An equation would be added for calculating a quarterly mean from three monthly means. The two supplemental diagnostic completeness tests would be changed so that the outcome depends on whether the quarterly mean with substituted data included for one or more incomplete months meets or exceeds the standard, rather than the monthly mean. The design value would be defined as the maximum quarterly mean concentration in the 3-year period. To be determined to violate the standard, at least one valid quarterly mean in the 3-year period would be required. To be determined to meet the standard, 12 valid quarterly means in the 3-year period would be required. EPA invites comment on the alternative of applying completeness tests only for whole calendar quarters rather than individual months, an approach that might allow attainment determinations to be made in some cases in which the by-month approach just described would prevent a determination.

As discussed in section II.E.1, EPA is inviting comment on the possibility of the final rule containing default scaling factors for adjusting Pb-PM$_{10}$ data for use as a surrogate for Pb-TSP data. This would give States the option of using a default scaling factor rather than conducting the site-specific paired monitor testing required in the proposed text of Appendix R. If EPA adopts this approach in the final rule, Appendix R would be modified to provide the default scaling factor values and explain their application. The appropriate default scaling factor would be used in calculation formulas exactly as the proposed Appendix R text requires the use of a site-specific scaling factor; other provisions would be unaffected. Because TSP samplers collect a broader range of particle sizes than PM$_{10}$ samplers, the scaling factor logically can not be less than 1.0. EPA is inviting comment on the selection of default scaling factors from within two ranges. The first range is 1.1 to 2.0 and would apply to Pb-PM$_{10}$ data collected at source-oriented monitoring sites. The other range is 1.0 to 1.4 [159] and would apply to Pb-PM$_{10}$ data collected at monitoring sites that are not source-oriented. These ranges are based on historical data from sites where the two types of monitors were operated on the same days, as explained in section II.E.1. Because there would be different default scaling factors for the two monitoring site types, a modification of the proposed Appendix R text would require for each monitoring agency to determine and designate, subject to EPA review, whether each Pb-PM$_{10}$ site is in fact source-oriented and to document that determination in the Annual Monitoring Plan required by 40 CFR 58.10 (see section V for more information on the requirement for this plan and for designating sites as source-oriented or not).

As explained in section II.E, EPA is inviting comment on the possibility of revising the Pb indicator to be Pb-PM$_{10}$. If a Pb-PM$_{10}$ indicator is adopted in the final rule, references to the two types of data would be reversed from the way they appear in the proposed text of Appendix R, so that Pb-PM$_{10}$ data when available would have primacy over scaled Pb-TSP data. If Pb-PM$_{10}$ is adopted as the indicator for the final standard, many areas may not have sufficient Pb-PM$_{10}$ data to allow a determination of compliance or violation with the Pb standard within the two or three years allowed under the Clean Air Act for initial designations. EPA is inviting comment on an approach that would allow the use of Pb-TSP data, with adjustment(s), for comparing ambient concentrations of Pb to a Pb-PM$_{10}$ NAAQS for the sole purpose of making initial designations. The scaling issues, relevant data, and possible approaches are similar to those described in section II.E.1. We invite comment on adding language to Appendix R restricting the use of scaled Pb-TSP data to determinations made for purposes of designations within three years of promulgation of the revised standard. (See section VI for discussion

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[159] EPA is also soliciting comment on a broader range of 1.0 to 1.9 for nonsource-oriented sites as discussed in section II.E.1.

of the schedule for designations.) This generally would mean that scaling factors would be used only on 2007–2009 and possibly on earlier Pb-TSP data, because Pb-PM$_{10}$ monitoring is proposed to be required to begin by January 1, 2010. Because scaling factors would need to be available for designations decisions which must be made within three years of promulgation of the NAAQS, there would be limited time for a State to do collocated testing to develop local scaling factors and then have them reviewed and approved by EPA. Requiring development of site-specific scaling factors might effectively prevent use of scaled Pb-TSP data in many States, resulting in more areas having to be designated unclassifiable initially. Therefore, we invite comment on removing the passages requiring the development of site-specific scaling factors from Appendix R and providing default scaling factors instead. Scaling factors would be 1.0 or less. EPA invites comment on the selection of appropriate default scaling factors for this situation.

C. Exceptional Events Information Submission Schedule

As explained above, 40 CFR 50.14 contains generic deadlines for a State to submit to EPA specified information about exceptional events and associated air concentration data. A State must initially notify EPA that data has been affected by an event by July 1 of the year after the data are collected; this is done by flagging the data in AQS. The State must also provide an initial description of the event by July 1. Also, the State must submit the full justification for exclusion within 3 years after the quarter in which the data were collected; however, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule for the full justification is foreshortened and all information must be submitted to EPA no later than a year before the decision is to be made.

These generic deadlines are suitable for the period after initial designations have been made under a NAAQS, when the decision that may depend on data exclusion is a redesignation from attainment to nonattainment or from nonattainment to attainment. However, these deadlines present problems with respect to initial designations under a revised NAAQS. One problem is that some of the deadlines, especially the deadlines for flagging data, can have already passed for some relevant data by the time the revised NAAQS is promulgated. However, until the level and form of the NAAQS have been promulgated a State does not know

whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met on a given day, so the only way a State can be sure to have flagged all data of concern and possible eligibility for exclusion by the deadline is to flag far more data than will eventually be eligible for exclusion. Another problem is that some of the data that may be used for final designations may not be collected and submitted to EPA until later than one year before the final designation decision, making it impossible to flag that data one year before the decision. When Section 50.14 was revised to add these deadlines in March 2007, EPA was mindful that designations were needed under the recently revised PM$_{2.5}$ NAAQS, and so exceptions to the generic deadline were included for PM$_{2.5}$ only.

The EPA was also mindful that similar issues would arise for subsequent new or revised NAAQS. The Exceptional Events Rule at section 51.14(c)(2)(v) indicates ''when EPA sets a NAAQS for a new pollutant, or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging data for initial designation of areas for those 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 is available), and thus will depend in part on air quality data collected as late as December 2010 (or December 2009). (See Section VI below for 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 involve only changes in submission dates for information regarding claimed exceptional events affecting Pb data. In the proposed rule text at the end of this notice, only the changes that would apply if designations are made three years after promulgation are shown; where a deadline would be different if designations were made at the two-year point, the difference in deadline is noted in the description immediately below. We propose 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

extension includes 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 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 data from 2008, and would thus be July 1, 2009. This would allow a State time following the September 2008 promulgation of the revised Pb NAAQS to consider what data it wishes to flag and to submit those flags. The Governor of a State would be required to submit designation recommendations to EPA in September 2009, and would therefore know what 2008 data have been flagged when formulating those recommendations.

For data collected in 2010 (or 2009), we propose 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 proposes 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 proposes 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 proposes to make the deadline for submission of justifications be May 1, 2010. Table 8 summarizes the proposed three year designation deadlines discussed in this section, and Table 9 summarizes the two year designation deadlines.

TABLE 8.—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 9.—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*.
2009	May 1, 2010*	May 1, 2010*.

* Indicates proposed change from generic schedule in 40 CFR 50.14.

EPA invites comment on these proposed changes in the exceptional event flagging and documentation submission deadlines.

V. Proposed Amendments to Ambient Monitoring and Reporting Requirements

As part of our proposal to revise and implement the Pb NAAQS, we are proposing several changes to the ambient air monitoring and reporting requirements for Pb. Ambient Pb monitoring data are used to determine whether an area is in violation of the Pb 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 explains aspects of the existing Pb monitoring and reporting requirements as background and discusses the changes we are proposing to support the changes being proposed in the Pb NAAQS and other options for the NAAQS on which EPA is inviting comments, discussed above in section II.E. These aspects include 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 proposing changes to the sampling and analysis methods for the Pb monitoring network. Specifically, we are proposing a new Federal Reference Method (FRM) for Pb in PM_{10} (Pb-PM_{10}) and revised Federal Equivalent Method (FEM) criteria. We are maintaining the

current FRM for Pb in TSP (Pb-TSP) and lowering the Pb concentration range required during Pb-TSP and Pb-PM_{10} candidate FEM comparability testing. The following sections provide background, rationale, and details for the proposed changes to the sampling and analysis methods.

1. Background

Lead monitoring data must be collected and analyzed using FRM or FEM methods in order to be comparable to the NAAQS. 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 part 50, Appendix G). There are 21 FEMs currently approved for Pb-TSP [160]. All 21 FEMs are based on the use of high-volume TSP samplers and a variety of approved equivalent analysis methods.[161]

Concerns have been raised over the use of the high-volume TSP samplers to collect samples for subsequent Pb analysis. It is known that the high-volume TSP sampler's particulate matter capture efficiency varies as a function of wind speed and wind direction due to the non-symmetrical inlet design and the lack of an integral particle separator. Early evaluations of the high-volume TSP sampler

demonstrated that the sampler's 50% collection efficiency cutpoint can vary between 25 and 50 µm depending on wind speed and direction (Wedding *et al.*, 1977, McFarland and Rodes, 1979). More recently, a study was conducted during the last Pb NAAQS review to evaluate the effect of wind speed and direction on sampler efficiency (Purdue, 1988). This study showed that despite the effect of wind speed and wind direction on the sampler's collection efficiency for larger particles, for particle distributions typical of those near industrial sources the overall Pb collection efficiency of the high-volume TSP sampler ranged from 80% to 90% over a wide range of wind speeds and directions.

CASAC commented in the context of their review of the Staff Paper that TSP samplers have poor precision, that the upper particle cut size of TSP samplers varies widely as a function of wind speed and direction, and that the spatial non-homogeneity of very coarse particles cannot be efficiently captured by a national monitoring network (Henderson, 2007a, Henderson, 2008). For these reasons, CASAC recommended considering a revision to the Pb reference method to allow sample collection using low-volume PM_{10} samplers.[162]

As part of preparing the ANPR for this rulemaking, we performed and reported in the ANPR the results of an analysis of the precision and bias of the high-volume TSP sampler based on Pb-TSP

[160] For a list of currently approved FRM/FEMs for Pb-TSP refer to: *http://www.epa.gov/ttn/amtic/criteria.html.*

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

[162] PM_{10} can be measured with either a "low-volume" or a "high-volume" sampler. CASAC specifically recommended the low-volume sampler, for reasons explained here and in section II.E.1.

data reported to AQS for collocated samplers and the results of in-field sampler flow audits and laboratory audits for lead (Camalier and Rice, 2007). The average precision of the high-volume Pb-TSP sampler was approximately 12% with a standard deviation of 19% and average sampling bias (based on flow audits) was -0.7% with a standard deviation of 4.2%. The average bias for the lab analyses of Pb-spiked audit strips was -1.1% with a standard deviation of 5.5%. Total bias, which includes bias from both sampling and laboratory analysis, was estimated at -1.7% with a standard deviation of 3.4%. These findings are specific for the times and sites of the sampling, including the nature and total quantity of TSP and Pb-TSP that prevailed during the sampling, and may not be indicative of the TSP FRM performance in other places. Also, we did not investigate to determine whether the physical arrangement of the collocated samplers was such as to provide a good test of sensitivity to wind speed and wind direction.[163] However, we note that at face value these bias and precision results are not greatly different than has historically been considered acceptable for other criteria pollutants.

The CASAC and some public comments on the ANPR again stressed concerns with the use of the high-volume TSP sampler and a strong interest in moving to a low-volume Pb-PM_{10} sampler. The CASAC reiterated the disadvantages of retaining TSP and of utilizing it as the "gold standard" against which new and better technologies are compared (Henderson 2008). On March 25, 2008, the AAMM Subcommittee of CASAC and EPA staff conducted a consultation by conference call, at which the subcommittee members confirmed and elaborated on the views CASAC expressed in their comments on the ANPR. Public comments were also generally supportive of moving away from the current high-volume PM sampling technology and moving toward modern, sequential, low-volume PM_{10} monitors, especially if sampling frequencies are increased. On the other hand, several monitoring agencies cautioned against moving to Pb-PM_{10} as the indicator because samplers for Pb-PM_{10} would miss much of the Pb in the atmosphere especially near Pb sources.

CASAC recommended that Pb-PM_{10} be measured with low-cost, multi-element analysis methods with improved detection limits (e.g., x-ray fluorescence, XRF) for measuring concentrations typical of today's ambient air. One public commenter suggested that the MDL be significantly reduced to enable measurement of average Pb levels of 0.08 µg/m³ or below.

The current post-sampling FRM analysis method for Pb-TSP is atomic absorption (AA) spectrometry. A typical or nominal lower detectable limit (LDL) for Pb, for high-volume sample collection followed by AA analysis, stated in the FRM regulation in Appendix G to Part 50 for informational purposes only, is 0.07 µg/m³. This value was calculated by doubling the between-laboratory standard deviation obtained for the lowest measurable lead concentration (Long 1979). This value can be considered a conservative (i.e., upper bound) estimate of the sensitivity for the AA method currently used by air monitoring laboratories, as evidence by the fact that data obtained from AQS includes reported locally determined MDL values for the AA FRM that are well below 0.07 µg/m³ (typically 0.01 (g/m³ or below).

One estimate of the method detection limit (MDL) for AA analysis of a low-volume sample of either Pb-PM_{10} or Pb-TSP, taking into account the nominal LDL of 0.07 µg/m³ (or 140 µg/L), and the smaller sample volume, extraction volume, and filter size for low-volume sampling, is about 0.12 µg/m³ (see Table 10). Assuming an LDL of 0.01 (g/m³ for TSP sampling, the MDL for low-volume sampling would be about 0.02 (g/m³. Other Pb-TSP FEM analysis methods currently used with the high-volume sampling method, such as XRF, inductively coupled plasma mass spectrometry (ICP/MS) and graphite furnace atomic absorption (GFAA) are more sensitive than AA analysis, and are clearly sensitive enough to support low-volume sampling and a reduced NAAQS level.

2. Proposed Changes

As discussed in Section II.E.3 of this preamble, after considering the CASAC and public comments on monitoring issues, we are proposing to retain Pb-TSP, as measured by the FRM method specified in 40 CFR part 50, appendix G (which cross references appendix B, the specification of the TSP FRM) as the indicator for the Pb standard, and to invite comment on a second option which would instead make Pb-PM_{10} measured by a low-volume monitor the indicator. We further propose that

monitoring agencies should be given the option to use adjusted or scaled low-volume Pb-PM_{10} monitoring data as a surrogate for Pb-TSP data. Details on how this option would work are discussed in the data handling section of this preamble (section IV). Also, in section IV.B we are inviting comment on whether, if low-volume Pb-PM_{10} is selected as the indicator, Pb-TSP data with an adjustment should be useable as a surrogate for Pb-PM_{10} data for the specific purpose of initial designations under the revised standard. In this section, we discuss the Pb-TSP and Pb-PM_{10} sampling and analysis issues themselves and propose approaches for these issues, as these issues are relevant to the use of data from each method directly or as surrogates for the other.

a. TSP Sampling Method

If the final standard is based on Pb-TSP we believe it is appropriate to continue to allow, although perhaps not to encourage, the use of the current high-volume FRM for measuring Pb-TSP. The selection of Pb-TSP as the NAAQS indicator would depend on a conclusion that the precision, bias, and MDL (discussed above) of the TSP sampler is adequate for continued use in the Pb monitoring network, including a conclusion that although the TSP sampler's size selection performance is affected by wind speed and wind direction, we do not believe that this effect is so significant as to prevent the continued use of this sampler in the Pb network. EPA proposes to make several minor clarifying changes in Appendix G to correct long-standing errors in reference citations. We are not proposing any other substantive changes to Appendix G.

However, we also believe that low-volume Pb-TSP samplers might be superior to high-volume TSP samplers. 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. A low-volume Pb-TSP monitoring system (including an analytical method for Pb) can in principle be designated as a FEM Pb-TSP monitor, if side-by-side testing is performed as prescribed by 40 CFR 53.33. We are proposing amendments to this CFR section, described below, to make such testing more practical and to clarify that both high-volume and low-volume TSP methods may use this route to FEM status. Note that the terms of the revised FEM procedures can also be used to obtain FEM status for Pb-PM_{10} samplers.

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[163] If the collocated TSP samplers were always oriented in the same direction, they would be exposed to the same wind speed and wind direction, and the appearance of good precision between them would not necessarily be indicative of the sensitivity of Pb-TSP measurements to wind speed and wind direction.

b. PM_{10} Sampling Method

If the final standard is based on Pb-PM_{10}, or if the final rule for a standard based on Pb-TSP includes an option to monitor Pb-PM_{10} instead of Pb-TSP, we will need to promulgate both an FRM for measuring Pb-PM_{10} and an appropriate set of FEM criteria. Accordingly, we are proposing new FRM and FEM criteria for measuring Pb-PM_{10}. The proposed FRM for Pb-PM_{10} can be broken down into two parts: (1) the sampling method (i.e., the procedures and apparatus used for collecting PM_{10} on a filter) and (2) the analysis method (i.e., the procedures and apparatus used to analyze the collected particulate matter for Pb content).

Currently, the FRM specification for PM_{10} monitoring, Appendix J to 40 CFR Part 50, is based on a performance test and does not specify whether a sampler is high-volume or low-volume. Early commercialized samplers were high-volume, but more recently a number of low-volume PM_{10} samplers have received FRM approvals. To be certain that Pb-PM_{10} monitoring is conducted with low-volume samplers without specifying the use of particular sampler brands or models, it is necessary to establish a new FRM specification for low-volume PM_{10} samplers. There is a recently promulgated FRM for particulate matter with aerodynamic diameter between 2.5 and 10 microns ($PM_{10-2.5}$) (Appendix O to 40 CFR part 50) that is based on a pair of low-volume samplers for $PM_{2.5}$ and PM_{10} to provide a $PM_{10-2.5}$ concentration by difference. We are proposing to create a FRM for Pb-PM_{10} sampling by cross-referencing to the specification for the PM_{10} sampler in this paired FRM (referred to as the PM_{10C} sampler, where the ''C'' refers to the use of this PM_{10}

sampler as part of a pair for measuring coarse PM). We are proposing to use the low-volume PM_{10C} sampler for the FRM for Pb-PM_{10} rather than the existing PM_{10} FRM specified by appendix J, for several reasons. Appendix J to part 50 has resulted in the designation of both high-volume and low-volume PM_{10} samplers as FRM for PM_{10}. We believe high-volume PM_{10} sampling should not be used to measure Pb-PM_{10} under a revised Pb standard. A low-volume PM_{10C} FRM sampler must meet more demanding performance criteria than is required for PM_{10} samplers in general in Appendix J. We note the current availability of samplers that meet these more demanding performance criteria (already in use for $PM_{2.5}$ and $PM_{10-2.5}$ sampling) that are equipped with sequential sampling capabilities (i.e., the ability to schedule multiple samples between operator visits, which is desirable if the proposed sampling frequency requirements are increased to support a monthly averaging form of Pb NAAQS). The geometry of commercial high-volume PM_{10} samplers makes sequential sampling with a single sampler impossible. The low-volume sampler also precisely maintains 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-PM_{10} 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 PM_{10} 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 (Henderson 2007a, Henderson 2008, Russell 2008).

Low-volume Pb-PM_{10} samplers and the data systems that they connect to can be configured to report concentrations corrected to standard conditions of temperature and pressure or based on local conditions of temperature and pressure. We are proposing that the FRM for samplers used to collect Pb data specify reporting of concentrations based on local conditions, for a few reasons. The actual concentration of Pb in the atmosphere is a better indicator of the potential for deposition than the concentration based on standard pressure and temperature. In addition, there are practical advantages to moving to local conditions since the FRM for both $PM_{2.5}$ and $PM_{10-2.5}$ are also based on local conditions.

c. Analysis Method

There are several potential analysis methods for a Pb-PM_{10} FRM. Atomic absorption (AA) is the analysis method for the current Pb-TSP FRM. In addition, there are several other analysis methods (e.g., XRF, ICP/MS) approved as FEMs for the measurement of Pb-TSP. Table 10 summarizes the estimated MDLs for the analysis methods considered in developing the proposed FRM for Pb-PM_{10}. The estimated MDLs are based on published instrument detection limits and LDLs, which typically take into account only instrument signal-to-noise ratios and laboratory-related variability but not variability related to sample collection and handling. It is important to note that the MDLs in Table 10 are estimates and these values will vary as a function of the specific instrument used, detector age, instrument signal-to-noise level, etc., and therefore, MDLs must be determined for the specific instrument used.

TABLE 10.—SUMMARY OF CANDIDATE ANALYSIS METHOD DETECTION LIMITS FOR A PB-PM_{10} FRM OR FEM WITH LOW-VOLUME SAMPLE COLLECTION

Analysis method	Estimated DLs [a]	Estimated MDL [b] ($\mu g/m^3$)
Atomic Absorption (AA)	0.07 $\mu g/m^3$ [c]	0.12 [f]
	0.01 $\mu g/m^3$ [d]	0.02 [f]
X-Ray Fluorescence (XRF)	1.5 ng/cm^2 [e]	0.001 [g]
Graphite Furnace Atomic Absorption (GFAA)	0.05 $\mu g/L$ [h]	0.00004 [f]
Inductively Coupled Plasma/Mass Spectrometry (ICP/MS)	0.08 $\mu g/L$ [e]	0.00006 [f]

[a] Detection limits (DLs) found in available literature as provided in footnotes below.

[b] Estimated MDLs determined using estimated DL, extraction volume, and sample volume as noted in footnotes provided.

[c] The lower detectable limit (LDL) for Pb-TSP taken from Appendix G to Part 50 based on $2400m^3$ sample volume, 0.10L extraction volume, and 12 strips per filter.

[d] Based on MDLs reported in AQS.

[e] DL expressed as nanogram per square centimeter of filter surface is taken from the Compendium of Methods for the Determination of Inorganic Compounds in Ambient Air (USEPA, 1999).

[f] Based on 46.2-mm filter extraction volume of 0.020 L and sample volume of 24 m^3 of air.

[g] Based on 46.2-mm filter area of 11.86 cm^2 and sample volume of 24 m^3 of air.

[h] Taken from the Perkin Elmer Guide to Atomic Spectroscopy Techniques and Applications (Perkin Elmer, 2000).

One disadvantage of the low-volume sampler is that the total mass of the PM_{10} sample collected is significantly lower than that of the high-volume sampler due to the lower volume of air sampled (24 m³ per 24 hours for the low-volume sampler versus. over 1500 m³ per 24 hours for a high-volume sampler). The lower mass of sample collected results in higher MDLs for any given analysis method when coupled with the low-volume sampler. As can be seen in Table 10, even assuming the smaller LDL reported to AQS for recent sampling, the estimated MDL for atomic absorption (the current FRM analysis method for Pb-TSP) when coupled with low-volume sampling is the highest (least sensitive) of all potential methods for use as an FRM/FEM method for Pb-PM_{10}.

AA, GFAA, and ICP/MS are destructive methods and require solvent extractions that possibly involve the use of strong acids to adequately extract Pb from the collected PM for analysis. The specific extraction solutions and methods are selected and optimized in order to meet the required extraction efficiency for a measurement program. Both methods are destructive, meaning that the sample collected on the filter is destroyed during analysis. These methods also have higher analysis costs relative to XRF.

While XRF, GFAA, and ICP/MS all have more than adequate MDLs to support a reduced NAAQS level, we believe that the XRF analysis method has several advantages which make it a desirable analysis method to specify as the FRM. 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 analysis or re-analysis if needed. XRF analysis is a cost-effective approach that could be used at the option of the monitoring agency 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 $PM_{2.5}$ speciation monitoring networks and for the mostly rural visibility monitoring program in Class I visibility areas, and is being considered for the $PM_{10-2.5}$ coarse speciation monitoring network that will be implemented by monitoring agencies as part of the NCore multi-pollutant network. The XRF analysis method should have acceptable precision, bias, and MDL for use as the FRM for Pb-PM_{10} when coupled with the low-volume PM_{10} sampler. Finally, CASAC recommended the use of XRF as a low-cost and sensitive analysis

method for the FRM (Henderson 2007a, Henderson 2008). For these reasons, we are proposing to base the analysis method for the proposed Pb-PM_{10} FRM on XRF.

d. FEM Criteria

The FEM criteria provide for approval of candidate methods that employ an alternative analysis method for Pb, an alternative sampler, or both.

The proposed Pb-PM_{10} FRM is based on the low-volume PM_{10c} sampler and XRF analysis. Under the proposed revisions to 40 CFR 53.33, Pb-PM_{10} data from any candidate FEM using an alternative sampler would be compared to side-by-side data from the low-volume PM_{10c} FRM sampler. An FEM candidate using only an alternative analysis method would be evaluated by collecting paired filters from paired low-volume PM_{10c} FRM samplers, and analyzing one filter of each pair with XRF and the other filter with the candidate method.

As mentioned above, there are other analysis methods commonly used which are also expected to meet the precision, bias, and MDLs necessary to be used in the Pb surveillance monitoring network (e.g., GFAA and ICP/MS). These analysis methods would be compared to the proposed XRF method and would be approvable as FEMs through the performance testing requirements outlined in regulation § 53.33 of 40 CFR part 53, subpart C. Several of these requirements need revisions for consistency with a potentially lowered Pb NAAQS and for the potential addition of a Pb-PM_{10} FRM. The following paragraphs describe the aspects of the FEM criteria that we are proposing to revise.

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 µg/m³. 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 µg/m³. In addition, the Agency is proposing to lower the Pb NAAQS level to between 0.10 and 0.30 µg/m³. As such, we are proposing to revise the Pb concentration requirements for candidate FEM testing to a range of 30% of the NAAQS to 250% of the NAAQS in µg/m³. For example, if the level of the Pb NAAQS is finalized at 0.20 µg/m³, the ambient concentrations that would be required for FEM testing would have to range between 0.06 µg/m³ to 0.50 µg/m³. The requirements were changed from actual concentration values to percentages of

the NAAQS to allow the FEM text to remain appropriate if subsequent changes to NAAQS levels occur in the future.

The current FEM requirements state that the maximum precision and accuracy for candidate analytical methods must be 15% and 5% respectively. No changes are proposed for these requirements. Based on the results for the current high-volume Pb-TSP precision and bias (Camalier and Rice, 2007), these requirement seem reasonable for the proposed FEM requirements. 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 are proposing to add a requirement that as part of the testing of a candidate FEM, the applicant must demonstrate that the MDL of the method is less than 1% of the level of Pb NAAQS. We believe this MDL requirement will ensure that FEM methods will have enough sensitivity to detect Pb concentrations much less than the proposed NAAQS level, but will not unnecessarily restrict methods which could be used to provide data sufficient for the purpose of determining compliance with the NAAQS. Subsequent users of a previously approved FEM would not be required to demonstrate the MDL of the method as implemented in their laboratories, but EPA plans to encourage them to do so periodically as a good quality assurance practice.

The existing FEM requirements require that audit samples (the known concentration or reference samples provided on request by EPA used to verify the accuracy with which a laboratory conducts the FRM analytical procedure before it may begin comparing the FRM to the candidate FEM) be analyzed at levels that are equal to 100, 300, and 750 µg per spiked filter strip (equivalent to 0.5, 1.5, and 3.75 µg/m³ of sampled air). We are proposing to revise the levels of the audit concentrations to percentages (30%, 100% and 250%) of the Pb NAAQS to provide for reduced audit concentrations for a lowered NAAQS. These percentages are roughly equivalent to the percentages of the current NAAQS level (1.5 µg/m³) used to set the spiked filter strip audit concentrations provided above in the original FEM regulation.

The existing FEM requirements are based on the high-volume TSP sampler, and as such, refer to ¾ x 8-inch glass fiber strips. In order to also accommodate the use of low-volume sample filters, we are proposing to add references to 46.2-mm sample filters

where appropriate. Pairs of these filters will be collected by a pair of FRM samplers, so that there is no need to cut the 46.2 mm filters into two parts before analysis.

e. Quality Assurance

Modifications are needed 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. Paragraph 3.3.4 specifies requirements for annual flow rate audits for TSP samplers used in Pb monitoring and Pb strip audits for laboratories performing analysis of TSP filters for Pb. Other QA requirements specified in paragraph 3.3.1 for all TSP samplers are also applicable to Pb-TSP samplers. As part of the overall Pb NAAQS review, it is appropriate to revise these requirements to consolidate all the QA requirements for Pb monitoring in paragraph 3.3.4, to add provisions specific for Pb-PM$_{10}$ measurements and to eliminate cross references to the general TSP provisions. The following paragraphs detail the QA requirements we are proposing to change.

The collocation requirement for all TSP samplers (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); as such, no changes are needed to accommodate low-volume Pb-PM$_{10}$. However, to clarify that this requirement also applies to Pb monitoring we are proposing to add a reference to this requirement in paragraph 3.3.4.

The sampler flow rate verifications requirement (paragraph 3.3.2) for low-volume PM$_{10}$ and for TSP are at different intervals. While this appears appropriate and no change is needed, to clarify that this requirement also applies to Pb monitoring we are proposing 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 are proposing to correct this error. Also, we are proposing to change the references to the Pb FRM to include the proposed Pb-PM$_{10}$ FRM.

Paragraph 3.3.4.2 discusses the audit procedures for the lead analysis method. This section assumes the use of a high-volume TSP sampler, and we are proposing edits to account for the proposed Pb-PM$_{10}$ FRM. In addition, the audit concentration ranges will not be appropriate if the NAAQS is lowered.

We are proposing to lower the audit ranges for Pb-TSP from the current range of 0.5–1.5 µg/m³ to a range from 30–100% of the proposed Pb NAAQS level for the low concentration audit and from 3.0–5.0 µg/m³ to 200–300% of the proposed NAAQS for the higher concentration audit standard. The requirements would also be changed from specific concentration value-based ranges to ranges based on the percentages of the NAAQS to allow these QA requirements to remain appropriate if changes to NAAQS levels occur during future reviews.

Unlike the PM$_{2.5}$ and PM$_{10–2.5}$ Performance Evaluation Program (PEP), the existing QA program requirements for Pb monitoring do not include a requirement for the collection of data appropriate for making an independent estimate of the overall sampling and analysis bias. We are proposing to require one PEP-like audit at one site within each primary quality assurance organization (PQAO) once per year. We are also proposing 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. The independent measurement on one filter from each pair would be compared to the monitoring agency's regular laboratory's measurement on the other filter of the pair, to allow estimation of any bias in the regular laboratory's measurements. EPA believes that the combination of the PEP data and the independent collocation data will be enough to provide a reasonable assessment of overall bias and data comparability on a PQAO basis over the designation period. As currently is the case for PEP auditing of PM$_{2.5}$ and PM$_{10–2.5}$ monitoring sites, it would be the responsibility of each State to ensure that Pb PEP testing and collocation testing as described here is performed as required. EPA plans to consult with monitoring agencies after completion of this rulemaking as to whether a centrally run program managed by EPA and funded with State and Tribal Assistance Grant funds would be a more efficient and preferred alternative than individual State-managed programs.

B. Network Design

As a result of this Pb NAAQS review and the proposed tightening of the standards, EPA recognizes that the current network design requirements are inadequate to assess compliance and determine the extent of all the areas that may violate the revised NAAQS. As such, we are proposing new network design requirements for the Pb NAAQS surveillance network. The following

sections provide background, rationale, and details for the proposed changes to the Pb network design requirements.

1. Background

The once large Pb surveillance network of FRM samplers for Pb-TSP has decreased substantially over the last few decades. In 1980 there were over 900 Pb surveillance sites. This number has been reduced to approximately 200 sites today. These reductions were made because of substantially reduced ambient Pb concentrations causing monitoring agencies to shift priorities to other criteria pollutants including PM$_{2.5}$ and ozone which were believed to pose a greater health risk. As a result of these reductions, many states currently have no ambient air Pb monitors resulting in large portions of the country with no data on current ambient Pb air concentrations. In addition, many of the largest Pb emitting sources in the country do not have nearby ambient Pb air monitors.

There is also a smaller network, the National Air Toxics Trends Stations network, of 27 monitoring sites measuring Pb-PM$_{10}$. Some of these use a high-volume PM$_{10}$ sampler to collect the particulate matter and some use a low-volume PM$_{10}$ sampler. Most are in urban areas.

The current network design requirements for Pb monitoring are given in 40 CFR part 58 appendix D section 4.5. The current minimum network design requirements are for two Federal Reference Method (FRM) or Federal Equivalent Method (FEM) sites in any area where Pb concentrations exceed or have exceeded the NAAQS in the most recent two years. These current minimum monitoring requirements cannot be relied upon to cause monitoring agencies to fill the existing gaps in the current network, and if they are not revised it will be difficult to develop the necessary network to properly evaluate ambient air concentrations during the designation process, especially if the NAAQS is finalized at a significantly lower level than the current standard.

For these reasons, EPA indicated in the Advanced Notice of Proposed Rulemaking (72 FR 71488) that the existing Pb NAAQS surveillance network may not be adequate for a lowered Pb NAAQS, and that if the NAAQS is substantially lowered as proposed additional monitoring sites would be needed to provide estimates of ambient Pb air concentrations near Pb emission sources and for characterizing ambient air concentrations in large urban areas. Comments received from CASAC and other public commenters

on the ANPR stated that the Pb surveillance network should be expanded in order to provide better coverage of Pb emission sources and to better understand population exposures to Pb from ambient air. After considering these comments and evaluating the existing network, EPA is proposing changes to the network as described below.

2. Proposed Changes

We are proposing 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 population exposure to Pb in large urban areas. The following paragraphs provide the rationale and details for the proposed changes.

The primary objective of the Pb monitoring network is to provide data on the ambient Pb air concentrations in areas where there is the potential for a violation of the NAAQS. Ambient Pb concentrations have dropped dramatically in most urban areas due to the elimination of Pb in gasoline. However, based on our analysis of the ambient Pb data, relatively large sources of Pb continue to have the potential to cause ambient air concentrations in excess of the proposed NAAQS (EPA, 2007c). Furthermore, it appears, based on the limited network still operating, that violations of the proposed range for the revised NAAQS levels are likely to exist only near such sources of Pb emissions, with lower levels of Pb away from such sources. Accordingly, we are proposing to require monitoring near Pb emission sources such as Pb smelters, metallurgical operations, battery manufacturing, and other source categories that emit Pb. By implementing the NAAQS through a source-oriented monitoring network, Pb concentrations will be kept below the NAAQS level for those living near these sources and for those living farther away.

The 2002 National Emissions Inventory (NEI) lists over 13,000 sources of Pb, with emission rates from as low as 1 pound to nearly 60 tons per year (according to the NEI 90% of lead sources emit less than 0.1 tpy). It is not practical to conduct monitoring at every Pb emission source, nor is it likely that very small Pb emission sources will cause ambient concentrations to exceed the proposed NAAQS. Therefore, it is appropriate to limit the source oriented monitoring requirement to emission sources that may have the potential to result in ambient air concentrations in excess of the proposed NAAQS.

We are proposing that monitoring be presumptively required at sources that have Pb emissions (as identified in the latest NEI or by other scientifically justifiable methods and data) that exceed a Pb "emissions threshold." This monitoring requirement would apply not only to existing industrial sources of lead, but also to fugitive sources of lead (e.g., mine tailing piles, closed industrial facilities) and airports where leaded aviation gas is used. In this context, the emissions threshold is the Pb emission rate for a source that may reasonably be expected to result in ambient air concentrations in excess of the proposed Pb NAAQS. We conducted an analysis to estimate the appropriate emission threshold (Cavender 2008b) which is available in the docket for this rulemaking. In this analysis, four different methods were used for calculating an appropriate threshold emissions rate based on the candidate NAAQS level. The arithmetic mean of the four methods suggests a maximum emission impact of 0.5 µg/m³ per 1,000 kg Pb emitted per year. Using the results from this analysis, we propose 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). We are proposing a range for the emission threshold since we are proposing a range for the level of the standard. If the final NAAQS is set at 0.10 µg/m³, we would set the emission threshold at 200 kg per year. Conversely, if the final NAAQS is set at 0.30 µg/m³, we would set the emission threshold at 600 kg per year. We solicit comments on the various methods for calculating emission rate thresholds, as well as using the arithmetic mean of these results in choosing the appropriate threshold for designing the monitoring network.

We recognize 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). As such, we are also proposing to allow monitoring agencies to petition the EPA Regional Administrator to waive this requirement for a source that emits less than 1 ton per year where it can be shown (by demonstrating actual emissions are less than the threshold, through modeling, historical monitoring data, or other means) that a source will not cause ambient air concentrations to exceed 50% of the NAAQS during a three year period. We are proposing that for facilities identified as emitting more than 1 tpy in the NEI, a waiver is possible only by demonstrating that

actual emissions are less than the emissions threshold. By requiring every source actually emitting more than 1 tpy to be monitored, we will avoid the possibility that faulty or uncertain modeling demonstrations or past monitoring programs would be the basis for not monitoring sources that are the most likely to cause NAAQS violations.

We seek comments on the appropriateness of requiring monitoring near Pb emissions sources and the proposed emission rate threshold. We also seek comments on the appropriateness of allowing monitoring agencies to seek waivers from this requirement and the upper emission threshold level at which waivers should no longer be allowed.

The required source-oriented monitors shall be located at sites of maximum impact and will be classified primarily as microscale monitors representative of small hot-spot areas adjacent or nearly adjacent to facility fence-lines. EPA takes comment on this monitoring requirement and whether monitors should only be placed in areas which are population-oriented. In some cases, source-oriented monitors may be representative of somewhat bigger areas due to the orientation of sources with respect to areas with locations appropriate for ambient monitoring. In these cases, the source-oriented monitors may be classified as middle-scale, but should still represent the locations where maximum Pb concentrations around a facility are expected to occur, consistent with applicable siting regulations and the outputs of quantitative tools (e.g., dispersion modeling) used to determine maximum impacts.

We are proposing to require a small network of nonsource-oriented monitors in urban areas in addition to the source oriented monitors discussed above, in order to gather information on the general population exposure to Pb in ambient air. While it is expected that these nonsource-oriented monitors will show lower concentrations than source oriented monitors, data from these nonsource-oriented monitors will be helpful in understanding the risk posed by Pb to the general population. Data from these monitors will also be useful in determining impacts on Pb concentrations from re-entrained roadway dust, construction and demolition projects, other nonpoint area sources; and in determining the spatial variation in Pb concentrations between areas that are and are not source impacted. Such data on spatial variations within an urban area could assist with the determination of non-attainment boundaries.

We are proposing to require one nonsource-oriented monitor in each Core Base Statistical Area (CBSA, as defined by the Office of Management and Budget)[164] 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, 50 CBSAs would be required to have nonsource-oriented population monitors. We request comments on the appropriateness of requiring nonsource-oriented monitors and the proposed population threshold of 1,000,000 people for this requirement.

Lead concentrations near roadways are not well understood at this time. The Pb critieria document discussed data for the South Coast Air Quality Management District where a modeling effort suggested that Pb deposited during the years when leaded gasoline was used could be a significant portion of their ambient Pb inventory. However, this work was conducted in an area of the country where quarterly average Pb-TSP concentrations are considerably less than 0.1 µg/m³. We analyzed ambient air Pb concentrations near a number of large roadways (Cavender 2008). Based on this analysis it appears unlikely that roadways will result in ambient Pb air concentrations in excess of the lowest Pb NAAQS level being proposed in this action. In addition, members of the CASAC AAMM Subcommittee agreed that a separate monitoring requirement for roadways was unnecessary based on the results of this analysis. As such, the proposed regulatory text does not include a requirement for Pb monitoring near roadways. We do, however, propose to allow monitoring near roadways to satisfy the requirements of the nonsource-oriented monitoring requirement discussed above. For example, a monitoring agency could place a monitor in a CBSA with a population greater than one million and locate that monitor nearly adjacent to a major roadway in a populated area. That monitor would satisfy the nonsource-oriented requirements while also gathering data on possible roadway exposure. We request comments on the need for monitoring near roadways and the appropriateness of allowing near roadway monitoring to be used to satisfy the requirement for nonsource-oriented monitoring.

Monitoring agencies would need to install new Pb monitoring sites as a result of these proposed revisions to the Pb monitoring requirements. We are

164 For the complete definition of CBSA refer to: *http://www.census.gov/population/www/estimates/aboutmetro.html.*

estimating that the size of the required Pb network will range from 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 are proposing 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 (16 months after the court-ordered deadline for promulgation of the final Pb NAAQS revision) 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 nonsource-oriented monitors being installed in the second year. The annual network plan due on July 1, 2009 would need to include the plan and schedule for installation and operation of the newly required Pb monitoring sites necessary to comply with these proposed requirements. We are also proposing 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. Monitoring agencies would be required to identify and propose new Pb monitoring sites as part of their annual network plan required under 40 CFR 58.10. We invite comments on the need for a staggered network deployment.

The type of monitor that must be used at these required monitoring sites will depend on whether for a final revised NAAQS based on Pb-TSP scaled monitoring data for Pb-PM$_{10}$ may be used as a surrogate. If cross-use of data is permitted, then either type of monitor could be used at a required monitoring site. EPA intends to encourage a relatively small number of sites to operate both types of monitors. The proposed appendix R (see section IV) explains how data would be selected for purposes of NAAQS compliance determinations if both types of monitors operate in the same month or quarter. One approach on which EPA is seeking comment would be to change the Pb indicator to Pb-PM$_{10}$ and allow the use of Pb-TSP data only for the purpose of initial designations. If this approach is adopted, a Pb-TSP monitor could not be used in lieu of a Pb-PM$_{10}$ sampler at a required monitoring site after the area containing the monitoring site had received its initial designation (see

section VI for an explanation of the anticipated designation schedule).

If the final Pb standard is based on Pb-TSP, the July 1, 2009 monitoring plan would be required to designate which Pb-PM$_{10}$ monitoring sites, if any, are source-oriented, so that this designation can be available for public comment and can be reviewed by the EPA Regional Administrator. This site designation information is needed to determine scaling factors for the Pb concentration data from these Pb-PM$_{10}$ monitoring sites (see section IV). Sites that are counted towards meeting the required number of source-oriented monitoring sites should of course be designated as source-oriented. It may be appropriate to designate other sites as source-oriented also. Because sources may come and go, or be newly discovered, the revised 40 CFR 58.10 requires the monitoring agency to consider whether revisions in site designations are needed as part of the preparation of each year's monitoring plan.

C. Sampling Schedule

We are proposing to increase the sampling frequency if the final Pb NAAQS is based on a monthly averaging form. Specifically, we are proposing to increase the sampling frequency to require one 24-hour sample taken every 3 days (referred to as ''1 in 3 day sampling'') if the final Pb NAAQS is based on a monthly average. The remainder of this section provides background, rationale, and details for the proposed changes to the Pb sampling frequency.

1. Background

The current required sampling frequency requirement for Pb is one 24-hour sample every six days (40 CFR 58.12(b)). For the current form of the NAAQS that is based on a quarterly average, the 1-in-6 day sampling schedule yields 15 samples per quarter on average with 100% completeness, or 12 samples with 75% completeness. A change to a monthly averaging period would result in between 4 and 6 samples per month at the current sampling frequency with 100% completeness, or between 3 and 5 samples with 75% completeness.

In the ANPR, we indicated that if we changed the averaging time to a monthly average, we would need to consider increasing the required sampling frequency from 1-in-6 days since 3 to 5 samples would likely not result in a reasonably confident estimate of the actual air quality for the period. We suggested several alternatives which included increasing the sampling frequency to 1-in-3 day, or increasing

the sampling frequency to 1-in-1 day sampling (i.e., every day sampling). In addition, we suggested an option that relates sampling frequency to recent ambient Pb-TSP concentrations, such that an increased sampling frequency is required as the recent ambient Pb-TSP concentration approaches the NAAQS level. In addition, we sought comments on several practices that would help to reduce the burden associated with more frequent sampling including:

• Increasing sampling time duration (e.g., changing from a 24-hour sampling time duration to a 48-hour or 72-hour sampling time duration),

• Allowing for compositing of samples (i.e., extracting and analyzing several sequential samples together), and

• Allowing for multiple samplers at one site.

In CASAC's comments on the ANPR, they recommended increasing the sampling frequency to 1-in-3 day sampling, or higher. They discouraged increasing the sample duration and the allowance for compositing of samples, as these practices would reduce the ability to use the samples in source apportionment techniques that may be useful in identifying what sources contributed to the ambient air Pb concentrations.

2. Proposed Changes

We propose increasing the sampling frequency to 1-in-3 day sampling if we change the form of the revised NAAQS to a monthly average in the final rule. A 1-in-3 day sampling frequency would yield 9 or 10 samples per month on average at 100% completeness. At 75% completeness, a 1-in-3 day sampling frequency would yield 7 or 8 samples per month at a minimum.

We recognize that at concentrations considerably below the level of the NAAQS there is less potential to misclassify an area due to the error resulting from less than complete sampling. We believe it is appropriate to allow for less frequent sampling in areas with low ambient air Pb concentrations relative to the level of the NAAQS. As such, we are proposing to allow monitoring agencies to request a reduction in the sampling frequency to 1-in-6 day sampling if the most recent 3-year design value is less than 70% of the NAAQS.

We request comment on the proposed change to 1-in-3 day sampling and the proposed option to reduce sampling to 1-in-6 day sampling in areas with low ambient Pb concentrations. We also seek comments on the need to increase sampling frequency further to 1-in-1 day sampling in areas with ambient air Pb

concentrations near the level of the final NAAQS.

We are currently assessing how different sampling schedules could affect the confidence in the estimate of a mean monthly Pb concentration as part of developing Data Quality Objectives (DQOs) for Pb monitoring. This assessment will include evaluating temporal variability at current Pb monitoring sites (both Pb-TSP and Pb-PM_{10}) in order to provide uncertainty estimates associated with various sampling frequency scenarios. We will evaluate 1-in-1 day, 1-in-3 day, and 1-in-6 day sampling frequencies, at varying degrees of completion between 50% and 100%, and for each we plan to estimate the margin of error about a mean monthly estimate, focusing on sites assumed to be close to the proposed NAAQS. Based upon this assessment, expected to be complete in June of 2008, we will be able to better understand the uncertainties around a monthly estimate. We will use this better understanding and information provided in public comment to choose the final sampling frequency requirements.

D. Monitoring for the Secondary NAAQS

We are not proposing additional monitoring requirements for the secondary NAAQS because the proposed monitoring requirements for the primary NAAQS will be sufficient to demonstrate compliance with the secondary NAAQS. The remainder of this section provides background and rationale on our decision to not propose additional monitoring requirements for the secondary NAAQS.

1. Background

CASAC has recommended additional monitoring to gather information to better inform consideration of the secondary NAAQS in the next and future reviews. Specifically, CASAC stated that "the EPA needs to initiate new measurement activities in rural areas—which quantify and track changes in lead concentrations in the ambient air, soils, deposition, surface waters, sediments and biota, along with other information as may be needed to calculate and apply a critical loads approach for assessing environmental lead exposures and risks in the next review cycle" (Henderson, 2007b).

We currently monitor ambient Pb in $PM_{2.5}$ (Pb-$PM_{2.5}$) as part of the Interagency Monitoring of Protected Visual Environments (IMPROVE) network. There are 110 formally designated IMPROVE sites located in or near national parks and other Class I

visibility areas, virtually all of these being rural. Approximately 80 additional sites at various urban and rural locations, requested and funded by various parties, are also informally treated as part of the IMPROVE network. While we believe it is not appropriate to rely on Pb-$PM_{2.5}$ monitoring to demonstrate compliance with a Pb-TSP NAAQS, we believe the Pb-$PM_{2.5}$ measurements provided by the IMPROVE network can be used as a useful indicator to temporal and spatial patterns in ambient Pb concentrations and resulting Pb deposition in rural areas that are not directly impacted by a nearby Pb emission source. In the ANPR, we suggested it might be desirable to augment the IMPROVE network with a small "sentinel" network of collocated Pb-TSP monitors for a period of time in order to develop a better understanding of how Pb-$PM_{2.5}$ and Pb-TSP relate in these rural areas. Alternatively, since it is likely that at rural locations nearly all ambient Pb is in the less than 10 μm size range, we suggested it might be possible to analyze the IMPROVE PM_{10} mass samples (which are already being collected) for Pb for a period of time to develop a better understanding of how Pb-$PM_{2.5}$ and Pb-PM_{10} relate in these rural areas.

The National Water-Quality Assessment (NAWQA), conducted by the United States Geological Survey, contains data on Pb concentrations in surface water, bed sediment, and animal tissue for more than 50 river basins and aquifers throughout the country (CD, AX7.2.2.2). NAWQA data are collected during long-term, cyclical investigations wherein study units undergo intensive sampling for 3 to 4 years, followed by low-intensity monitoring and assessment of trends every 10 years. Similarly, the USGS is collaborating with Canadian and Mexican government agencies on a multi-national project called "Geochemical Landscapes" that has as its long-term goal a soil geochemical survey of North America (*http://minerals.cr.usgs.gov/projects/geochemical_landscapes/index.html*). The Geochemical Landscapes project has the potential to fill the need for periodic Pb soil sampling. We note the value of the NAWQA and Geochemical Landscapes data in the assessment of trends in Pb concentrations in both soil and aquatic systems, and support the continued collection of this data by the USGS.

2. Proposed Changes

As discussed in Section III of this preamble, we are proposing to set the secondary NAAQS equal to the primary NAAQS. Based on our analysis of the

existing ambient Pb monitoring data (EPA 2007c), we do not expect there to be ambient air concentrations in excess of the proposed secondary NAAQS in rural areas that are not associated with a Pb emission source. As noted earlier in this section, we are proposing Pb surveillance monitoring requirements for Pb sources to demonstrate compliance with the primary NAAQS that will also be sufficient to determine compliance with the secondary NAAQS.

The Pb-PM$_{2.5}$ data collected as part of the IMPROVE program provides useful information on Pb concentrations in rural areas that can be used to track trends in ambient air Pb concentrations in rural areas and important ecosystems. These data are available through the VIEWS Web portal (*http://vista.cira.colostate.edu/views/*) and are also reported to AQS. While collection of a limited amount of collocated Pb-TSP or Pb-PM$_{10}$ would be useful in understanding the relationship between Pb-PM$_{2.5}$ and Pb-TSP (or Pb-PM$_{10}$) in rural areas, we do not believe it is appropriate to establish a regulatory requirement for the collection of these data. Rather, we believe it is more appropriate to work with the monitoring agencies responsible for IMPROVE monitoring to encourage the collection of a limited amount of collocated Pb data from PM$_{10}$ or TSP samplers. We seek comments on our decision to not require additional monitoring requirements for the proposed secondary Pb NAAQS.

E. Other Monitoring Regulation Changes

We are proposing to make two other minor changes to various aspects of the Pb monitoring regulations to make them consistent with the proposed NAAQS. The remainder of this section discusses the proposed changes.

1. Reporting of Average Pressure and Temperature

The high-volume FRM for Pb-TSP monitoring is based on standard pressure and temperature (25 degrees C, and 760 mmHg). We are not proposing to change this. As discussed in section II.E of this preamble, we are proposing to adopt a new FRM for low-volume Pb-PM$_{10}$ monitoring with concentration reporting based on local temperature and pressure. We are proposing to specify reporting based on local temperature and pressure because the actual concentration of Pb in the atmosphere is a better indicator of the potential for deposition than the concentration based on standard pressure and temperature. In addition, there are practical advantages to moving to local conditions since both PM$_{2.5}$ and

PM$_{10-2.5}$ are also based on local conditions. We are proposing to revise 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-PM$_{10}$ monitoring, consistent with the requirements for such reporting contained in the PM$_{2.5}$ and PM$_{10-2.5}$ FRMs. For low-volume Pb-PM$_{10}$ monitors, this requirement is easily met because the monitors incorporate temperature and pressure sensors and the monitor software makes reporting these parameters automatic. High-volume TSP samplers do not incorporate these sensors, so more effort may be needed to report the data. We note that sampler-generated average daily temperature and pressure are already required to be reported to AQS from filter-based PM$_{2.5}$ FRM/FEM samplers, and that the current submission of these data would fulfill the temperature and pressure reporting requirements for any Pb-TSP sampling at the same site. Relevant measurements could also be obtained from nearby National Weather System (NWS) monitoring sites, nearby low-volume PM$_{2.5}$ or PM$_{10}$ samplers, and other nearby meteorological measurements that undergo routine quality control checks and quality assurance; relying on one of these sources would mean that a separate data submission action would be needed to associate the data with the Pb-TSP monitoring site. The reporting of average pressure and temperature data would support the ability to investigate data quality and other data analysis questions that may be arise with regard to the Pb-TSP or Pb-PM$_{10}$ monitors.

We seek comment on the requirement to report the average temperature and pressure recorded during Pb measurements and the usefulness of such data in supporting data analysis purposes.

2. Special Purpose Monitoring Exemption

According to 40 CFR 58.20(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, SO$_2$, NO$_2$, Pb, or 24-hour PM$_{10}$ 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.'' When this provision was added in the October 2006 revisions to the ambient monitoring regulations, we stated that the basis for finalizing a prohibition on the use of SPM data to designate an area as nonattainment for

Pb (as well as CO, SO$_2$, NO$_2$, and PM$_{10}$) was EPA's discretion to not make a finding of nonattainment even though a SPM indicated a violation of the relevant NAAQS (see 71 FR 61252). We stated that even though the NAAQS for these pollutants have forms that allow a nonattainment finding based on less than 24 months of data, EPA does not have a mandatory duty to make nonattainment redesignations until such time as the NAAQS are revised. Since EPA is proposing to revise the Pb NAAQS, and the form of the proposed NAAQS would allow a nonattainment finding to be based on only 1 or 2 years of data, and such a NAAQS revision must be followed by a mandatory round of designations, we are proposing to revise 40 CFR Section 58.20(e) by removing the specific reference to Pb in the rule language.

VI. Implementation Considerations

This section of the proposal discusses the specific CAA requirements that must be addressed when implementing any new or revised Pb NAAQS based on the structure outlined in the CAA, existing rules, existing guidance, and in some cases proposed revised guidance. We intend the preamble to the final rule revising the Pb NAAQS to provide EPA's final implementation 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.

Currently only two areas in the United States are designated as nonattainment and eleven areas are designated as maintenance areas for the current Pb NAAQS. If the Pb NAAQS is lowered to the range proposed, it is likely (based on a review of the current air quality monitoring data) that

additional areas would be designated as nonattainment. States determined to have lead nonattainment areas would be required to submit SIPs that identify and implement specific air pollution control measures to reduce the ambient concentrations of lead to meet the NAAQS.

The EPA's analysis of the available Pb monitoring data suggests that a large majority of recent exceedances of Pb levels in the range of 0.10 to µg/m³ have occurred in locations with active or retired industrial sources of Pb. Accordingly, if this pattern also prevails for concentrations observed from new monitoring sites, many states 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 fabric filter particulate matter control measures 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 sources. Based on these considerations, EPA believes that some of the regulations and guidance being used to implement the current Pb NAAQS is still appropriate to implement any of the options being proposed in this rulemaking for a new or revised Pb NAAQS.

The regulations and guidance for implementing the current 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 at 40 CFR 51.117. The aforementioned 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. We have summarized the most relevant information from these documents below for your convenience. The EPA believes that there is sufficient guidance and regulations to fully implement the proposed revised Pb NAAQS, although EPA may review and revise or update as

necessary, policies, guidance, and regulations for implementing the Pb NAAQS in the future. The EPA solicits comment on whether additional guidance is necessary for implementation of the revised Pb NAAQS.

A. Designations for the Lead NAAQS

After EPA establishes or revises a 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 for 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 be signature and dissemination of a rule.[165] 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. Whether or not a state or a Tribe provides a recommendation, EPA must promulgate the designation that it deems appropriate.

Accordingly, Governors of states and Tribal leaders will be required to submit their initial designation recommendations to EPA no later than September 2009. The initial designation of areas for any new or revised NAAQS for lead must 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. As

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[165] *American Petroleum Institute* v. *Costle,* 609 F.2d 20 (D.C. Cir. 1979).

discussed below, EPA is anticipating a designations schedule that provides the full 3 years allowed under the CAA, and is taking comment on issues related to the anticipated designation schedule.

1. Potential Schedule for Initial Designations of a Revised Lead NAAQS

As stated previously, section 107(d)(1)(B)(i) requires EPA to promulgate initial designations for all areas of the country for any new or revised NAAQS, as expeditiously as practicable, but in no case later than 3 years from the date of promulgation of the new or revised NAAQS. Two key considerations in establishing a schedule for designating areas are: (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.

EPA continues to believe, consistent with its past practice, that there are important advantages to promulgating designations for all areas at the same time. This practice provides helpful uniformity for the deadlines for SIP submissions and attainment. Moreover, since a key question for the designation process is delineating the boundaries of nonattainment areas, establishing appropriate nonattainment boundaries in a two-stage process is likely to generate significant issues. Thus, EPA intends to promulgate designations for all areas at the same time.

As discussed in section V.B, the existing Pb monitoring network is not adequate to evaluate attainment of the proposed revised Pb NAAQS at locations consistent with EPA's proposed new network siting criteria and data collection requirements. These new requirements would result in a more strategically targeted network that would begin to be in operation by January 1, 2010. Thus, taking the additional year provided under section 107(d)(1)(B)(1) of the CAA (which would allow up to 3 years to promulgate designations following the promulgate of a new NAAQS) would allow the first year of data from this network to be available. The EPA believes that, due to the updated network design requirements, this additional data would be of significant benefit for designating areas for a new NAAQS. If EPA completes the initial designations within 2 years of new NAAQS promulgation, it is likely that large areas of the country will be designated "unclassifiable" because the monitoring network will not be sufficient to make clear decisions. Even if EPA takes an extra year for final initial designation

decisions we recognize that some areas may still have to be designated as unclassifiable or attainment/ unclassifiable because of the lack of a sufficient record of FRM (FEM) monitoring data.[166] If sufficient monitoring data become available for "unclassifiable" areas subsequent to the time EPA finalizes initial designations, EPA may use the discretion provided to the Administrator under the CAA pursuant to section 107(d)(3) to revise the initial designations for these areas.

Under the initial designation schedule described above, states (and Tribes) would be required to submit designation recommendations to EPA no later than September 2009 (i.e., one year following promulgation of a new NAAQS). States will be able to consider ambient data collected with FRM (FEM) samplers through the end of 2008 and part way through 2009 when formulating their recommendations. As stated previously, by no later than 120 days prior to promulgating designations, EPA is required to notify states or Tribes of any intended modifications to their recommended boundaries as EPA may deem necessary. This would occur no later than in May 2011. If EPA promulgates designations in September 2011, EPA will have access to Pb air quality data from 2010 which state monitoring officials have certified is complete and accurate, since the deadline for such certification is May 1, 2011. Under this schedule, EPA would 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 will then have an opportunity to comment on EPA's proposed modifications

As described above, EPA is currently anticipating that there will be insufficient information to promulgate designations in 2010. The EPA is soliciting comment on whether we have the authority to determine in the final rule that three years are necessary to promulgate designations based on the availability of appropriate information. EPA is also soliciting comment on whether designations should be made within the 2 year period provided under section 107(d)(1)(B)(i) utilizing all data available by that time.

2. Ambient Data For Designations

The proposed alternative forms of the NAAQS, maximum quarterly average

concentration over three years and second maximum monthly concentration over three years, would both allow a nonattainment determination based on less than three years of data, if the monitoring data in a more limited time period includes a quarterly average above the level of the NAAQS or if it includes two monthly averages above the level of the NAAQS. In such a case, EPA intends to designate the affected area nonattainment even though less than three years of data are available. EPA would designate an area attainment only if three calendar years of data indicate the absence of a violation. As stated above, EPA anticipates that some areas will have to be designated as unclassifiable. If sufficient monitoring data become available for "unclassifiable" areas subsequent to the time EPA finalizes initial designations, EPA may use the discretion provided to the Administrator under the CAA pursuant to section 107(d)(3) to revise the initial designations for these areas.

B. Lead Nonattainment Area Boundaries

As stated previously, the process for initially designating areas following the promulgation of a new 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 contributed to violations. Since lead has been successfully phased out of motor

vehicle gasoline, mobile sources are no longer a significant source of violations of the current Pb NAAQS. At the current standard level, EPA expects stationary sources to be the primary contributor to violations of the NAAQS. At the lower standard levels contemplated in this proposal, it is possible that fugitive dust emissions from area sources containing deposited lead will also contribute to violations of a revised Pb NAAQS. The location and dispersion characteristics of these sources of ambient lead concentrations are important factors in determining nonattainment area boundaries. The EPA is proposing that the county boundary be the presumptive boundary for lead nonattainment areas. However, we are also taking comment on whether urban-based Metropolitan Statistical Area (MSA) boundaries should be the presumptive boundaries for lead nonattainment areas.

The EPA is proposing 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 is the existing EPA recommendation for defining the nonattainment boundaries for the current Pb NAAQS, and is described in the 1992 General Preamble (57 FR 13549). The EPA is also taking 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 is used, by CAA requirement, for the ozone and CO NAAQS nonattainment boundaries, and was recommended by EPA as the appropriate presumption for the 1997 PM$_{2.5}$ NAAQS nonattainment boundaries. Under either option, the state and/or EPA may conduct additional area-specific analyses that could lead EPA to depart from the presumptive boundary. Factors relevant to such an analysis are described below.

1. County-Based Boundaries

The option being proposed by EPA is that lead nonattainment boundaries would be presumptively defined by the perimeter of the county in which the ambient lead monitor(s) recording a violation of the NAAQS is located, unless area-specific information indicates that some other boundary is more appropriate. In addition, if the relevant air quality monitor measuring a violation(s) is located near another county, then EPA would presume that the contributing county should also be designated as nonattainment for the Pb NAAQS. In some instances, a boundary other than the county perimeter, that

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[166] As discussed in Section IV of this notice, EPA is soliciting comment on the use of Pb-TSP monitoring data, with or without a scaling factor, as a surrogate for Pb-PM$_{10}$ data where Pb-PM$_{10}$ data are not available, particularly for initial designations.

addresses areas impacted by specific sources of lead, may also be appropriate.

For the new proposed Pb NAAQS, EPA is recommending 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. EPA intends to apply these factors in evaluating boundary modifications. For this particular option, 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.

Analyses of these factors may suggest nonattainment boundaries that are either larger or smaller than the county. A demonstration supporting the designation of boundaries that are less than the full county must 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. EPA will consider these factors 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 PM$_{10}$ NAAQS Using Total Suspended Particulate or PM$_{10}$ Data,'' December 1986 (see 57 FR 13549).

EPA solicits comments on the use of these factors and modeling techniques, and other approaches, for adjusting county boundaries in designating nonattainment areas.

2. MSA-Based Boundaries

The EPA is also taking comment on the alternative that lead nonattainment boundaries should be presumptively defined by the perimeter of a metropolitan area as defined by OMB's Metropolitan Statistical Areas (MSAs), or appropriate divisions thereof, within which a violating monitor(s) is located. The Metropolitan Statistical Area, as delineated by the Office of Management and Budget (OMB), provides a presumptive definition of the populated area associated with a core urban area. Accordingly, EPA is taking comment on the alternative option that the Metropolitan Statistical Area would provide the presumptive definition of the source area that contributes to a lead nonattainment problem. This presumption would take the view that, in the absence of evidence to the contrary, violations of the Pb NAAQS in urban-oriented areas may be presumed attributable, at least in part, to contributions from large sources of lead emissions distributed throughout the Metropolitan Area. The last revision to the OMB listing of MSAs was published November 20, 2007. As in the EPA's preferred proposed option, EPA would consider state, local, and tribal recommendations of nonattainment area boundaries based on the same set of factors listed in the previous subsection.

As stated previously, EPA is proposing that the county boundaries be used as the presumptive boundaries for any new or revised Pb NAAQS, but is also requesting comments the MSA boundaries being used as the presumptive boundaries for any new or revised Pb NAAQS.

C. Classifications

Section 172(a)(1)(A) of the CAA authorizes EPA to classify areas designated as nonattainment for the purposes 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 is proposing 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 in the 1992 General Preamble (See 57 FR 13549, April 16, 1992).

D. Section 110(a)(2) Lead NAAQS Infrastructure Requirements

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 demonstrating these basic program elements within 3 years of the promulgation of any new or revised NAAQS. Subsections (A) through (M), of section 110(a)(2), set forth the elements that a state's program must contain in their SIP. The list below identifies the required program elements contained in section 110(a)(2).[167] The list of section 110(a)(2)

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[167] 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. The 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.

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 of new/modified (permitted) sources.

• *Interstate transport:* Section 110(a)(2)(D) requires SIPs to include provisions prohibiting any source or other type of emissions activity in one 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 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 provide for authority to implement the emergency episode provisions in their SIPs.

• *Provisions for SIP revision due to NAAQS changes or findings of inadequacies:* Section 110(a)(2)(H) requires States to revise 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 from 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.

E. Attainment Dates

Generally, the 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 any new or revised primary 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). So, for example, if final designations are effective in Fall 2011, then nonattainment areas must plan to attain the NAAQS by no later than Fall 2016. For an area with an attainment date of September 2016, EPA would determine whether it had attained the Pb NAAQS by evaluating air quality monitoring data from the 1, 2, or 3 previous calendar years (i.e., 2013, 2014, and 2015) as available.

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 (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 an areas nonattainment designation. So, for example, if final designations are effective in Fall 2011, the part D SIPs must be submitted by Spring 2013. 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 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 (e.g., applicable provisions of section 110(a)(2)).

1. RACM for Lead Nonattainment Areas

Lead nonattainment area SIPs must contain RACM (including RACT) that addresses sources of ambient lead concentrations. In general, as stated previously, EPA believes that lead nonattainment area issues are usually attributed to emissions from stationary sources, but some emissions may also be attributed to smaller area sources. As a general rule, the stationary sources in lead nonattainment areas tend to emit a relatively large amount of particulate matter containing lead. In EPA's 2002 National Emissions Inventory (NEI), there were 29 stationary sources in the country with lead emissions over 5 tons per year, and 239 sources over 1 ton of lead emissions per year.

At primary lead smelters, for example, 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 which 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 re-entrained fugitive lead bearing dust may contribute to violations of the Pb NAAQS in the affected area. There are also potential sources of lead that are under federal control. As a part of the Regulatory Impact Analysis for this rule, the EPA is reviewing the impact of these and other sources of lead emissions to assess their impact on any new or revised Pb NAAQS. States must also meet the requirements outlined in 40 CFR 51.117(a) related to control strategy demonstrations.

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 receives substantive public comments that demonstrate through appropriate documentation, that additional control measures may be reasonably available in a particular circumstance for an area, those 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 and as a group, are unreasonable because emissions from the affected sources are insignificant, those measures may be excluded from further consideration as they would not be representative of RACM for an 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 an 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 presumes 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 source category have in fact applied the control technology or process change in question. 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,[168] 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 time frames.

The fact that a measure has been adopted or is in the process of being adopted by other states is 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 or other states 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.

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[168] *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.

In considering what level of control is reasonable, EPA is not proposing 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. 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. The Pb NAAQS RIA will provide information on the estimated benefits per ton of reducing Pb emissions from various emissions sources. 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 established because it cannot afford the technology that appears to be RACT for other sources in its source category, 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 RACM 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.[169] RACT applies to the ''existing sources'' of lead 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)). EPA's most recent guidance for implementing the current Pb NAAQS recommends that stationary sources

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[169] 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.

which actually emit a total of 5 tons per year 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 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 a state's control technology analysis may need to include sources which actually emit less than 5 tons per year 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 for promulgating a new or revised Pb NAAQS significantly lower than the current standard, EPA is seeking comment on an appropriate threshold for the minimum starting point for future Pb RACT analyses for stationary lead sources in nonattainment areas. In the monitoring section of today's proposal, EPA is taking comment on minimum network monitoring requirements based on emissions source sizes ranging from 200 kg/yr to 600 kg/yr. One possible approach for RACT is to recommend that RACT analyses for Pb sources be consistent with the monitoring requirements, such that all stationary sources above from 200 kg/yr to 600 kg/yr should undergo a RACT review. EPA is also taking comment on source monitoring for stationary sources that emit Pb emissions in amounts that have potential to cause ambient levels at least one-half the selected NAAQS level. This suggests another potential recommended starting point for RACT analysis. EPA is seeking comment on these ideas as well as any information commenters can provide that would help inform EPA recommendations on an appropriate emissions threshold for initiating RACT analyses.

2. Demonstration of Attainment for Lead Nonattainment Areas

The SIPs for lead nonattainment areas should provide for the implementation of control measures for point and area stationary 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 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.

3. Reasonable Further Progress (RFP)

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. Requiring linear emission reduction progress to maintain RFP may be appropriate where:

- Pollutants are emitted by numerous and diverse sources;
- The relationship between any individual source and the overall air quality is not explicitly quantified;
- There is a chemical transformation involved; and
- The emission control system utilized (*e.g.*, at major point sources) will result in swift and significant emission reductions.

The EPA believes that it may not be reasonable to require linear reductions in emissions in SIPs for lead nonattainment areas because the air quality problem is not usually due to a vast inventory of sources. However, this is not to suggest that generally it would be unreasonable for EPA to require annual incremental reductions in emissions in lead nonattainment areas. RFP for lead nonattainment areas should be met, at least in part, by ''adherence to an ambitious compliance schedule'' which is expected to periodically yield significant emission reductions, and as appropriate, linear

progress.[170] The EPA recommends that SIPs for lead nonattainment areas provide a detailed schedule for compliance of RACM (including RACT) in the 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, it should be noted that 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 sections 110(m) and 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.

4. Contingency Measures

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. 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 is 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 fugitive emissions may include stabilizing additional storage piles, etc. Examples of contingency measures for processed-related fugitive emissions include increasing the enclosure of buildings, increasing air flow in hoods, increasing operation and maintenance procedures, etc. Examples for 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 increasing operation and maintenance procedures, etc.

Section 172(c)(9) provides that contingency measures should be included in the 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 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.

5. Nonattainment New Source Review (NSR) and Prevention of Significant Deterioration (PSD) Requirements

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. EPA rules addressing these regulations can be found at 40 CFR 51.165, 51.166, 52.21, 52.24, and part 51, appendix S.

Areas designated as nonattainment for the Pb NAAQS must submit SIPs that address the requirements of nonattainment area 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.

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 any major and minor stationary sources of any air pollutant for which there is a NAAQS to undergo review and approval prior to the commencement of construction.[171] The NSR program is composed of three different permit programs:

The NSR program is composed of three different permit programs:
• Prevention of Significant Deterioration (PSD);
• Nonattainment NSR (NA NSR); and,
• 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.[172] The NA NSR program applies when a major source that is located in an area that is designated as nonattainment for any criteria pollutant is constructed or undergoes a major modification. The minor NSR program addresses both major and minor sources that underground 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:

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[170] As previously stated most of the lead nonattainment problems are caused by point sources. 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).

[171] 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.

[172] In addition, the PSD program applies to most non-criteria regulated pollutants.

	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 citing analysis demonstrating that the benefits of 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 the NA 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.

6. Emissions Inventories

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 the case of lead, the emission inventory provisions are in the general provisions pursuant to section 173(c)(3) of the CAA.

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 CFR, and establishes new requirements for the state wide reporting of area source and mobile source emissions. States should follow the requirements under the CERR as well as any new or revised guidance related to emissions inventories for criteria pollutants. 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 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 regulations at 40 CFR 51.117(e) require states to include in the inventory all point sources that emit 5 or more tons of lead emissions per year. EPA is also considering whether revision to the recommended threshold for RACT analysis is appropriate in light of the proposed revision to the Pb NAAQS. In this proposed rulemaking we are taking comment on whether the recommended threshold for RACT analysis should be less than the current 5 tons/yr (see section VI.F.1). If EPA lowers the recommended threshold for RACT at the time of the final rulemaking, we propose also to revise, to be consistent, the emissions threshold for including sources in the inventory pursuant to 40 CFR 51.117. We solicit 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 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 would update the CERR reporting requirements by consolidating and harmonizing new emissions reporting requirements with pre-existing sets of reporting requirements under the Clean Air Interstate Rule (CAIR) and the NO_X SIP Call. At this time, EPA expects to finalize the AERR rulemaking in the Fall of calendar year 2008. 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.

7. Modeling

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 are used, 12 months of data are required in order to demonstrate attainment for the affected area).

G. General Conformity

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 practically 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 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: [173] carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), particulate matter ($P_{M-2.5}$ and PM_{10}), and sulfur dioxide (SO_2). 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.[174]

H. Transition From the Current NAAQS to a Revised NAAQS for Lead

EPA is proposing to revise the level of the Pb NAAQS significantly, as well as changing the indicator and averaging time. The 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, in this section, EPA is proposing that the existing NAAQS will 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.,

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[173] Criteria pollutants are those pollutants for which EPA has established a NAAQS under section 109 of the CAA.

[174] 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.

following 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.

Because it is EPA's belief that Congress did not intend to permit states to remove control measures when EPA revises a standard until the new or revised standard is implemented, we believe that controls that are required under the current Pb NAAQS, or that are currently in place under the current Pb NAAQS, should remain in place until designations are promulgated and, for current nonattainment areas, attainment SIPs are approved for any new or revised standard. As a result, EPA is proposing 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. 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. Unlike the transition from the 1-hour ozone standard to the 8-hour ozone standard, 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 attainment 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. The EPA requests comment on this proposed approach for transitioning to the proposed revised Pb NAAQS.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under section 3(f)(1) of Executive Order 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 0.30 µg/m³, 0.20 µg/m³, 0.10 µg/m³ and 0.05 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 proposed rule.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been 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 Request (ICR) document prepared by EPA for these proposed revisions to part 58 has been assigned EPA ICR numbers 0940.21.

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 proposed 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). Because this rulemaking includes a range of proposals for the level and averaging time, it is not possible accurately predict the size of the final network, and its associated burden. Rather we have estimated the upper range of burden possible based on the regulatory options being proposed which would result in a higher reporting burden (i.e., a final level for the standard of 0.1 µg/m³ with a 2nd maximum monthly averaging form). Based on these assumptions, 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 90,434 labor hours per year with an increase of $6,599,653 per year. Burden is defined at 5 CFR 1320.3(b). State, local, and tribal entities are eligible for State assistance grants provided by the Federal government under the CAA which can be used for monitors and related activities.

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

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA–HQ–OAR–2006–0735. Submit any comments related to the ICR to EPA and OMB. See **ADDRESSES** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after May 20, 2008, a comment to OMB is best assured of having its full effect if OMB receives it by June 19, 2008. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

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 proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed 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'ns* 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 proposed 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. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. 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 proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or 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 proposed 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 proposed 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 proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. 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, this rule does not impact CAA section 107 which establishes that 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.

However, EPA recognizes that States will have a substantial interest in this rule and any corresponding revisions to associated air quality surveillance requirements, 40 CFR part 58. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to

ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This proposed rule does not have tribal implications, as specified in Executive Order 13175. 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. Thus, Executive Order 13175 does not apply to this rule. However, EPA specifically solicits additional comment on this proposed rule from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks

This action is subject to Executive Order (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and we believe that the environmental health risk addressed by this action has a disproportionate effect on children. The proposed rule will establish 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 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 104–113, section 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 proposed rulemaking involves technical standards. EPA proposes to use low-volume PM_{10} samplers coupled with XRF analysis as the FRM for Pb-PM_{10} 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, we do not propose to use it in this rule. 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 proposed revisions to the Pb NAAQS.

EPA welcomes comments on this aspect of the proposed rule, and specifically invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in the regulation.

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 proposed 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 proposed rule will establish uniform national standards for Pb in ambient air.

EPA is continuing to assess the impact of Pb air pollution on minority and low-income populations, and plans to prepare a technical memo as part of its assessment to be placed in the docket by the date of publication of this proposed rule in the **Federal Register**. EPA solicits comment on environmental justice issues related to the proposed revision of the Pb NAAQS.

References

Adgate, J. L.; Willis, R.D.; Buckley, T.J.; Chow, J.C.; Watson, J.G.; Rhoads, G.G.; Lioy, P.J. (1998) Chemical mass balance source apportionment of lead in house dust. Environ. Sci. Technol. 32: 108–114.

Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) (2007) Interpreting and managing blood lead levels <10 ug/dL in children and reducing childhood exposures to lead: Recommendations of CDC's Advisory Committee on Childhood Lead Poisoning Prevention. Morbidity and Mortality Weekly Report. 56(RR–8). November 2, 2007.

Alliance to End Childhood Lead Poisoning. 1991. The First Comprehensive National Conference; Final Report. October 6, 7, 8, 1991.

American Academy of Pediatrics. 2008. Letter to Stephen Johnson from Renee R. Jenkins. January 16, 2008. Available in docket number EPA–HQ–OAR–2006–0735.

Auinger, 2008. E-mail message to Jee-Young Kim, U.S. EPA. February 10, 2008. Docket number EPA–HQ–OAR–2006–0735.

Axelrad, D. 2008. E-mail message to Deirdre Murphy, U.S. EPA. January 4, 2008. Docket number EPA–HQ–OAR–2006–0735.

Bellinger, D.C. (2004) What is an adverse effect? A possible resolution of clinical and epidemiological perspectives on neurobehavioral toxicity. Environ. Res. 95: 394–405.

Bellinger, D.C. and Needleman, H.L. (2003) Intellectual impairment and blood lead levels [letter]. N. Engl. J. Med. 349: 500.

Bellinger, D. 2008. E-mail message to Jee-Young Kim, U.S. EPA. February 13, 2008. Docket number EPA–HQ–OAR–2006–0735.

Billick, I.H.; Curran, A.S.; Shier, D.R. (1979) Analysis of pediatric blood lead levels in New York City for 1970–1976. Environ. Health Perspect. 31: 183–190.

Billick, I.H.; Curran, A.S.; Shier, D.R. (1980) Relation of pediatric blood lead levels

to lead in gasoline. Environ. Health Perspect. 34: 213–217.

Billick, I.H. (1983) Sources of lead in the environment. In: Rutter, M.; Russell Jones, R., eds. Lead versus health: Sources and effects of low level lead exposure. New York, NY: John Wiley and Sons, Ltd; pp. 59–77.

Black M.M. and Baqui A.G. (2005) Reply to E Pollitt question regarding are the psychologically tests valid. Am J Clin Nutr. 2005. Jul;82(1):201–2.

Boyle, E.A., Bergquist, B.A., Kayser, R.A. and Mahowald, N. (2005) Iron, manganese, and lead at Hawaii Ocean Time-series station ALOHA: Temporal variability and an intermediate water hydrothermal plume. Geochimica et Cosmochimica Acta, Vol. 69, No. 4, pp. 933–952.

Brion, G. Co-located PM–10/Hi-Vol Monitoring Results for E. Helena. July 22, 1988. Memorandum. EPA–HQ–OAR–2006–0735.

Brunekreef, B.; Noy, D.; Biersteker, K.; Boleij, J. (1983) Blood lead levels of Dutch city children and their relationship to lead in the environment. J. Air Pollut. Control Assoc. 33: 872–876.

Brunekreef, B. (1984) The relationship between air lead and blood lead in children: a critical review. Science of the total environment, 38: 79–123.

California Environmental Protection Agency (Cal-EPA). (2007) Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): Child-Specific Benchmark Change in Blood Lead Concentration for School Site Risk Assessment. Final Report. Integrated Risk Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency.

Camalier, L.; Rice, J. (2007) Evaluation of the Precision and Bias for Lead in Total Suspended Particulate (TSP). Memorandum to the Lead NAAQS Review Docket. EPA–HQ–OAR–2006–0735.

Canfield, R.L.; Henderson, C.R., Jr.; Cory-Slechta, D.A.; Cox, C.; Jusko, T.A.; Lanphear, B.P. (2003a) Intellectual impairment in children with blood lead concentrations below 10 μg per deciliter. N. Engl. J. Med. 348: 1517–1526.

Canfield, R.L., Kreher, D.A., Cornwell, C., and Henderson, C.R., Jr. (2003b) Low-level lead exposure, executive functioning, and learning in early childhood. Child Neuropsychol. 9: 35–53.

Canfield, R.L. 2008. E-mail message to Jee-Young Kim, U.S. EPA. February 7, 2008. Docket number EPA–HQ–OAR–2006–0735.

Caravanos, J.; Weiss, A.L.; Jaeger, R.J. (2006) An exterior and interior leaded dust deposition survey in New York City: Results of a 2-year study. Environ. Res. 100: 159–164.

Caravanos, J.; Weiss, A.L; Blaise, M.J.; Jaeger R.J.(2006b) A survey of spatially distributed exterior dust lead loadings in New York City. Environ Res 100: 165–172.

Cavender, K.; Schmidt. M. (2007) Review of Collocated Lead in Total Suspended Particulate and Lead in Particulate Matter Less than Ten Micrometers. Memorandum to the Lead NAAQS Review Docket. EPA–HQ–OAR–2006–0735.

Centers for Disease Control (1991) Preventing lead poisoning in young children:

A statement by the Centres for Disease Control. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service; October 1. *http://wonder.cdc.gov/wonder/prevguid/p0000029/p0000029.asp*

Centers for Disease Control and Prevention (2005a) Preventing lead poisoning in young children: A statement by the Centers for Disease Control and Prevention. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. August.

Centers for Disease Control and Prevention (2005b) Third National Report on Human Exposure to Environmental Chemicals. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

Chen, A.; Dietrich, K.N.; Ware, J.H.; Radcliffe, J.; Rogan, W.J. (2005) IQ and blood lead from 2 to 7 years of age: Are the effects in older children the residual of high blood lead concentrations in 2-year-olds? Environ. Health Perspect. 113: 597–601.

Chiodo, L.M., Jacobson, S.W., Jacobson, J.L. (2004) Neurodevelopmental effects of postnatal lead exposure at very low levels. Neurotoxicol. Teratol. 26: 359–371.

Chiodo, L. 2008. E-mail message to Jee-Young Kim, U.S. EPA. February 19, 2008. Docket number EPA–HQ–OAR–2006–0735.

Clayton, C.A.; Pellizzari, E.D.; Whitmore, R.W.; Perritt, R.L., Quackenboss, J.J. (1999) National human exposure assessment survey (NHEXAS): Distributions and associations of lead, arsenic, and volatile organic compounds in EPA Region 5. J. Exposure Anal. Environ. Epidemiol. 9: 381–392.

Clean Air Scientific Advisory Committee (1990) Report of the Clean Air Scientific Advisory Committed (CASAC), Review of the OAQPS Lead Staff Paper and the ECAO Air Quality Criteria Document Supplement. EPA–SAB–CASAC–90–002. Washington, DC. January.

Dudka, S.; Miller, W.P. (1999) Accumulation of potentially toxic elements in plants and their transfer to human food chain. J. Environ. Sci. Health B 34: 681–708.

Farfel, M.R.; Orlova, A.O.; Lees, P.S. J.; Rohde, C.; Ashley, P.J.; Chisolm, J.J., Jr. (2003) A study of urban housing demolitions as sources of lead in ambient dust: Demolition practices and exterior dust fall. Environ. Health Perspect. 111: 1228–1234.

Flegal, A.R.; Smith, D.R.; Elias, R.W. (1990) Lead contamination in food. In: Nriagu, J.O.; Simmons, M. S., eds. Food contamination from environmental sources. New York, NY: John Wiley & Sons, Inc.; pp. 85–120.

Hayes, E.B.,; McElvaine, M.D.; Orbach, H.G.; Fernandez, A.M.; Lyne, S.; Matte, T.D. (1994) Long-term trends in blood lead levels among children in Chicago: Relationship to air lead levels. Pediatrics 93:195–200.

Henderson, R. (2006) Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Administrator Stephen L. Johnson. Re: Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel's Consultation on EPA's draft Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards. July 26, 2006.

Henderson, R. (2007a) Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to

Administrator Stephen L. Johnson. Re: Clean Air Scientific Advisory Committee's (CASAC) Review of the 1st Draft Lead Staff Paper and Draft Lead Exposure and Risk Assessments. March 27, 2007.

Henderson, R. (2007b) Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Administrator Stephen L. Johnson. Re: Clean Air Scientific Advisory Committee's (CASAC) Review of the 2nd Draft Lead Human Exposure and Health Risk Assessments. September 27, 2007.

Henderson, R. (2008) Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Administrator Stephen L. Johnson. Re: Clean Air Scientific Advisory Committee's (CASAC) Review of the Advance Notice of Proposed Rulemaking (ANPR) for the NAAQS for lead. January 22, 2008.

Hilts, S.R. (2003) Effect of smelter emission reductions on children's blood lead levels. Sci. Total Environ. 303: 51–58.

Hornung, R. 2008. E-mail message to Jee-Young Kim, U.S. EPA. February 11, 2008. Docket number EPA–HQ–OAR–2006–0735.

ICF, 2005. Estimating near roadway populations and areas for HAPEM6. Memorandum to Chad Bailey, Office of Transportation and Air Quality, U.S. EPA. December 28. Docket EPA–HQ–OAR–2005–0036.

ICF International. (2006) Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas. Pilot Phase. Draft Technical Report. Prepared for the U.S. EPA's Office of Air Quality Planning and Standards, Research Triangle Park, NC. December.

Juberg, D.R.; Kleiman, C.F.; Kwon, S.C. (1997) Position paper of the American Council on Science and Health: lead and human health. Ecotoxicol. Environ. Saf. 38: 162–180.

Kordas, K. 2008. E-mail message to Jee-Young Kim, U.S. EPA. February 29, 2008. Docket number EPA–HQ–OAR–2006–0735.

Lanphear, B.P.; Roghmann, K.J. (1997) Pathways of lead exposure in urban children. Environ. Res. 74: 67–73.

Lanphear, B.P.; Burgoon, D.A.; Rust, S.W.; Eberly, S.; Galke, W. (1998) Environmental exposures to lead and urban children's blood lead levels. Environ. Res. 76: 120–130.

Lanphear, B.P.; Dietrich, K.N.; Auinger, P.; Cox, C. (2000) Cognitive deficits associated with blood lead concentrations <10 μg/dL in U.S. children and adolescents. Public Health Reports. 115: 521–529.

Lanphear, B.P.; Hornung, R.; Khoury, J.; Yolton, K.; Baghurst, P.; Bellinger, D.C.; Canfield, R.L.; Dietrich, K.N.; Bornschein, R.; Greene, T.; Rothenberg, S. J.; Needleman, H.L.; Schnaas, L.; Wasserman, G.; Graziano, J.; Roberts, R. (2005) Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environ. Health Perspect. 113: 894–899.

Long, S.J., Suggs J.C., and Walling J.F., Journal of the Air Pollution Control Association, Vol. 29, No. 1 January 1979; pp 28–3, ''Lead Analysis of Ambient Air Particulates: Interlaboratory Evaluation of EPA Lead Reference Method.''

MacDonald, D.D., Ingersoll, C.G., and Berger, T.A. (2000) Development and evaluation of consensus-based sediment quality guidelines for freshwater ecosystems. Archives of Environmental Contamination and Toxicology. 39:20–31.

MacDonald, D.D., Ingersoll, C.G., Smorong, D.E., Lindskoog, R.A., Sloane, G., and Biernacki, T. (2003) Development and Evaluation of Numerical Sediment Quality Assessment Guidelines for Florida Inland Waters. British Columbia: MacDonald Environmental Sciences, Lt. Columbia, MO: U.S. Geological Survey. Prepared for: Florida Department of Environmental Protection, Tallahassee, FL. January.

McFarland, A. R.; Rodes, C.E. (1979) Characteristics of Aerosol Samplers Used in Ambient Air Monitoring. Presented at 86th National Meeting of the American Institute of Chemical Engineers April 1–5, 1979 Houston, Texas.

Martin, A.; Volkmar, F.R. [eds] (2007) Lewis's Child and Adolescent Psychiatry, A comprehensive textbook. Fourth Edition. Section IV. Nosology, Classification and Diagnostic Assessment, Chapter 4.2.1. Lippincott, Williams and Wilkins, Philadelphia, PA.

Melnyk, L.J.; Berry, M.R.; Sheldon, L.S.; Freeman, N.C.; Pellizzari, E.D.; Kinman, R.N. (2000) Dietary exposure of children in lead-laden environments. J. Exposure Anal. Environ. Epidemiol. 10: 723–731.

Mielke, H.W. (1991) Lead in residential soils: Background and preliminary results of New Orleans. In: Adriano, D.C., ed. Metals in soils, waters, plants and animals: Proceedings of an international conference; April 1990; Orlando, FL. Water Air Soil Pollut. 57–58: 111–119.

Murphy, D.L. and Pekar, Z. (2008) Air-related IQ Loss Evidence-based Framework. Memorandum to the Lead NAAQS Review Docket. EPA–HQ–OAR–2006–0735.

National Center for Health Statistics (NCHS). (2005) Health, United States, 2005. With Chartbook on Trends in the Health of Americans. Hyattsville, Maryland.

Needleman, H.L., Leviton, A., Bellinger, D. (1982) Lead-associated intellectual deficit [letter]. N. Engl. J. Med. 306: 367.

O'Rourke, M.K.; Van De Water, P.K.; Jin, S.; Rogan, S.P.; Weiss, A.D.; Gordon, S.M.; Moschandreas, D.M.; Lebowitz, M.D. (1999) Evaluations of primary metals from NHEXAS Arizona: Distributions and preliminary exposures. J. Exp. Anal. Environ. Epidemiol. 9: 435–444.

Perkin Elmer (2000) Guide to Atomic Spectroscopy Techniques and Applications: AA, GFAA, ICP, ICP–MS; PerkinElmer instruments, Norwalk, CT. *http://www.perkinelmer.com*

Purdue, L.J. Use of the High-Volume Sampler for the Determination of Lead in Ambient Air. September 9, 1988. Memorandum. EPA–HQ–OAR–2006–0735.

Rabinowitz, M. and Needleman, H.L. (1983) Petrol Lead sales and umbilical cord blood lead levels in Boston, Massachusetts [Letter]. Lancet 1(8314/5:63.

Rice, D.C. (1992a) Lead exposure during different developmental periods produces different effects on FI performance in monkeys tested as juveniles and adults. Neurotoxicology 13: 757–770.

Rice, D.C.; Gilbert, S.G. (1990a) Lack of sensitive period for lead-induced behavioral impairment on a spatial delayed alternation task in monkeys. Toxicol. Appl. Pharmacol. 103: 364–373.

Rice, D.C. (1992a) Lead exposure during different developmental periods produces different effects on FI performance in monkeys tested as juveniles and adults. Neurotoxicology 13: 757–770.

Rice, D.C. (1996) Behavioral effects of lead: commonalities between experimental and epidemiologic data. Environ Health Persp 104 (Suppl 2): 337–351.

Rice, J. (2007) Summary of Method Detection Limits for Ambient Lead Methods. Memorandum to the Lead NAAQS Review Docket. EPA–HQ–OAR–2006–0735.

Roels, H.A., Buchet, J.P., Lauwerys R.R., Bruaux P., Claeys-Thoreau F., Lafontaine A., Verduyn G. (1980) Exposure to lead by the oral and the pulmonary routes of children living in the vicinity of a primary lead smelter. Environ Res 2(1): 81–94.

Rothenberg, S.J.; Rothenberg, J.C. (2005) Testing the dose-response specification in epidemiology: public health aand policy consequences for lead. Environ. Health Perspect. 113: 1190–1195.

Russell, T. (2008) Letter from Dr. Armistead (Ted) Russell, Chair, Clean Air Scientific Advisory Committee Ambient Air Monitoring and Methods Subcommittee, to Administrator Stephen L. Johnson. Re: Clean Air Scientific Advisory (CASAC) Ambient Air Monitoring & Methods (AAMM) Subcommittee Consultation Concerning Ambient Air Monitoring Issues related to the Lead NAAQS. April 14, 2008.

Schmidt, M., and Cavender, K. (2008) Lead NAAQS Review: Development of Pb-PM$_{10}$ to Pb-TSP Scaling Factors. Memorandum to the Lead NAAQS Review Docket. EPA–HQ–OAR–2006–0735.

Schwartz, J., and Pitcher, H. (1989) The relationship between gasoline lead and blood lead in the United States. J Official Statistics 5(4):421–431.

Schwemberger, MS, JE Mosby, MJ Doa, DE Jacobs, PJ Ashley, DJ Brody, MJ Brown, RL Jones, D Homa. May 27, 2005 Mortality and Morbidity Weekly Report 54(20):513–516.

Slob, W.; Moerbeek, M.; Rauniomaa, E.; Piersma , A.H. (2005) A statistical evaluation of toxicity study designs for the estimation of the benchmark dose in continuous endpoints. Toxicol. Sci. 84: 167–185.

Téllez-Rojo, M.M.; Bellinger, D.C.; Arroyo-Quiroz, C.; Lamadrid-Figueroa, H.; Mercado-García, A.; Schnaas-Arrieta, L.; Wright, R.O.; Hernández-Avila, M.; Hu, H. (2006) Longitudinal associations between blood lead concentrations < 10 μg/dL and neurobehavioral development in environmentally-exposed children in Mexico City. Pediatrics 118: e323–e330.

Tellez-Rojo, M. 2008. E-mail message to Jee-Young Kim, U.S. EPA. February 11, 2008. Docket number EPA–HQ–OAR–2006–0735.

Thomas, V.M.; Socolow, R.H.; Fanelli, J.J.; Spiro, T.G. (1999) Effects of reducing lead in gasoline: an analysis of the international experience. Environ. Sci. Technol. 33: 3942–3948.

Tripathi, R.M.; Raghunath, R.; A.V. Kumar; V.N. Sastry; S. Sadasivan. (2001) Atmospheric and children's blood lead as indicators of vehicular traffic and other emission sources in Mumbai, India. Sci Total Enviro 267: 101–108.

U.S. Census Bureau. 2006. American Housing Survey for the United States: 2005. Current Housing Reports, Series H150/05. U.S. Government Printing Office, Washington DC.

U.S. Environmental Protection Agency. (1977) Air quality criteria for lead. Research Triangle Park, NC: Health Effects Research Laboratory, Criteria and Special Studies Office; EPA report No. EPA–600/8–77–017. Available from: NTIS, Springfield, VA; PB–280411.

U.S. Environmental Protection Agency (USEPA). (1984) Ambient Water Quality Criteria for Lead—1984. Washington, DC: Office of Water Regulations and Standards, Criteria and Standards Division. EPA 440/5–B4–027.

U.S. Environmental Protection Agency. (1986a) Air quality criteria for lead. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; EPA report No. EPA–600/8–83/028aF–dF. 4v. Available from: NTIS, Springfield, VA, PB87–142378.

U.S. Environmental Protection Agency. (1986b) Lead effects on cardiovascular function, early development, and stature: An addendum to U.S. EPA Air Quality Criteria for Lead (1986). In: Air quality criteria for lead, v. 1. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; pp. A1–A67; EPA report No. EPA–600/8–83/028aF. Available from: NTIS, Springfield, VA; PB87–142378.

U.S. Environmental Protection Agency. (1989) Review of the national ambient air quality standards for lead: Exposure analysis methodology and validation: OAQPS staff report. Research Triangle Park, NC: Office of Air Quality Planning and Standards; report No. EPA–450/2–89/011. Available on the web: *http://www.epa.gov/ttn/naaqs/standards/pb/data/rnaaqsl_eamv.pdf*.

U.S. Environmental Protection Agency. (1990a) Air quality criteria for lead: Supplement to the 1986 addendum. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; report No. EPA/600/8–89/049F. Available from: NTIS, Springfield, VA; PB91–138420.

U.S. Environmental Protection Agency. (1990b) Review of the national ambient air quality standards for lead: assessment of scientific and technical information: OAQPS staff paper. Research Triangle Park, NC: Office of Air Quality Planning and Standards; report No. EPA–450/2–89/022. Available from: NTIS, Springfield, VA; PB91–206185. Available on the web: *http://www.epa.gov/ttn/naaqs/standards/pb/data/rnaaqsl_asti.pdf*.

U.S. Environmental Protection Agency. (1991) U.S. EPA Strategy for Reducing Lead Exposure. Available from U.S. EPA Headquarters Library/Washington, DC (Library Code EJBD; Item Call Number: EAP 100/1991.6; OCLC Number 2346675).

U.S. Environmental Protection Agency. (1998) Methodology for Assessing Health

Risks Associated with Multiple Pathways of Exposure to Combustor Emissions. Cincinnati, OH: Update to EPA/600/6–90/003, EPA/NCEA (EPA 600/R–98/137). Available at *oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=427339.*

U.S. Environmental Protection Agency. (1999) Inorganic Compendium Method IO–3.3; Determination of Metals in Ambient Particulate Matter Using X-Ray Fluorescence (XRF) Spectroscopy; U.S. Environmental Protection Agency, Cincinnati, OH 45268. EPA/625/R–96/010a. June 1999.

U.S. Environmental Protection Agency. (2003) Framework for Cumulative Risk Assessment. Risk Assessment Forum, Washington, DC, EPA/630/P–02/001F. May.

U.S. Environmental Protection Agency. (2005a) Project Work Plan for Revised Air Quality Criteria for Lead. Research Triangle Park, NC: National Center for Environmental Assessment—RTP Report No. NCEA–R–1465. CASAC Review Draft.

U.S. Environmental Protection Agency. (2005b) Air Quality Criteria for Lead (First External Review Draft). Washington, DC, EPA/600/R–05/144aA–bA. Available online at: *http://www.epa.gov/ncea/.*

U.S. Environmental Protection Agency. (2005c) Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. EPA–452/R–05–005a. Office of Air Quality Planning and Standards, Research Triangle Park.

U.S. Environmental Protection Agency. (2005d) Guidance for Developing Ecological Soil Screening Levels. Washington, DC: Office of Solid Waste and Emergency Response.OSWER Directive 9285.7–55. November.

U.S. Environmental Protection Agency. (2005e) Ecological Soil Screening Levels forLead, Interim Final. Washington, DC: Office of Solid Waste and Emergency Response. OSWER Directive 9285.7–70. Available at *http://www.epa.gov/ecotox/ecossl/pdf/eco-ssl_lead.pdf.*

U.S. Environmental Protection Agency. (2006a) Air Quality Criteria for Lead. Washington, DC, EPA/600/R–5/144aF. Available online at: *www.epa.gov/ncea/*

U.S. Environmental Protection Agency. (2006b) Air Quality Criteria for Lead (Second External Review Draft). Washington, DC, EPA/600/R–05/144aB–bB. Available online at: *http://www.epa.gov/ncea/.*

U.S. Environmental Protection Agency. (2006c) Plan for Review of the National Ambient Air Quality Standards for Lead. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available online at: *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_pd.html.*

U.S. Environmental Protection Agency. (2006d) Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available online at: *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_pd.html.*

U.S. Environmental Protection Agency (2006e). Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA/240/B–06/001. Available: *http://www.epa.gov/quality/qs-docs/g4-final.pdf* (February 2006).

U.S. Environmental Protection Agency. (2007a) Lead Human Exposure and Health Risk Assessments for Selected Case Studies (Draft Report) Volume I. Human Exposure and Health Risk Assessments—Full-Scale and Volume II. Appendices. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA–452/D–07–001a and EPA–452/D–07–001b.

U.S. Environmental Protection Agency. (2007b) Lead: Human Exposure and Health Risk Assessments for Selected Case Studies, Volume I. Human Exposure and Health Risk Assessments—Full-Scale and Volume II. Appendices. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA–452/R–07–014a and EPA–452/R–07–014b.

U.S. Environmental Protection Agency. (2007c) Review of the National Ambient Air Quality Standards for Lead: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. EPA–452/R–07–013. Office of Air Quality Planning and Standards, Research Triangle Park.

U.S. Environmental Protection Agency. (2007d) Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. EPA–452/R–07–007. Office of Air Quality Planning and Standards, Research Triangle Park.

U.S. Environmental Protection Agency. (2007e) E-mail Correspondence between Elizabeth Margosches of USEPA and Richard Hornung of Cincinnati Children's Hospital Medical Center. Title of E-mail: Piecewise model with lifetime average. July 20, 2007. Available in docket number EPA-HQ-OPPT–2005–0049.

U.S. Environmental Protection Agency. (2008) Economic Analysis for the TSCA Lead Renovation, Repair, and Painting Program Final Rule for the Target Housing and Child-Occupied Facilities. Office of Pollution Prevention and Toxics. March 2008.

U.S. Geological Survey. (2004) National Water Quality Assessment Program. Available at *http://water.usgs.gov/nawqa/data.*

U.S. Housing and Urban Development. (2002) National Survey of Lead and Allergens in Housing, Volume I: Analysis of Lead Hazards, Final Report, Revionsion 7.1 (October 2002).

Von Lindern, I.H.; Spalinger, S.M.; Bero, B.N.; Petrosyan, V.; Von Braun, M. C. (2003a) The influence of soil remediation on lead in house dust. Sci. Total Environ. 303: 59–78.

Von Lindern, I.; Spalinger, S.; Petroysan, V.; Von Braun, M. (2003b) Assessing remedial effectiveness through the blood lead soil/dust lead relationship at the Bunker Hill Superfund site in the Silver Valley of Idaho. Sci. Total Environ. 303: 139–170.

Walkowiak, J.; Altmann, L.; Krämer, U.; Sveinsson, K.; Turfeld, M.; Weishoff-Houben, M.; Winneke, G. (1998) Cognitive and sensorimotor functions in 6-year-old children in relation to lead and mercury levels: adjustment for intelligence and contrast sensitivity in computerized testing. Neurotoxicol. Teratol.20: 511–521.

Wedding, J.B.; McFarland, A.R.; Cermak, J.E. (1977) Large Particle Collection Characteristics of Ambient Aerosol Samplers. Environ. Sci. Technol. 11: 387–390.

Weiss, B. (1988) Neurobehavioral toxicity as a basis for risk assessment. Trends Pharmacol. Sci. 9: 59–62.

Weiss, B. (1990) Risk assessment: The insidious nature of neurotoxicity and the aging brain. Neurotoxicology 11: 305–314.

World Health Organization. (2000) Air Quality Guidelines for Europe. Chapter 6.7 Lead. WHO Regional Publications, European Series, No. 91. Copenhagen, Denmark.

Yohn, S.; Long, D.; Fett, J.; Patino, L. (2004) Regional versus local influences on lead and cadmium loading to the Great Lakes region. Appl. Geochem. 19: 1157–1175.

Zielhuis, R.L.; del Castilho, P.; Herber, R.F.M.; Wibowo, A.A.E.; Salle, H.J.A. (1979) Concentrations of lead and other metals in blood of two and three year-old children living near a secondary smelter. Int. Arch. Occup. Environ. Health 42: 231–239.

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: May 1, 2008.

Stephen L. Johnson,

Administrator.

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

PART 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 (PM2.5) 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 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 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 September 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 is [0.10–0.30] micrograms per cubic meter (μ/m³), [arithmetic mean concentration averaged over a calendar quarter or second highest arithmetic mean concentration averaged over a calendar month] measured in the ambient air as Pb either by:

(1) A reference method based on (Appendix G or Appendix Q 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 [quarterly or second highest monthly] arithmetic mean concentration, as determined in accordance with Appendix R of this part, is less than or equal to [0.10–0.30] 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; and
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, NW., Washington, DC: 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 PM$_{10}$ 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 (PM$_{10}$) in ambient air. PM$_{10}$ is collected on a 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 PM$_{10}$ is performed on each individual 24-hour sample. For the purpose of this method, PM$_{10}$ 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, PM_{10} 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 $PM_{10-2.5}$ 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).

1.4 An electrically powered air sampler for PM_{10c} 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 PM_{10} size range is separated for collection on a PTFE filter over the specified sampling period. The lead content of the PM_{10c} 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 emitted characteristic line intensity 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. An EPA method for the EDXRF analysis of ambient particulate matter is described in reference 1 of section 8. A detailed explanation of quantitative X-ray spectrometry is described in references 2 and 3.

1.5 *Quality assurance* (QA) procedures for the collection of monitoring data are contained in Part 58, Appendix A.

2. *PM_{10c} Lead Measurement Range and Method 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 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 *Method Detection Limit (MDL).* A typical one-sigma estimate of the method detection limit (MDL) is about 1.5 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 MDL is an estimate of the lowest amount of lead that can be detected by the analytical instrument. 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. The sources of random error which are considered are calibration uncertainty; system stability; peak and background counting statistics; uncertainty in attenuation corrections; uncertainty in peak overlap corrections; and uncertainty in flow rate, but the dominating source is by far peak and background counting statistics. Laboratories are to estimate the MDLs using 40 CFR Part 136, Appendix B, ''Definition and Procedure for the Determination of the Method Detection Limit.'' (Reference 4).

3. Factors Affecting Bias and Precision of Lead Determination by EDXRF

3.1 *Filter Deposit.* Too much deposit material can be problematic because XRF analysis and data processing programs for aerosol samples are designed specifically for a thin film or thin layer of material to be analyzed. The 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. The optimum filter loading is about 150 μg/cm² or 1.6 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. A properly collected sample will have a uniform deposit over the entire collection area. Sample heterogeneity can lead to very large systematic errors. Samples with physical deformities (including a visually non-uniform deposit area) should not be quantitatively analyzed.

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. There are only a few cases where this may occur and they are instrument specific: Si/Rb, Si/Ta, S/Mo, S/Tl, Al/Br, Al/Tm. These interferences are determined during instrument calibration and automatically corrected for by the XRF instrument software. Interferences need to be addressed when multi-elemental analysis is performed. The presence of arsenic (As) is a problematic interference for EDXRF systems which use the Pb Lα line exclusively to quantify the Pb concentration. This is because the Pb Lα line and the As Kα lines severely overlap. However, if the instrument software is able to use multiple Pb lines, including the Lβ and/or the Lγ lines for quantification, then the uncertainty in the Pb determination in the presence of As can be significantly reduced. 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. Some of the overlaps may be very small and some severe. 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. The effect is especially significant and more complex for PM_{10} measurements, especially for the lighter elements that may also be measured. An average attenuation and uncertainty for each coarse particle element is based on a broad range of mineral compositions and is a one-time calculation that gives an attenuation factor for use in all subsequent particle analyses. See references 6, 7, and 8 of section 8 for more discussion on addressing this issue. Essentially no attenuation corrections are necessary for Pb in PM_{10}: 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. However, this issue must be addressed when doing multi-element analyses.

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 15 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 10 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 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 batches of filters (greater than 500 filters) randomly select 50 filters from a given batch. For small batches (less than 500 filters) a lesser number of filters may be taken. Analyze each filter separately and calculate the average lead concentration in ng/cm². Ninety percent, or 45 of the 50 filters, must have an average lead concentration that is less than 4.8 ng Pb/cm².

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.

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 including Thermo (*www.thermo.com*) and PANalytical (*www.panalytical.com*). Note the mention of commercial products does not imply endorsement by the U.S. Environmental Protection Agency. 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 films standards are typically deposited on Nuclepore substrates. The preparation of thin film standards is discussed in reference 6, and 9. Thin film standards are commercially available from MicroMatter Inc. (Arlington, WA).[1]

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. Filters are typically archived in cold storage prior to analysis. Filters that are scheduled for XRF analysis are removed from storage and allowed to reach room temperature. All filter samples received for analysis are checked for any holes, tears, or a non-uniform deposit which would prevent quantitative analysis. A properly collected sample will have a uniform deposit over the entire collection area. 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 to avoid contamination prior to analysis. Filters must be kept covered when not being analyzed. No other preparation of the 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 peak shapes for interfering element energies and spectral backgrounds. Pure element thin film standards are used for the element peak shapes and clean filter blanks from the same lot as unknowns are used for the background. The analysis of PM filter deposits is based on the assumption that the thickness of the deposit is small with respect to the characteristic lead X-ray transmission thickness. Therefore, the concentration of lead in a sample is determined by first calibrating the spectrometer with thin film standards to determine sensitivity factors and then analyzing the unknown samples under identical excitation conditions as used to determine the calibration factors. Calibration is performed only when significant repairs occur or when a change in fluorescers, X-ray tubes, or detector is made. 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 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. The background shape standards which are used for background fitting are created at the time of calibration. About 20–30 clean blank filters 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 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 The PM₁₀ lead concentration in the atmosphere (μg/m³) 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 μg/m³;

C_{Pb} is the mass per unit area for lead in μg/cm² as provided by the XRF instrument software;

A is the filter deposit area in cm²;

V_{LC} is the total volume of air sampled by the PM₁₀c sampler in actual volume units measured at local conditions of temperature and pressure, as provided by the sampler in m³.

8. References

1. Inorganic Compendium Method IO–3.3; Determination of Metals in Ambient Particulate Matter Using X–Ray Fluorescence (XRF) Spectroscopy; U.S. Environmental Protection Agency, Cincinnati, OH 45268. EPA/625/R–96/010a. June 1999.

2. Jenkins, R., Gould, R.W., and Gedcke, D. Quantitative X-ray Spectrometry: Second Edition. Marcel Dekker, Inc., New York, NY. 1995.

3. Jenkins, R. X–Ray Fluorescence Spectrometry: Second Edition in Chemical Analysis, a Series of Monographs on Analytical Chemistry and Its Applications, Volume 152. Editor J.D.Winefordner; John Wiley & Sons, Inc. New York, NY. 1999.

4. Code of Federal Regulations (CFR) 40 part 136, Appendix B; Definition and Procedure for the Determination of the Method Detection Limit—Revision 1.11

5. Dzubay, T.G. X-ray Fluorescence Analysis of Environmental Samples, Ann Arbor Science Publishers Inc., 1977.

6. Drane, E.A, Rickel, D.G., and Courtney, W.J., "Computer Code for Analysis X–Ray Fluorescence Spectra of Airborne Particulate Matter," in *Advances in X–Ray Analysis,* J.R. Rhodes, Ed., Plenum Publishing Corporation, New York, NY, p. 23 (1980).

7. Analysis of Energy-Dispersive X-ray Spectra of ambient Aerosols with Shapes Optimization, Guidance Document; TR–WDE–06–02; prepared under contract EP–D–05–065 for the U.S. Environmental Protection Agency, National Exposure Research Laboratory. March 2006.

8. Billiet, J., Dams, R., and Hoste, J. (1980) Multielement Thin Film Standards for XRF Analysis, X–Ray Spectrometry, 9(4): 206–211.

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, the resulting concentrations then multiplied by an appropriate site-specific scaling factor to represent Pb-TSP. 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, including Pb-PM$_{10}$ to Pb-TSP scaling instructions, 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 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 refers 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 the second highest monthly mean Pb-TSP or surrogate Pb-TSP concentration for the most recent valid 3-year calendar period.

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-ups 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-PM$_{10}$ 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 supplant missed or invalidated required scheduled samples. Make-ups can be made by either the primary or collocated (same size cut) instruments. 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, or 6. Section 3(e) explains how such month-spanning make-up samples are to be treated for purposes of data completeness and monthly means. 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 Also, to be considered a valid make-up, the sampling must be conducted with equipment and procedures that meet the requirements for scheduled sampling. For purposes of determining whether a sample must be treated as a make-up sample or an extra sample, Pb-TSP and Pb-PM$_{10}$ 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, as defined in section 4.3 of this appendix. Monthly means are one of two specific types, "monthly parameter means" or "monthly site means". Monthly means are computed at each monitoring site separately for Pb-TSP and Pb-PM$_{10}$ (i.e., by site-parameter-year-month); these parameter-specific means are referred to as monthly parameter means. Monthly parameter means are validated according to the criteria stated in section 4 of this appendix. A "monthly site mean" (i.e., one for a site-year-month level) will be the valid monthly Pb-TSP mean if available, or the valid Pb-PM$_{10}$ (scaled) monthly mean when it is available and a valid Pb-TSP monthly mean is not. If neither a valid Pb-TSP nor a valid Pb-PM$_{10}$ monthly (parameter) mean exists for a particular site-year-month then there will be no corresponding valid monthly site mean.

Parameter refers either to Pb-TSP or to Pb-PM$_{10}$.

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.

Year refers to a calendar year.

2. Monitoring Considerations for Use of Scaled Pb-PM$_{10}$ Data as Surrogate Pb-TSP Data

(a) Monitoring agencies are permitted to monitor for Pb-PM$_{10}$ at a required Pb monitoring site rather than monitoring for Pb-TSP, but only after the monitoring agency develops, and the Regional Administrator approves, a site-specific scaling factor to be used to adjust Pb-PM$_{10}$ data before comparison to the standard. The development of such a factor must meet the criteria stated below (in sections 2(b)(i) through 2(b)(iv)), and the factor and

associated analysis must be documented in the monitoring agency's Annual Monitoring Network Plan. The site-specific scaling factor meeting all of these requirements shall take effect on January 1 following Regional Administrator approval of the Plan. The data criteria for establishing a site-specific alternative Pb-PM$_{10}$ to Pb-TSP scaling factor are:

(i) A scaling factor shall be based on a minimum of 12 consecutive months of collocated Pb-TSP and Pb-PM$_{10}$ FRM/FEM monitoring which produces at least 6 pairs of valid collocated measurements for each of at least 10 months of each period of 12 months.

(ii) Calculated Pearson correlation coefficients for the paired data shall equal or exceed 0.60 for each individual month of the evaluation period (for months containing at least 6 pairs), and a calculated overall (using all 10 or more months with at least 6 pairs of valid collocated measurements) Pearson correlation coefficient shall equal or exceed 0.80.

(iii) The site-specific scaling factor shall be equal to the mean of the ratios of monthly mean Pb-TSP concentration to monthly mean Pb-PM$_{10}$ concentration, using all 10 or more months with at least 6 pairs of valid collocated measurements and only using the days with valid collocated measurements. The scaling factor shall be rounded to two decimal places.

(iv) Each monthly ratio of Pb-TSP to Pb-PM$_{10}$ shall be within twenty percent of the 10-month (or more) mean ratio. Ratios shall be computed from unrounded means but monthly ratios shall be rounded to two decimal places before making the comparison.

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-PM$_{10}$ 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-PM$_{10}$ 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-PM$_{10}$ measurement data shall be reported to AQS in units of micrograms per cubic meter (μg/m^3) at local conditions (local temperature and pressure, LC) to three decimal places, with additional digits to the right being truncated. Pb-PM$_{10}$ data shall be reported without application of a scaling factor. Pre-rule Pb-TSP and Pb-PM$_{10}$ 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 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-PM_{10} 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-PM_{10} data are to be processed separately when selecting daily data by day (as specified in 3(d) below) and when aggregating daily data by month (per 4(2)(a) below), however, when deriving the design value for the three-year period, monthly means for the two data types may be combined; see section 4(e) below.

(d) Daily values for sites will be selected for a site on a size cut (Pb-TSP or Pb-PM_{10}, i.e., "parameter") basis; Pb-TSP concentrations and Pb-PM_{10} 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 composite record (i.e., that site-parameter's set of daily values); this includes all creditable samples and all extra samples.

(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.

(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.

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 0.20 [0.10, 0.30] micrograms per cubic meter ($\mu g/m^3$). A Pb design value of 0.20 [0.10, 0.30] $\mu g/m^3$ or less is valid if it encompasses 3 consecutive calendar years of valid monthly means (i.e., 36 valid monthly means). See 4(c) below for the definition of a valid monthly mean and 6(c) below for the definition of the design value. A Pb design value of 0.20 [0.10, 0.30] $\mu g/m^3$ or less will also be considered valid if it encompasses 35 valid monthly means (out of 36 possible over 3 consecutive calendar years) and the highest of the 35 is equal to or less than 0.20 [0.10, 0.30] $\mu g/m^3$.

(b) The Pb NAAQS is violated at a monitoring site when the identified design value is valid and is greater than 0.20 [0.10, 0.30] micrograms per cubic meter ($\mu g/m^3$). A Pb design value greater than 0.20 [0.10, 0.30] $\mu g/m^3$ is valid if it encompasses at least two valid monthly means. A site does not have to have valid monitoring data for three full calendar years in order to have a valid violating design value. For example, a site could start monitoring in November of a given calendar year and violate the NAAQS for any three-year period that includes that given calendar year, if the November and December means are valid and greater than 0.20 [0.10, 0.30] $\mu g/m^3$.

(c) (i) A monthly mean is considered valid (i.e., meets data completeness requirements) if for one or both of the Pb parameters measured at the site, the 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 (previous) month in question) divided by the number of scheduled samples for the month, the result then multiplied by 100 and rounded to the nearest integer. As noted above, Pb-TSP and Pb-PM_{10} 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-PM_{10} value or vice versa. For purposes of assessing data capture, Pb-TSP and Pb-PM_{10} data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

(ii) A monthly parameter mean that does not have at least 75 percent data capture and thus cannot be considered valid under 4(c)(1) shall still 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 mean (using actual "low" reported values from the site), and the second test for validating a below-NAAQS level mean (using actual "high" values reported for the site). Note that both tests are merely diagnostic in nature, intending to confirm that there is a very high likelihood if not certainty that that original mean (the one with less than 75% data capture) reflects the true over/under NAAQS-level status for that month; the result of these data substitution tests (i.e., the test means, as described below) is never considered the actual monthly parameter mean and shall not

be used to determine the design value. For both types of data substitution, substitution is permitted only if there are a sufficient number of 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 possible year-months. Data substitution may only use data of the same parameter type. For Pb-PM_{10} data, the "test" monthly mean after data substitution shall be scaled using Equation 2 of section 6(b) before being compared to the level of the standard.

(A) The "above NAAQS level" test is as follows: If by substituting the lowest reported daily value for that month over the 3-year design value period in question (year non-specific; e.g., for January) 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 monthly parameter mean concentration above the level of the standard, then the month is deemed to have passed the diagnostic test and the level of the standard is deemed to have been exceeded in that month. As noted above, in such a case, the monthly 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: A monthly parameter mean that does not have at least 75 percent data capture but does have at least 50 percent data capture shall still be considered valid (and complete) if, by substituting the highest reported daily value for that month 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 monthly parameter mean concentration equal or less than the level of the standard, then the month is deemed to have passed the diagnostic test and the level of the standard is deemed not to have been exceeded in that month. As noted above, in such a case, the monthly 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) above, and design values that do not meet the completeness criteria stated in 4(a) or 4(b) above, 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 three calendar year period is identified from the available valid monthly parameter means. In a situation where there are valid monthly means for both parameters (Pb-TSP and Pb-PM_{10}), 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. A monitoring site will have only one site-level monthly

mean per month; however, the set of site-level monthly means considered for design value identification (i.e., two to 36 site-level monthly means) can be a combination of Pb-TSP and scaled Pb-PM$_{10}$ data.

(f) The procedures for calculating monthly means, scaling Pb-PM$_{10}$ monthly means to a surrogate Pb-TSP basis, and identifying Pb design values are given in section 6 of this appendix.

5. Rounding Conventions

(a) Monthly 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 monthly mean of 0.104925 rounds to 0.10, and a monthly mean of .10500 rounds to 0.11.

(b) Because a Pb design value is simply a (second highest) monthly mean and because the NAAQS level is stated to two decimal places, no additional rounding beyond what is specified for monthly means is required before a design value is compared to the NAAQS.

6. Procedures and Equations for the Pb NAAQS.

(a) A monthly mean value for Pb-TSP (or Pb-PM$_{10}$) is determined by averaging the daily values of a calendar month using equation 1 of this appendix:

$$\text{Equation 1}$$
$$\bar{X}_{m,y,s} = \frac{1}{n_m} \sum_{i=1}^{n_m} X_{i,m,y,s}$$

Where:

$\bar{X}_{m,y,s}$ = the mean for quarter q of the year y for site s; and
n_m = the number of daily values in the month; and
$X_{i,m,y,s}$ = the ith value in month m for year y for site s.

(b) Monthly means for reported Pb-PM$_{10}$ data are scaled to a surrogate Pb-TSP basis using Equation 2 of this appendix.

$$\text{Equation 2}$$
$$\bar{Z}_{m,y,s} = \bar{X}_{m,y,s} \times F_{m,y,s}$$

Where:

$\bar{Z}_{m,y,s}$ = the surrogate Pb-TSP mean for month m of the year y for site s; and
$\bar{X}_{m,y,s}$ = the Pb-PM$_{10}$ mean for month m of the year y for site s; and
$F_{m,y,s}$ = the scaling factor for year y and for site s determined through collocated testing in accordance with section 2.0(b).

(c) The site-level identified Pb design value is the second highest valid site-level monthly mean over the most recent 3-year period. Section 4 above 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 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

9. 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]

10. Section 53.33 is revised to read as follows:

§ 53.33 Test Procedure for Methods for Lead (Pb).

(a) *General.* The reference method for collection of Pb in TSP includes two parts, the reference method for high-volume sampling of TSP as specified in 40 CFR part 50, appendix B and the analysis method for Pb in TSP as specified in 40 CFR part 50, appendix G. Correspondingly, the reference method for Pb in PM$_{10}$ includes the reference method for low-volume sampling of PM$_{10}$ in 40 CFR part 50, appendix O and the analysis method of Pb in PM$_{10}$ as specified in 40 CFR part 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 PM$_{10}$ 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 part 50, appendix G must be made in a consistent manner with regard to temperature and pressure.

(2) Pb in PM$_{10}$—A candidate method for Pb in PM$_{10}$ 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 part 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 (filters) of Pb at the test site or sites with both the reference and candidate methods until at least 10 filter pairs have been obtained. 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 part 50, 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. A candidate method for Pb in PM$_{10}$ 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 part 50, appendix Q, requires the use of two PM$_{10}$ reference samplers because a single 46.2-mm filter from a reference sampler may not be divided prior to analysis.

(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 PM$_{10}$ 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 (Tqi), in total μg/strip (for TSP) or total μg/filter (for PM$_{10}$), will be provided with each audit sample.

(g) *Filter analysis.*

(1) For both the reference method samples and the audit samples, 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 PM$_{10}$ 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}, * * *, Q_{1A}, Q_{1B}, Q_{1C}, * * *, 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}, * * *, where C denotes results from the candidate method. For candidate methods which provide a direct 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 paragraph (g)(1) of this section 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) *Accuracy.*

(1)(*i*) For the audit samples, calculate the average Pb concentration for each strip or filter 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.

(*ii*) Calculate the percent difference (D_q) between the indicated Pb concentration for each audit sample and the true Pb concentration (T_q) using equation 3 of this section:

Equation 3

$$D_{qi} = \frac{Q_{iave} - T_{qi}}{T_{qi}} \times 100$$

(2) If any difference value (D_{qi}) exceeds ±5 percent, the accuracy 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 PM_{10}. 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 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.

(3) If any candidate method precision value (P_{Ci}) exceeds 15 percent, the

candidate method fails the precision test.

(4) 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

$$D_{in} = \frac{C_{ij} - R_{jk}}{R_{jk}} \times 100$$

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 aliquots of the sample to be used to calculate the method detection limit and process each through the entire analytical method. Make all computations according to the defined method with the final results in µg/m³. The MDL must be equal to, or less than 1% of the level of the Pb NAAQS.

10a. Revise Table C–3 to Subpart C of Part 53 to read as follows:

TABLE C–3 TO SUBPART C OF PART 53.—TEST SPECIFICATIONS FOR PB IN TSP AND PB IN PM_{10} METHODS

Concentration range equivalent to percentage of NAAQS in µg/m³.	30% to 250%.
Minimum number of 24-hr measurements.	5.
Maximum precision, P_R or P_C	≤15%.
Maximum analytical accuracy, D_q.	±5%
Maximum difference (D), percent of reference method.	±20%.

TABLE C–3 TO SUBPART C OF PART 53.—TEST SPECIFICATIONS FOR PB IN TSP AND PB IN PM_{10} METHODS—Continued

Estimated Method Detection Limit (MDL), µg/m³.	1% of NAAQS level.

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

11. 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]

12. Section 58.10, is amended by adding paragraphs (a)(4) and (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 by July 1, 2009. The plan shall provide for at least one half of the required Pb monitoring sites to be operational by January 1, 2010, and for all required Pb monitoring sites to be operational by January 1, 2011. Source oriented Pb monitoring sites for the highest emitting half of Pb sources shall be installed by January 1, 2010.

(b) * * *

(9) The designation of any Pb monitors as either source-oriented or non-source oriented according to appendix D to this part.

*   *   *   *   *

13. Section 58.12 is amended by revising paragraph (b) to read as follows:

§ 58.12   Operating schedules.

*   *   *   *   *

(b) For Pb manual methods, at least one 24-hour sample must be collected every 3 days except during periods or seasons exempted by the Regional Administrator. The Regional Administrator can allow a reduction in the sampling schedule to one 24-hour sample every 6 days if the Pb design value over the previous 3 years is less than 70% of the Pb NAAQS.

14. Section 58.13 is amended by revising paragraph (b) to read as follows:

§ 58.13   Monitoring network completion.

*   *   *   *   *

(b) Not withstanding 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.

15. 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 SO_2; CO; O_3; NO_2; NO; NO_Y; NO_X; Pb-TSP mass concentration; Pb-PM_{10} mass concentration; PM_{10} 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*). 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 C—[Amended]

16. 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, SO_2, NO_2, or 24-hour PM_{10} 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.

*   *   *   *   *

17. Appendix A to part 58 is amended by revising paragraph 3.3.4 and Table A–2.

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

*   *   *   *   *

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/m³ [1]
1	30–100% of Pb NAAQS.
2	200–300% of Pb NAAQS.

[1] Equivalent ambient Pb concentration in µg/m³ is based on sampling at 1.7 m³/min for 24 hours on a 20.3 cm × 25.4 cm (8 inch × 10 inch) glass fiber filter.

(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 relative percent differences between the concentrations are used to calculate analytical accuracy as described in section 4.4.2 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-PM_{10} shall be determined using the same procedures described in sections 3.3.1 of this appendix.

3.3.4.4   *Pb Performance Evaluation Program (PEP) Procedures.* 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 each year. The calculations for evaluating bias between the primary monitor(s) and the performance evaluation monitors for Pb are the same as those for $PM_{10-2.5}$ which are described in section 4.1.3 of this appendix. In addition, for each

quarter, one half of a collocated sample pair (from the designated collocated sampler)

from one site within each PQAO must sent to an independent laboratory for analysis.

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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	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.
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 valid audit for primary QA orgs.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.

[1] Effective concentration for open path analyzers.
[2] Corrected concentration, if applicable, for open path analyzers.

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18. Appendix D to part 58 is amended as 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 Pb monitoring near lead sources which emit more than [200 to 600] kilograms per year. At a minimum, there must be one source-oriented SLAMS site located (taking into account logistics and other limitations) to measure the maximum Pb concentration in ambient air resulting from the lead source.

(b) The Regional Administrator may waive the requirement in paragraph 4.5(a) for monitoring near Pb sources emitting less than 1000 kilograms if the State or, where appropriate, local agency can demonstrate (via historical monitoring data, modeling, or other means) that the Pb source will not contribute to a maximum Pb concentration in ambient air in excess of 50% of the NAAQS.

(c) State and, where appropriate, local agencies are required to conduct Pb

monitoring in each CBSA with a population greater than 1,000,000 people as determined based on the latest available census figures. At a minimum, there must be one nonsource-oriented SLAMS site located to estimate typical Pb concentrations in the urban area. Consideration should be given to locating these monitors in neighborhoods near heavily trafficked roadways.

(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 nonsource-oriented sites to characterize typical lead concentrations in urban areas is the neighborhood scale.

(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. Data collected at microscale sites provide information for evaluating and developing "hot-spot" control measures.

(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.

(e) Pb monitoring required in paragraphs 4.5(a) and 4.5(c) can be conducted with either Pb-TSP or Pb-PM$_{10}$.

(f) 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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