# Integrated Review Plan for the National Ambient Air Quality Standards for Lead

## External Review Draft

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# Integrated Review Plan for the National Ambient Air Quality Standards for Lead

## External Review Draft

**U. S. Environmental Protection Agency**

National Center for Environmental Assessment
Office of Research and Development
and
Office of Air Quality Planning and Standards
Office of Air and Radiation

Research Triangle Park, North Carolina 27711

# DISCLAIMER

This draft integrated review plan for the national ambient air quality standards for lead serves as a public information document and as a management tool for the U.S. Environmental Protection Agency's National Center for Environmental Assessment and the Office of Air Quality Planning and Standards in conducting the review of the national ambient air quality standards for lead. The approach described in this draft plan may be modified for presentation in the final plan to reflect consultation with the Clean Air Scientific Advisory Committee and public comments. Subsequent modifications to the plan may result from information developed during this review, and in consideration of advice and comments received from the Clean Air Scientific Advisory Committee and the public during the course of the review. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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# 1 INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is conducting a review of the air quality criteria and the national ambient air quality standards (NAAQS) for lead (Pb). The purpose of this document is to communicate the plan for this review. This review will provide an integrative assessment of relevant scientific information for Pb and will focus on the basic elements of the NAAQS for Pb: the indicator,[1] averaging time, form,[2] and level. These elements, which together serve to define each ambient air quality standard, must be considered collectively in evaluating the protection to public health and public welfare afforded by the standards.

This draft Integrated Review Plan (IRP) contains the plans for this review of the air quality criteria for Pb-related effects on public health and public welfare and of the current Pb NAAQS. This draft IRP is being released for the purpose of consulting with the Clean Air Scientific Advisory Committee (CASAC) and obtaining public comment on the Agency's plans. The final IRP will be informed by comments received from the CASAC and the public.

This document is organized into eight chapters. Chapter 1 presents background information on the review process, the legislative requirements for the review of the NAAQS, and past reviews of the NAAQS for Pb. Chapter 2 presents the current review schedule. Chapter 3 presents a set of policy-relevant questions that will serve to focus this review on the critical scientific and policy issues. Chapters 4 through 7 discuss the planned scope and organization of key assessment documents, the planned approaches for preparing the documents, specific monitoring considerations and plans for scientific and public review of the documents. Complete reference citations are provided in chapter 8.

## 1.1 LEGISLATIVE REQUIREMENTS

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. section 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her "judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;" "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;" and "for which . . .

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

[2] 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. For example, the form of the annual $PM_{2.5}$ NAAQS is the 3-year average of the weighted annual mean $PM_{2.5}$ concentrations, while the form of the current 3-month Pb NAAQS is a 3-month average concentration not to be exceeded during a 3-year period.

[the Administrator] plans to issue air quality criteria…" Air quality criteria are intended 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 the ambient air . . ." 42 U.S.C. § 7408(b). Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[3] 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 such 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."[4]

The requirement that primary standards provide 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. See *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); *American Farm Bureau Federation v. EPA,* 559 F. 3d 512, 533 (D.C. Cir. 2009); *Association of Battery Recyclers v. EPA*, 604 F. 3d 613, 617-18 (D.C. Cir. 2010). 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 provide 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 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.

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[3] 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).

[4] 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."

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Association v. EPA*, 647 F.2d at 1161-62; *Whitman v. American Trucking Associations*, 531 U.S. 457, 495 (2001).

In setting primary and secondary standards that are "requisite" to protect public health and welfare, respectively, 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. In so doing, EPA may not consider the costs of implementing the standards. See generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." *American Petroleum Institute v. Costle*, 665 F. 2d at 1185.

Section 109(d)(1) requires that "not 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 . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . ." Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC).[5]

## 1.2 OVERVIEW OF THE NAAQS REVIEW PROCESS

Since completion of the last Pb NAAQS review, the Agency has made a number of changes to the process for reviewing the NAAQS. The current process, which is being applied to this review of the NAAQS for Pb, has four major phases: (1) planning, (2) science assessment, (3) risk/exposure assessment, and (4) policy assessment and rulemaking. An overview of the process is illustrated in Figure 1-1 below and each of these phases is described in this section.[6] The Agency maintains a web site on which key documents developed for NAAQS reviews are made available (http://www.epa.gov/ttn/naaqs/).

[5] Lists of CASAC members and of members of the CASAC Pb Review Panel are available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument.

[6] Information on changes to the NAAQS review process since the last Pb NAAQS review is available at: http://www.epa.gov/ttn/naaqs/review.html.

The planning phase of the NAAQS review process begins with a science policy workshop, which is intended to identify issues and questions to frame the review. Drawing from the workshop discussions, a draft IRP is prepared jointly by EPA's National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD), and EPA's Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation (OAR). The draft IRP is made available for consultation with CASAC and for public comment. The final IRP is prepared in consideration of CASAC and public comments. This document presents the current plan and specifies the schedule for the entire review, the process for conducting the review, and the key policy-relevant science issues that will guide the review.

The second phase of the review, science assessment, involves the preparation of an Integrated Science Assessment (ISA) and supplementary materials. The ISA, prepared by NCEA, provides a concise review, synthesis, and evaluation of the most policy-relevant science, including key science judgments that are important to the design and scope of exposure and risk assessments, as well as other aspects of the NAAQS review. The ISA and its supplementary materials provide a comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of the pollutant in the ambient air, emphasizing information that has become available since the last air quality criteria review in order to reflect the current state of knowledge. As such, the ISA forms the scientific foundation for each NAAQS review and is intended to provide information useful in forming judgments about air quality indicator(s), form(s), averaging time(s) and level(s) for the NAAQS. Hence, the ISA and its associated materials function in the current NAAQS review process as the Air Quality Criteria Document (AQCD) did in the previous review process. The current review process generally includes production of a first and second draft ISA, both of which undergo CASAC and public review prior to completion of the final ISA. Section 4 below provides a more detailed description of the planned scope, organization and assessment approach for the ISA and its supporting materials.

In the third phase, the risk/exposure assessment phase, OAQPS staff considers information and conclusions presented in the ISA, with regard to support provided for the development of quantitative assessments of the risks and/or exposures for health and/or welfare effects. As an initial step, staff prepares one or more planning documents that consider the extent to which newly available scientific evidence and tools/methodologies warrant the conduct of quantitative risk and exposure assessments. To the extent warranted, this document(s) outlines a general plan, including scope and methods, for conducting the assessments. This planning document(s) is generally prepared in conjunction with the first draft ISA and presented for consultation with CASAC and for public comment. As discussed in chapter 5 below, this planning document for the current Pb NAAQS review will focus on consideration of the newly

available data, methods and tools in light of areas of uncertainty in the assessments conducted for the last review and of the potential for new or updated assessments to provide notably different exposure and risk estimates with lower associated uncertainty. Comments received on the planning document(s) are considered in the Agency's decision as to whether to conduct such assessments. When an assessment is performed, one or more drafts of each risk and exposure assessment document (REA) undergoes CASAC and public review, with the initial draft REA(s) generally being reviewed in conjunction with review of the second draft ISA, prior to completion of final REA(s). The REA provides concise presentations of methods, key results, observations, and related uncertainties. Chapter 5 discusses possible approaches being considered with regard to human health- and welfare-related assessments for this review.

The review process ends with a policy assessment and rulemaking phase. Under the current NAAQS review process (Jackson, 2009), the EPA Administrator has reinstated the use of a Policy Assessment (PA). The PA, like the previous OAQPS Staff Paper, is a document that provides a transparent OAQPS staff analysis and staff conclusions regarding the adequacy of the current standards and potential alternatives that are appropriate to consider prior to the issuance of proposed and final rules. The PA integrates and interprets the information from the ISA and REA(s) to frame policy options for consideration by the Administrator. Such an evaluation of policy implications is intended to help ''bridge the gap'' between the Agency's scientific assessments, presented in the ISA and REA(s), and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS. In so doing, the PA is also intended to facilitate CASAC's advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the CAA. In evaluating the adequacy of the current standards and, as appropriate, a range of alternative standards, the PA considers the available scientific evidence and, as available, quantitative risk-based analyses, together with related limitations and uncertainties. The PA focuses on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: indicator, averaging time, form, and level. One or more drafts of a PA are released for CASAC review and public comment prior to completion of the final PA.

Following issuance of the final PA and consideration of conclusions presented therein, the Agency develops and publishes a notice of proposed rulemaking that communicates the Administrator's proposed decisions regarding the standards review. A draft notice undergoes interagency review involving other federal agencies prior to publication.[7] Materials upon which

[7] Where implementation of the proposed decision would have an annual effect on the economy of $100 million or more, e.g., by necessitating the implementation of emissions controls, EPA develops and releases a draft regulatory impact analysis (RIA) concurrent with the notice of proposed rulemaking. This activity is conducted

this decision is based, including the documents described above, are made available to the public in the regulatory docket for the review. A public comment period, during which public hearings are generally held, follows publication of the notice of proposed rulemaking. Taking into account comments received on the proposed rule,[8] the Agency develops a final rule which undergoes interagency review prior to publication to complete the rulemaking process. Chapter 7 discusses the development of the PA and the rulemaking steps for this review.

under Executive Order 12866. The RIA is conducted completely independent of and, by statute, is not considered in decisions regarding the review of the NAAQS.

[8]When issuing the final rulemaking, the Agency responds to all significant comments on the proposed rule.

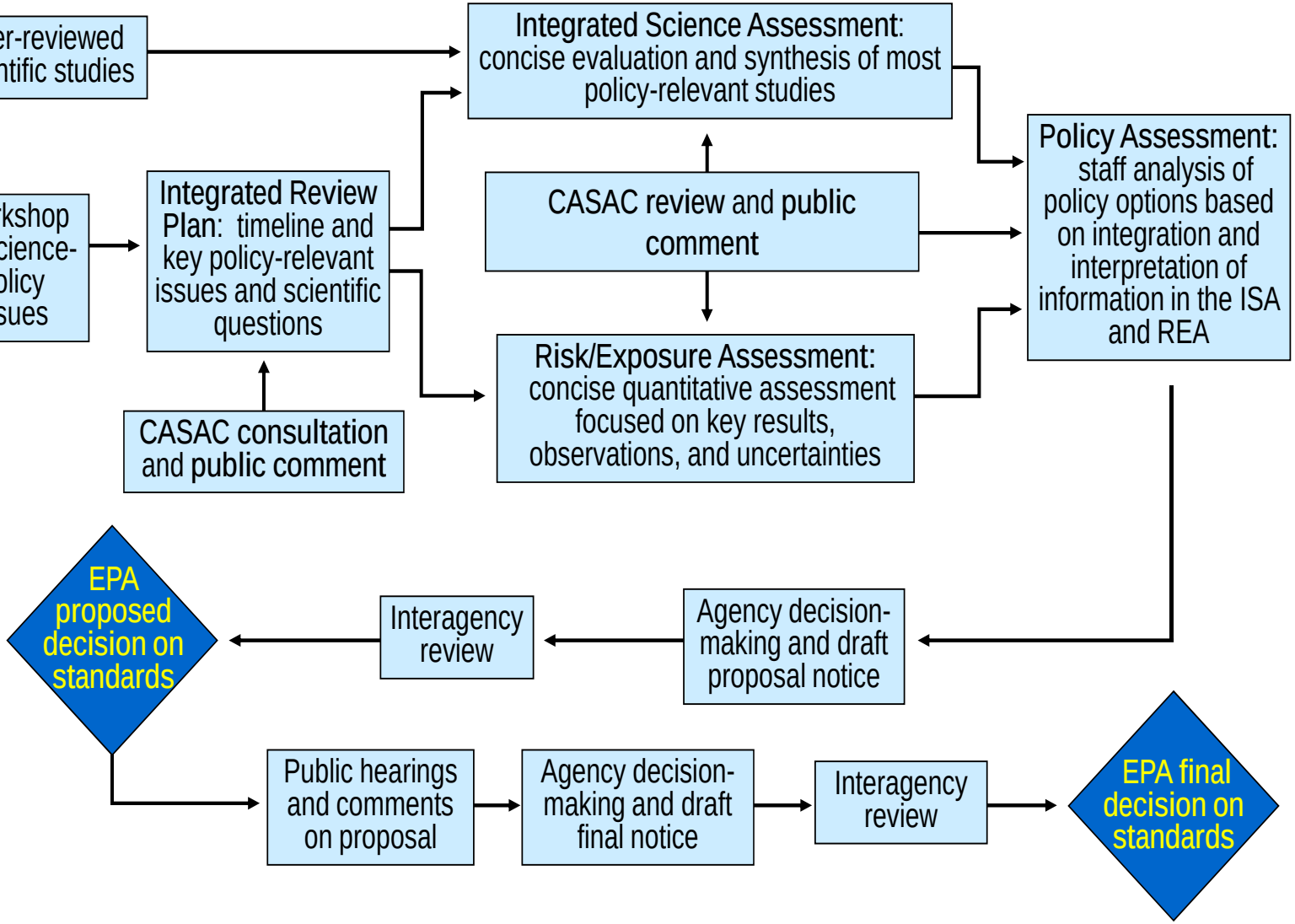


**Figure 1-1. Overview of the NAAQS Review Process.**

## 1.3 REVIEW OF AIR QUALITY CRITERIA AND STANDARDS FOR LEAD

On October 5, 1978, EPA initially promulgated primary and secondary NAAQS for Pb under section 109 of the Act (43 FR 46246). Both primary and secondary standards were set at a level of 1.5 micrograms per cubic meter ($\mu g/m^3$), measured as Pb in total suspended particles (Pb-TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. These standards were based on the 1977 Air Quality Criteria for Lead (USEPA, 1977).

The first 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 recommendations for consideration by the Administrator (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).

The most recent review of the Pb air quality criteria and standards was initiated in November, 2004 (69 FR 64926) and the Agency's plans for preparation of the Air Quality Criteria Document and conduct of the NAAQS review were contained in two documents: *Project Work Plan for Revised Air Quality Criteria for Lead* (USEPA, 2005); and *Plan for Review of the National Ambient Air Quality Standards for Lead* (USEPA 2006a).[9] The schedule for completion of this review was governed by a judicial order in Missouri Coalition for the Environment v. EPA (No. 4:04CV00660 ERW, Sept. 14, 2005; and amended on April 29, 2008 and July 1, 2008,), which specified a schedule for the review of duration substantially shorter than five years.

[9] In the current review, these two documents have been combined into an integrated plan (this document).

The scientific assessment for the review is described in the 2006 Air Quality Criteria for Lead (USEPA, 2006b), multiple drafts of which received review by CASAC and the public. EPA also conducted human exposure and health risk assessments and a pilot ecological risk assessment for the review, after consultation with CASAC and receiving public comment on a draft analysis plan (USEPA, 2006c). Drafts of these quantitative assessments were reviewed by CASAC and the public. The pilot ecological risk assessment was released in December 2006 (ICF, 2006) and the final health risk assessment report was released in November 2007 (USEPA, 2007a). The policy assessment based on both of these assessments, air quality analyses and key evidence from the AQCD was presented in the Staff Paper (USEPA, 2007b), a draft of which also received CASAC and public review. The final Staff Paper presented 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 presented and interpreted results from the quantitative risk/exposure analyses conducted for this review. Based on this evaluation, the Staff Paper presented OAQPS staff recommendations that the Administrator give consideration to substantially revising the primary and secondary standards to a range of levels at or below 0.2 micrograms per cubic meter ($\mu g/m^3$).

Immediately 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).[10] CASAC provided advice and recommendations to the Administrator with regard to the Pb NAAQS based on its review of the ANPR and the previously released final Staff Paper and Risk Assessment Report. The proposed decision on revisions to the Pb NAAQS was signed on May 1, 2008 and published in the Federal Register on May 20, 2008 (73 FR 29184). In addition to public comments on the proposal received during the public comment period, both written and oral at two public hearings, the CASAC Pb Panel provided advice and recommendations to the Administrator based on its review of the proposal notice. The final decision on revisions to the Pb NAAQS was signed on October 15, 2008 and published in the Federal Register on November 12, 2008 (73 FR 66964).

The November 2008 notice described EPA's revisions to the primary and secondary NAAQS for Pb. In consideration of the much-expanded health effects evidence on neurocognitive effects of Pb in children, EPA substantially revised the primary standard from a level of 1.5 micrograms per cubic meter ($\mu g/m^3$) to a level of 0.15 $\mu g/m^3$. EPA's decision on the level for the standard was based on the weight of the scientific evidence and guided by an evidence-based framework that integrates evidence for relationships between Pb in air and Pb in

[10] The ANPR was one of the features of the revised NAAQS review process that EPA instituted in 2006. In 2009 (Jackson, 2009), this component of the process was replaced by reinstatement of the OAQPS policy assessment (previously termed the Staff Paper).

children's blood and Pb in children's blood and IQ loss. The level of 0.15 μg/m3 was estimated to protect against air Pb-related IQ loss in the most highly exposed children, those exposed at the level of the standard. Results of the quantitative risk assessment were judged supportive of the evidence-based framework estimates. The averaging time was revised to a rolling 3-month period with a maximum (not-to-be-exceeded) form, evaluated over a 3-year period. As compared to the previous averaging time of calendar quarter, this revision was considered to be more scientifically appropriate and more health protective. The rolling average gives equal weight to all three-month periods, and the new calculation method gives equal weight to each month within each three-month period. Further, the rolling average yields 12 three-month averages each year to be compared to the NAAQS versus four averages in each year for the block calendar quarters pertaining to the previous standard. The indicator of Pb in total suspended particles (Pb-TSP) was retained, reflecting the evidence that Pb particles of all sizes pose health risks. The secondary standard was revised to be identical in all respects to the revised primary standards.[11]

Revisions to the NAAQS were accompanied by revisions to the data handling procedures, the treatment of exceptional events and the ambient air monitoring and reporting requirements, as well as emissions inventory reporting requirements.[12] As described in chapter 6 below, one aspect of the new data handling requirements is the allowance for the use of Pb-$PM_{10}$ monitoring for Pb NAAQS attainment purposes in certain limited circumstances at non-source-oriented sites. Subsequent to the 2008 rulemaking, additional revisions were made to the monitoring network requirements as described in chapter 6 below.

## 1.4 SCOPE OF THE CURRENT REVIEW

For the current review of the Pb standards, relevant scientific information will be assessed with regard to human exposures and health effects associated with exposure to ambient air-related Pb. The review will also assess any relevant scientific information associated with known or anticipated public welfare effects that may be identified. Unlike the other pollutants for which NAAQS are established, Pb is a multimedia pollutant. Lead emitted into ambient air may subsequently occur in multiple environmental media, contributing to multiple pathways of exposure for humans and ecological receptors. This multimedia distribution of and

[11] The current NAAQS for Pb are specified at 40 CFR 50.16.

[12] The current federal regulatory measurement methods for Pb are specified in 40 CFR 50, Appendix G and 40 CFR part 53. Consideration of ambient air measurements with regard to judging attainment of the standards is specified in 40 CFR 50, Appendix R. The Pb monitoring network requirements are specified in 40 CFR 58, Appendix D, section 4.5. Guidance on the approach for implementation of the new standards was described in the Federal Register notices for the proposed and final rules (73 FR 29184; 73 FR 66964).

multipathway exposure to air-related Pb has a key role in the Agency's consideration of the Pb NAAQS. Some associated considerations include the following (73 FR 66971):

- Lead emitted into the air is predominantly in particulate form, which can be transported long or short distances depending on particle size.
- Once deposited out of the air, Pb can subsequently be resuspended in the ambient air and, because of the persistence of Pb, Pb emissions contribute to media concentrations for some years into the future.
- Exposure to Pb emitted into the ambient air (air-related Pb) can occur directly by inhalation, or indirectly by ingestion of Pb-contaminated food, water or other materials including dust and soil.[13] These exposures occur 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.
- Air-related exposure pathways are affected by changes to air quality, including changes in concentrations of Pb in air and changes in atmospheric deposition of Pb. Further, because of its persistence in the environment, Pb deposited from the air may contribute to human and ecological exposures for years into the future. Thus, the roles of both air concentration and air deposition in human exposure pathways, and the persistence of Pb once deposited, influence the dynamics of the response of the various Pb exposure pathways to changes in air quality.

The current review of the Pb standards builds on the substantial body of work done during the course of the last review. In addition to a comprehensive Air Quality Criteria Document, EPA staff designed and conducted a complex multimedia, multipathway health risk assessment involving case studies represented different ambient air Pb exposure circumstances, and an assessment of the available information on ecological impacts of Pb, including the consideration of potentially vulnerable ecosystems. These different types of information were evaluated in a Staff Paper and provided the basis for the notice of proposed rulemaking and for the substantial revisions made to the Pb NAAQS. In light of the extensive and detailed quantitative analysis of health risks in the last review, as well as the substantial revisions made to the standard and the period of time elapsed since then in which new data may have been collected, the information newly available in the current review will be considered with regard to the extent to which an update or expansion to the last quantitative risk assessment is warranted.

[13] In general, air-related pathways include those pathways where Pb passes through ambient air on its path from a source to human exposure or to an ecological receptor.

# 2 REVIEW SCHEDULE

In April 2010, EPA's National Center for Environmental Assessment in Research Triangle Park, NC (NCEA-RTP) announced the initiation of the current periodic review of the air quality criteria for Pb and the Pb NAAQS and issued a call for information in the Federal Register (75 FR 20843). Also, as an initial step in the NAAQS review process described in Section 1.1 above, EPA invited a wide range of external and internal EPA experts, representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science) to participate in a workshop to discuss the policy-relevant science to inform development of this plan. This workshop was held May 10-11, 2010 in Research Triangle Park, NC (75 FR 20843). This workshop provided an opportunity for the participants to broadly discuss the key policy-relevant issues around which EPA would structure the Pb NAAQS review and to discuss the most meaningful new science that would be available to inform our understanding of these issues. Based in part on the workshop discussions, EPA has developed this draft integrated review plan outlining the schedule, the process, and the key policy-relevant science issues that will guide the evaluation of the air quality criteria for Pb and the review of the primary and secondary Pb NAAQS.

Table 2-1 outlines the schedule under which the Agency is currently conducting this review. The scopes of the review and of the key documents to be prepared during the review are discussed throughout the rest of this document.

**Table 2-1. Proposed Schedule for Review of Ambient Air Quality Criteria and NAAQS for Pb.**

| Stage of Review | Major Milestone | Draft Target Dates |
|---|---|---|
| Integrated Plan | Literature Search | Ongoing |
| | Federal Register Call for Information | April 2010 |
| | Workshop on science/policy issues | May 2010 |
| | Draft Integrated Review Plan (IRP) | March 2011 |
| | CASAC consultation on IRP | May 5, 2011 |
| | Final IRP | June 2011 |
| Science Assessment | First draft of ISA | End April 2011 |
| | CASAC public meeting for review of first draft ISA | July 20-21, 2011 |
| | Second draft of ISA | December 2011 |
| | CASAC/public review of second draft ISA | February/March 2012 |
| | Final ISA | June 2012 |
| Risk/Exposure Assessment | Planning document | June 2011 |
| | CASAC public meeting for consultation on planning document | July 21, 2011 |
| | If warranted, | |
| | First draft risk and/or exposure assessments (REA) | January 2012 |
| | CASAC/public review of first draft REA | February/March 2012 |
| | Second draft REA | July 2012 |
| | CASAC/public review of second draft REA | September/October 2012 |
| | Final REA | January 2013 |
| Policy Assessment/ Rulemaking | First draft of policy assessment (PA) | August 2012 |
| | CASAC/public review of first draft PA | September 2012 |
| | Second draft of PA | February 2013 |
| | CASAC/public review of second draft PA | March 2013 |
| | Final PA | June 2013 |
| | Notice of proposed rulemaking | January 2014 |
| | Notice of final rulemaking | November 2014 |

# 3 KEY POLICY-RELEVANT ISSUES

For our purposes in considering the overarching questions regarding the adequacy of the current Pb NAAQS, we have identified key policy-relevant issues to be addressed in this review. They are presented below as a series of policy-relevant questions that will frame our approach to considering whether the current primary and secondary NAAQS for Pb should be retained or revised. The ISA, REAs (if conducted), and PA developed in this new review will provide the basis for addressing these questions and will inform the Agency's judgment as to the adequacy of the current primary and secondary standards for Pb, and decisions as to whether to retain or revise these standards.

## 3.1 ISSUES RELATED TO THE PRIMARY NAAQS

The first step in reviewing the adequacy of the current primary NAAQS is to consider whether the available body of scientific evidence, assessed in the ISA, and used as a basis for any analyses that might be presented in an REA, supports or calls into question the scientific conclusions reached in the last review regarding health effects related to exposure to ambient air-related Pb. This evaluation of the available scientific evidence will focus on key policy-relevant issues by addressing a series of questions including the following:

- To what extent has new information altered the scientific support for the occurrence of health effects associated with exposure to levels of Pb found in the ambient air?
- To what extent has new information altered conclusions from previous reviews regarding the plausibility of adverse health effects caused by Pb exposure?
- To what extent does the evidence suggest that alternate dose indicators other than blood Pb levels should be evaluated to characterize the biological effect?
- At what levels of Pb exposure do health effects of concern occur?
- To what extent has new information altered scientific conclusions regarding the relationships between Pb in ambient air and Pb in children's blood and between Pb in children's blood and reduced IQ?
- Has new information altered our understanding of human subpopulations that are particularly sensitive to Pb exposures? Is there new or emerging evidence on health effects beyond neurocognitive endpoints in children that suggest additional sensitive subpopulations should be given increased focus in this review?
- To what extent is key scientific evidence becoming available to improve our understanding of the health effects associated with various time periods of Pb exposures, including not only daily, but also chronic (months to years) exposures? To what extent is critical research becoming available that could improve our understanding of the relationship between various health endpoints and different lag periods (e.g., single day, multi-day distributed lags)?

- To what extent do any risk or exposure analyses developed for the review suggest that exposures of concern for Pb-related health effects are likely to occur with current ambient levels of Pb or with levels that just meet the Pb standard? If estimates are developed, are the estimated risks/exposures of sufficient magnitude such that the health effects might reasonably be judged to be important from a public health perspective? What are the important uncertainties associated with any risk/exposure estimates?
- To what extent have important uncertainties identified in the last review been reduced and/or have new uncertainties emerged?
- To what extent does newly available information reinforce or call into question any of the basic elements of the current Pb standard?

If the evidence suggests that revision of the current standards might be appropriate, EPA will evaluate how the standards might be revised. Specifically, we will evaluate how the scientific information and assessments inform decisions regarding the basic elements of the Pb NAAQS: indicator, averaging time, level, and form. These elements will be considered collectively in evaluating the health protection afforded by the current or any alternative standards considered. Specific policy-relevant questions that will be addressed include:

- To what extent is there any new information that would support consideration of a different indicator for Pb?
- To what extent does the health effects evidence evaluated in the ISA, air quality analyses and, if available, the REA, provide support for considering different exposure indices or averaging times?
- To what extent do air quality analyses and other information provide support for consideration of alternative standard forms?
- What range of alternative standard levels should be considered based on the scientific evidence evaluated in the ISA, air quality analyses and, if available, REA?
- What are the important uncertainties and limitations in that evidence and assessments and how might those uncertainties and limitations be taken into consideration in identifying alternative standards for consideration?

## 3.2 ISSUES RELATED TO THE SECONDARY NAAQS

As with the review of the primary NAAQS, the first step in reviewing the adequacy of the current secondary NAAQS is to consider whether the available body of scientific evidence, assessed in the ISA, and used as a basis for any analyses that might be presented in an REA, supports or calls into question the scientific conclusions reached in the last review regarding welfare effects related to exposure to ambient air-related Pb. This evaluation of the available scientific evidence will focus on key policy-relevant issues by addressing a series of questions for each category of Pb-related welfare effects identified in the ISA as being associated with the presence of Pb in the ambient air, while taking into account multimedia, multipathway exposures:

- To what extent does the available information demonstrate or suggest that Pb-related effects are occurring at current ambient conditions or at levels that would meet the current standard?
- To what extent does the available information inform judgments as to whether any observed or anticipated effects are adverse to public welfare?
- To what extent is the current secondary standard likely to be effective in achieving protection against any identified adverse effects?
- Are there new empirical data or modeling results that would enhance our understanding of the movement of lead in ecosystems, or improve our understanding of bioavailability and mechanisms of exposure?
- What new information is available about the nature of lead effects on aquatic ecosystems? What new evidence is there regarding critical loads for these systems?
- Does the newly available evidence alter the scientific support for lead effects on terrestrial or aquatic ecosystems associated with the levels of Pb found in ambient air?
- Does the newly available evidence indicate different exposure levels at which ecological receptors are expected to experience effects?
- What new information, methods or tools are available to inform or facilitate assessment of the accumulation and movement of air-deposited Pb through terrestrial and aquatic ecosystems over time?
- To what extent does newly available information reinforce or call into question any of the basic elements of the current Pb standard?

To the extent that the evidence suggests that revision of the current secondary Pb NAAQS would be appropriate to consider, the staff then identifies ranges of standards (in terms of exposure indices, averaging times, levels, and forms) that would reflect a range of alternative policy judgments as to the degree of protection that is requisite to protect public welfare from known or anticipated adverse effects. In so doing, the staff addresses the following questions taking into account multimedia, multipathway exposures:

- Does the available information provide support for considering different Pb exposure indices?
- Does the available information provide support for considering different averaging times?
- What range of levels and forms of alternative standards is supported by the information, and what are the uncertainties and limitations in that information?
- To what extent do specific levels and forms of alternative standards reduce adverse impacts attributable to Pb, and what are the uncertainties in the estimated reductions?

# 4 SCIENCE ASSESSMENT

## 4.1 SCOPE AND ORGANIZATION

The science assessment for Pb will consist of the ISA as well as supplementary materials (see Section 4.5) if additional documentation is required to support information contained within the ISA. The ISA will critically evaluate and integrate the scientific information on the health and welfare effects associated with exposure to Pb. The ISA is not intended to provide a detailed literature review; but rather, will draw from the existing body of evidence to synthesize the current state of knowledge on the most relevant issues pertinent to the review of the NAAQS for Pb. The ISA provides an updated comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of Pb in the ambient air, thus revising the assessment available at the time of the last review.

Discussions in the ISA will primarily focus on scientific evaluations that can inform the key policy questions described in Chapter 3 of this document. Although emphasis is placed on discussion of health and welfare effects information, other scientific information is also presented and evaluated in order to provide a better understanding of the sources of Pb to ambient air, measurement and concentrations of Pb in ambient air, its subsequent fate and transport in the environment, pathways of human and ecological exposure, and toxicokinetic characteristics of Pb in the human body, as well as the characterization of population exposures to Pb.

The ISA will build on the conclusions of the last review of the air quality criteria for Pb, presented in the 2006 air quality criteria document (AQCD) (U.S. EPA, 2006), and focus on peer reviewed literature published thereafter and on any new interpretations of previous literature. The 2006 AQCD (U.S. EPA, 2006) evaluated literature published through December 2005. The ISA will begin with a discussion of major legal and historical aspects of prior review documents as well as key milestones and procedures for document preparation. In subsequent chapters, the results of recent scientific studies will be integrated with previous findings. Important older studies may be discussed in detail to reinforce key concepts and conclusions and/or if they are open to reinterpretation in light of newer data. Older studies also may be the primary focus in some areas of the document where research efforts have subsided, and these older studies remain the definitive works available in the literature. Emphasis will be placed on studies that examine effects associated with Pb concentrations relevant to current population and ecosystem exposures, and particularly those pertaining to Pb concentrations currently found in ambient air. Other studies may be included if they contain unique data, such as a previously unreported effect

or mechanism for an observed effect, or examine multiple concentrations to elucidate exposure-response relationships.

## 4.2 ASSESSMENT APPROACH

### 4.2.1 Introduction

The EPA's National Center for Environmental Assessment in Research Triangle Park (NCEA-RTP) is responsible for preparing the ISA for Pb. In each NAAQS review, development of the science assessment begins with a "Call for Information" published in the Federal Register. This notice announces EPA's initiation of activities in the preparation of the ISA for the specific NAAQS review and invites the public to assist through the submission of research studies in the identified subject areas. This and subsequent key components of the process currently followed for the development of an ISA (i.e., the standard protocol) are presented in Figure 4.1. How the ISA fits into the larger NAAQS review process is briefly described in section 1.2, the Overview of the NAAQS Review Process. Important aspects of the development of the ISA are described in the sections below, including the approach for searching the literature and identifying relevant publications and specific policy-relevant questions intended to guide the assessment. These responsibilities are undertaken by expert authors of the ISA chapters that include EPA staff with extensive knowledge in their respective fields and extramural scientists solicited by EPA for their expertise in specific fields. The process for scientific and public review of drafts of the ISA is described in Section 4.6.

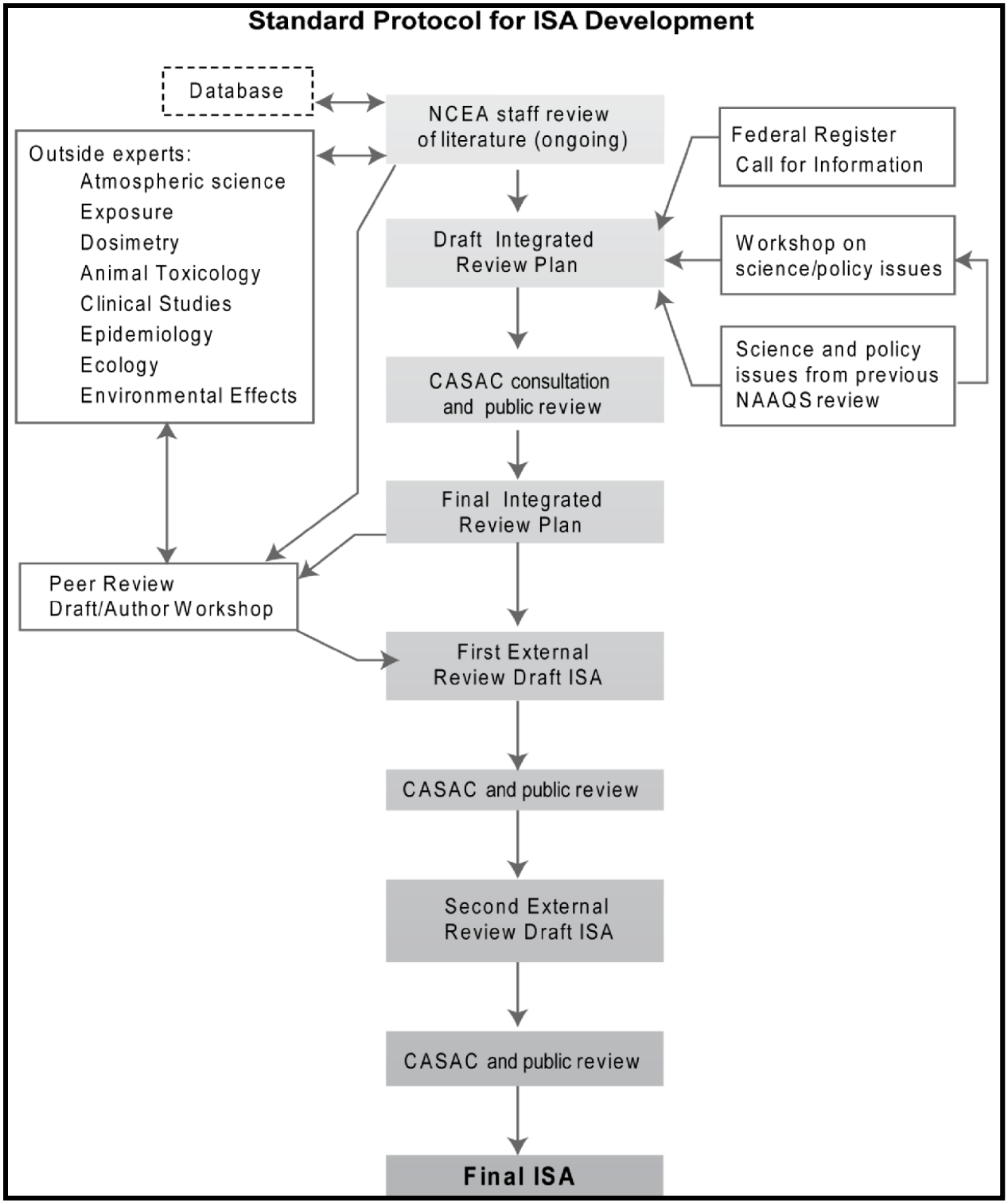


**Figure 4-1. Standard steps in the development of Integrated Science Assessments (ISAs).**

### 4.2.2 Literature Search and Identification of Relevant Studies

The NCEA-RTP will use a systematic approach to identify relevant studies for inclusion in the Pb assessment. The EPA has already published a Federal Register notice (75 FR 8934, February 26, 2010) to announce the initiation of this review and request information from the public. In addition to the call for information, publications will be identified through an ongoing literature search process that includes extensive computer database mining on specific topics in a variety of disciplines. Additional publications will be identified by EPA scientists by reviewing previous EPA reports and reviewing reference lists from key publications; studies also will be identified in the course of CASAC and public review.

From the lists of publications broadly compiled from the search methods described above, EPA will identify relevant studies to be reviewed as part of the assessment. Epidemiologic studies, animal toxicological studies, and studies of ecological or welfare effects of Pb, including those related to exposure-response relationships, mode(s) of action (MOA), and susceptible populations and lifestages will be identified. Additionally, air quality and emissions data, studies on atmospheric chemistry, environmental fate and transport, as well as issues related to Pb toxicokinetics and exposure will also be identified. The assessment will include research published or accepted for publication since the 2006 air quality review and through approximately one month prior to the release of the second external review draft of the ISA (see Table 2-1). Studies published after that date may also be assessed if they provide new information that impacts one or more key scientific issues. Once identified, studies are reviewed with regard to quality assurance criteria described in section 4.2.3 below before including them in the assessment document.

The combination of the approaches described here is expected produce the comprehensive collection of studies to be included in the assessment and from which the most informative and policy relevant studies will be selected for particular focus.

### 4.2.3 Criteria for Study Selection

In general, in assessing the scientific quality and relevance of health and environmental effects studies, the following quality assurance criteria are considered when selecting studies for inclusion in the ISA.

1. Are the study populations, subjects, or animal models adequately selected and are they sufficiently well defined to allow for meaningful comparisons between study or exposure groups?
2. Are the statistical analyses appropriate, properly performed, and properly interpreted? Are likely covariates adequately controlled or taken into account in the study design and statistical analysis?
3. Are the air quality data, exposure, or dose metrics of adequate quality?

4. Are the health or welfare effect measurements meaningful and reliable?

Studies published since the last air quality criteria review will be emphasized in the ISA; however, evidence from studies described in last assessment that are needed to characterize the current state of the science as well as new interpretations of older evidence will also will be included in the assessment.

Among the studies included in the ISA, EPA will give particular focus to those containing information in the following areas:

1. new studies with adequate data at the low end of the exposure distribution (e.g. <10 µg/dL blood);
2. new studies that provide quantitative effect estimates for populations or lifestages and concentrations of interest;
3. Pb exposure or effects in susceptible populations and lifestages;
4. issues related to the potential for confounding of study effects/responses by non-Pb exposure-related factors or variables, and to the modification of Pb-related effects;
5. the timing (e.g., across/within specific lifestages) and duration of exposure associated with specific responses;
6. concentration-response relationships for specific Pb-related effects;
7. the interpretation of Pb biomarkers in epidemiological studies; and/or air-to-blood Pb or air-to-bone Pb relationships;
8. studies that evaluate Pb as a component of a complex mixtures of pollutants.

In selecting epidemiologic studies for inclusion in the present assessment, EPA will consider studies containing information on (1) recent or cumulative exposures relevant to current population exposure levels of Pb; (2) health endpoints that repeat or extend findings from earlier assessments as well as those not previously extensively researched; (3) populations and lifestages that are susceptible to Pb exposures; (4) issues related to potential confounding, and modification of effects; and/or (5) important methodological issues (e.g., timing and duration of exposure, concentration-response relationships, interpretation of biomarkers in epidemiological studies, and air-to-blood/bone relationships) related to Pb exposure effects. In selecting the most informative and policy relevant epidemiologic studies on which to give particular focus in the Pb ISA, emphasis will be placed on those most relevant to standard setting in the United States. Informative studies conducted in other countries will be discussed, as appropriate (e.g. studies for which the mean blood Pb level in the population studied is comparable to the current mean blood Pb level in the corresponding U.S. population).

In reviewing new studies in the ISA that have evaluated the response of laboratory animals to Pb exposure, we will review studies that reveal the effects of Pb exposure within the

previously identified target biological systems (e.g. neurological, cardiovascular, renal, immune). Additionally, particular focus will be given to those studies that involve doses or body burdens that approximate human doses or body burden conditions relevant to current U.S. exposures. Studies at higher exposure or doses that result in body burdens above what is found in the current U.S. population will be discussed when the study can provide information relevant to potential mechanisms of action, information on exposure-response relationships, or otherwise improve our understanding of susceptible populations and lifestages.

In reviewing informative studies of welfare effects, emphasis will be placed on recent studies that: (1) evaluate the occurrence of effects associated with Pb exposure at current ambient levels, with a particular focus on ambient levels resulting from ambient air Pb, and/or (2) investigate the effects of Pb on ecosystems at any scale. Studies conducted in geographical areas outside the U.S. will be included in the assessment if they contribute to the general knowledge of the effects of Pb irrespective of species or locality. As in the selection of health-related scientific studies, welfare-related studies will be selected that advance our understanding of mechanisms by which Pb directly affects terrestrial and aquatic biota. These mechanisms, as they pertain to Pb exposures of short or longer duration, will inform our understanding of indirect effects that Pb may exert more broadly on ecosystem structure, function and services. Key studies identified for welfare effects will be integrated into the discussion to inform our interpretation of the ecological literature and our characterization of uncertainties.

The criteria described here provide generalized benchmarks to guide the inclusion in the ISA of the highest quality and most policy-relevant studies. Detailed critical analysis of all studies of the effects of Pb on health and welfare, especially in relation to the above criteria, is beyond the scope of this document. Since the last scientific review was completed within the past five years, it is expected that a considerable portion of the current ISA may be devoted to summarizing previously available evidence that contributed to the basis for the last rulemaking.

### 4.2.4 Quality Assurance

NCEA participates in the Agency-wide Quality Management System, which requires the development of a Quality Management Plan (QMP). Implementation of the NCEA QMP ensures that all data generated or used by NCEA scientists are "of the type and quality needed and expected for their intended use" and that all information disseminated by NCEA adheres to a high standard for quality including objectivity, utility and integrity. Quality assurance (QA) measures detailed in the QMP will be implemented beginning with the start of the current Pb review, including the development of the Pb ISA.

The NCEA QA staff is responsible for the review and approval of quality-related documentation. NCEA scientists are responsible for the evaluation of all inputs to the ISA,

including primary (new) and secondary (existing) data, to ensure their quality is appropriate for their intended purpose. NCEA follows the Data Quality Objectives, which identify the most appropriate inputs to the science assessment, and provides QA instruction for researchers citing secondary information. The approaches utilized to search the literature and criteria for study selection were detailed in the two preceding subsections. Generally, NCEA scientists rely on scientific information found in peer-reviewed journal articles, books, and government reports. Where information is integrated or reduced from multiple sources to create new figures, tables, or summation, the data generated are considered to be new and subject to rigorous quality assurance measures to ensure their accuracy.

## 4.3 CONTENT AND ORGANIZATION OF THE ISA

Generally, the organization of the Pb ISA will be similar to the organization of the integrative synthesis chapter of the 2006 Pb AQCD (U.S. EPA, 2006) and recent assessments for other criteria pollutants (e.g. Carbon Monoxide (U.S. EPA, 2010)).

The ISA for Pb will contain information relevant to considering whether it is appropriate to retain or revise the current ambient air Pb standards. Decisions on the specific content of the ISA will be guided by the series of policy-relevant questions outlined in Chapter 3 in addition to a set of policy-relevant questions more specifically related to scientific evidence that may become newly available in the current review process. These policy-relevant questions for the ISA are related to two overarching issues. The first issue is the extent to which new scientific evidence has become available that alters or substantiates the scientific evidence presented and evaluated in the last Pb NAAQS review. The second issue is whether uncertainties from the last air quality criteria review have been addressed and/or whether new uncertainties have emerged. The specific questions related to the review of the scientific literature for Pb that stem from these two issues were derived from the last Pb NAAQS review, as well as from discussions of the scientific evidence that occurred at the May 2010 Science Policy Workshop for the current review (75 FR 20843). These specific questions, which will guide decisions on content for the Pb ISA, are listed below by topic area.

**Source to Exposure**

<u>Ambient Air Sources and Multimedia Environmental Distribution</u>: The ISA will present and evaluate current information related to sources of Pb to ambient air, ambient air concentrations and size distributions of Pb measured as a component of particulate matter. Note that gas phase Pb data are not available in the EPA Air Quality System (AQS) for assessment of Pb in the vicinity of gaseous Pb emissions where leaded gasoline is still used (e.g. airports, certain automotive racing facilities). The available information will be presented concerning sources of

freshly and previously emitted Pb including resuspension of previously deposited Pb. The ISA will evaluate relevant information concerning the transport and fate of Pb released into the air directly and via other environmental media (e.g., soil, surface and ground water). The ISA will discuss Pb fluxes into and distribution among different media. Where available, the ISA will draw from information in the literature about the bioavailability of Pb in different media to organisms based on the organisms' biochemical characteristics.

The assessment will also describe the distribution of air monitors in the federal regulatory Pb monitoring network and consider new studies that address the precision and accuracy of the Federal Reference and Federal Equivalent Methods (FRM and FEM, respectively) for Pb. The assessment will also consider information on the design of other air monitoring networks in which Pb measurements are taken, such as the Chemical Speciation Network (CSN), Interagency Monitoring of Protected Visual Environments (IMPROVE), and National Air Toxics Trends Stations (NATTS). Additionally, new information regarding Pb techniques for the analysis of particulate matter samples will be discussed. In reviewing the currently available evidence, we will consider the following specific questions:

1. What new evidence is available on primary and secondary sources of Pb?
2. What new information is available regarding the fate and transport of Pb in the environment? What new data exists to characterize atmospheric deposition and resuspension of Pb.
3. What new information is available regarding monitoring Pb in the environment and analyzing Pb species within particulate matter samples?
4. What data are available to characterize airborne Pb concentrations, spatial and temporal variability of concentrations, size distributions of Pb in the environment as a function of different sources of Pb, and covariation of Pb concentrations with other ambient air pollutant concentrations?

<u>Exposure</u>: The ISA will compile and evaluate evidence developed since the last assessment that helps characterize the variability and uncertainty in the relationships between ambient Pb concentrations and exposures to Pb of humans and ecosystems relevant to the primary and secondary standards. A conceptual model of Pb exposure through various pathways, including exposure to airborne Pb and Pb deposited onto soil, as well as that which contributes to indoor dust and dietary exposures, will be discussed. EPA will also assess studies relevant to the assessment of errors in measurement or estimation of human exposure to Pb as well as the possibly differential exposures of some populations. The following questions will be considered during review of the available evidence:

1. What new evidence is available on exposure to Pb through air-related pathways? Can air-related pathways be disentangled from water- and soil-related pathways using available data?

2. What new evidence is available regarding observational studies of Pb exposure? How do these studies inform the assessment of exposure to air-related pathways?
3. What new studies address susceptibility to elevated Pb exposure?

**Toxicokinetics, Biological Markers, and Models of Lead Burden in Humans**

The ISA will evaluate the literature relating to the toxicokinetics[14] of Pb, including the application of available models to evaluate the storage of Pb in the body, biological markers of Pb that indicate exposure and body burden, and the quantification of Pb exposure or dose from air-related exposure pathways (e.g. air-to-blood ratios). During the last review, uncertainties were identified including the blood Pb-air Pb relationship in slope-factor models, and the interpretation of blood Pb and bone Pb concentrations reported in epidemiologic studies. The ISA will consider these key uncertainties and evaluate the extent to which new scientific evidence may inform our ability to characterize and/or reduce those uncertainties during the current review. In reviewing the currently available evidence, we will consider the following specific questions:

1. What new evidence is available on biological and other factors that could affect the distribution and accumulation of Pb into blood and bone (e.g., age, nutrition, gender, race)?
2. What new evidence is available on population and lifestage variability in Pb biokinetics?
3. What new developments are available in biokinetic models that can be used for estimating impacts of multimedia human lead exposures on internal body burden, generally indicated by blood or bone Pb levels? Is there new evidence to inform our understanding of the response of blood Pb to changes in ambient air Pb and associated exposure pathways?
4. What new evidence is available to characterize biomarkers of concurrent and cumulative exposures? What are the related uncertainties with interpreting biomarker data for exposure assessment?
5. How and to what extent does previous or concurrent Pb exposure, including duration (e.g., acute, subchronic, chronic) and pattern (e.g., continuous low, extreme peak) impact blood Pb and bone Pb?
6. What new evidence is available on the relationship between air Pb and blood Pb levels and uncertainties in that relationship? What new knowledge exists regarding the characterization of changes in this relationship when accounting for the multiple pathways of Pb exposure and body burden associated with Pb exposure? What does the current evidence indicate regarding variation in the relationship with variation in blood Pb levels or air Pb levels?

[14] The phrase toxicokinetics refers generally to the quantitative aspects and timing of absorption, distribution, biotransformation and excretion of xenobiotic chemicals in the body.

7. To what extent does new scientific evidence increase our understanding of the contributions of Pb from different sources and exposure pathways to blood Pb levels or to other indicators of Pb body burden (e.g., contributions from various air-related pathways, including diet and indoor dust pathways)?

**Human Health Effects**

The ISA will evaluate the scientific literature related to neurological, cardiovascular, renal, immune, hematological and other health effects associated with exposures to Pb. Building upon the last review, EPA will continue to review the available epidemiologic and toxicological evidence related to these health effects and, to the extent data are available, additional endpoints (e.g., mortality, developmental, carcinogenic/mutagenic, and cellular outcomes). The results of new studies will be integrated with the previous findings and with any new interpretations of previous findings. The ISA will also integrate previous information on susceptible populations and lifestages (e.g., children, lactating women, and older adults) or factors affecting susceptibility (e.g., genetic polymorphisms and health status) with any new evidence on susceptibility factors, lifestages or populations.

For a given type of health outcome, the ISA will fully integrate findings across the different disciplines to evaluate the strength, robustness and consistency of evidence, which contribute to EPA's assessment of causal relationships. Integration will also entail using the toxicological findings to assess biological plausibility for the epidemiologic findings, including the coherence of epidemiologic observations with known mechanisms of toxicity. Efforts will be directed at identifying the lower blood Pb levels at which adverse effects are observed and at describing concentration-response relationships with a focus on Pb exposures at the lower end of the distribution. Concentration-response relationships also will be evaluated for comparability across the studies. Another area of focus includes assessment of the durations of exposure and specific developmental periods of exposure that are most strongly associated with particular health effects. The ISA will also assess the evidence for uncertainties related to these associations and evaluate information on the public health implications related to ambient Pb exposure. Grouped by topic area, some of the specific scientific questions that EPA will seek to address in the ISA are as follows:

<u>Health Endpoints:</u> The ISA will evaluate health effects evidence for a multitude of outcomes assessed in epidemiologic and toxicological studies guided by the following questions:

1. How do results of recent epidemiologic studies and current or new interpretations of previous findings expand our understanding of the relationship between body burdens of Pb and neurological effects in children and adults, including deficits in IQ, behavior, learning, and motor skills, as well as risk of neurodegenerative diseases? What new evidence is available on the potential clinical relevance of these effects?

Do recent studies expand the current understanding of concentration-response relationships pertinent to the range of Pb exposures currently experienced by the U.S. population?

2. How do different indicators of Pb body burdens (e.g., Pb in blood or bone) compare in terms of their associations with adverse health outcomes? What do these findings contribute to the understanding of how effects may differ for more recent and cumulative lifetime exposure?

3. What new epidemiological evidence is available on health outcomes associated with measures of Pb exposure in the elderly (e.g., total mortality and cardiovascular mortality)? What does such evidence indicate regarding the potential for different impacts of early-life, current, and cumulative lifetime Pb exposures?

4. Within the epidemiologic literature, is there consistency between associations observed in children and adults and between related health outcomes (e.g., cardiovascular and renal)?

5. Does new evidence from the literature on effects observed in adult animals in response to experimental exposures to Pb during development inform the understanding of populations and life stages that are susceptible to Pb exposure (e.g., children, elderly, obese)? Within the sensitive in utero period of development, is there evidence of Pb causing epigenetic changes or evidence of Pb effects differing between the sexes or genetic variants?

6. For what Pb-induced health effects, is there sufficient evidence in multiple species to support a quantitative comparison of exposures that induce the effects?

7. To what extent does exposure to Pb contribute to health effects in organ systems other than the neurological, cardiovascular, and renal systems (e.g., hepatic, gastrointestinal, skeletal)? Is there epidemiological evidence that Pb exposure is associated with new biological markers of effect (e.g. cortisol, brain imaging endpoints, glomerular filtration) that combined with mechanistic evidence may support conclusions regarding biological plausibility?

8. What new evidence has become available to help discern how the effects of Pb exposure on a health outcome are modified when it occurs within mixtures that include other toxic metals, ambient pollutants, or other environmental exposures versus Pb alone (e.g., additive, synergistic, or antagonistic effects)?

<u>Uncertainties</u>: The ISA will evaluate uncertainty in the scientific data, particularly in relation to observed epidemiologic findings and their consistency with toxicological studies in terms of observed effects and biological pathways. In this vein, the following questions will be considered:

1. To what extent are the health effects observed in epidemiological studies attributable to exposure to Pb rather than co-exposures to other toxic metals or environmental contaminants?

2. In epidemiologic studies, what are the uncertainties in Pb effect estimates due to potential confounding factors (e.g., demographic and lifestyle attributes,

socioeconomic status [SES], genetic susceptibility factors, occupational exposure, and access to medical care)?

3. Based on the new body of evidence, what uncertainties remain regarding the nature and shape of concentration-response relationships (e.g., threshold, linear, nonlinear)? What evidence is newly available on the uncertainties related to other aspects of statistical model specification and how can it be used to assess the influence of these uncertainties on the results of epidemiologic studies? What evidence is available from toxicological studies of dose-response relationships?

4. What uncertainties surround the evidence for long-term effects such as those that shorten life duration and/or affect the development or progression of disease?

Biological Mechanism(s) or Modes of Action: In evaluating the current information from studies that investigate mechanisms for the health outcomes that have been associated with exposure to Pb, EPA will address the following questions in the ISA:

1. To what extent is evidence now available regarding mechanisms for neurological effects associated with "lower" (< 10 µg/dL or < 5 µg/dL) blood Pb levels (e.g., oxidative stress)? What toxicological evidence is available on mechanisms and dose-response relationships for other health outcomes (e.g., cardiovascular, renal, or immunological effects) or dose metrics, and is there coherence between this and epidemiologic findings for these endpoints?

2. To what extent is key evidence now available regarding mechanisms of action and concentration-response relationships at various ages and developmental stages, including critical windows of exposure that result in different effects and/or effects at lower exposures? Are new animal models available to better characterize mechanisms of action at various lifestages?

3. What mechanistic evidence is available on common modes of action that would help our understanding of health effects of exposure to Pb when it occurs within mixtures versus alone (e.g., evidence for additive, synergistic, or antagonistic effects)?

Susceptible Populations and Lifestages: The ISA will examine the evidence for different health effects or outcomes to identify specific population groups that may have a greater likelihood of experiencing health effects related to Pb exposure. In identifying these groups, the ISA will consider a variety of defining factors including, but not limited to lifestage (e.g., childhood), lifestyle (e.g., smoking status, nutrition), genetic or developmental factors, race, sex, preexisting disease, access to health care, and factors affecting exposure to Pb such as neighborhood characteristics. In the ISA, the evaluation of susceptibility factors will consider the following issues:

1. To what extent is key new evidence available that could inform the understanding of populations that are particularly susceptible to Pb exposures? What is known about genetic traits, pre-existing conditions (obesity), or other factors that affect susceptibility (sex)? To what extent is the strength of epidemiologic or toxicological evidence driven by effects observed in populations with increased susceptibility?

a. Is there evidence from new animal models of susceptibility factors that improves our characterization of susceptible populations and is there coherence between findings for these models and epidemiologic findings?

2. To what extent is key evidence now available to inform our understanding of developmental lifestages that are particularly susceptible to Pb exposures? What is known about critical windows of exposure for Pb with regard to their impact on concentration-response relationships and/or effects elicited?

   a. To what extent is susceptibility to the effects of early life Pb exposure associated with the development and or persistence/progression of Pb effects in adults? Are there new animal models that follow these windows of susceptibility?

   b. Are new animal models available that may help us to characterize the critical windows of exposure to Pb and, is there coherence between findings from these models and epidemiologic findings? Do any of these models show differential responses by sex of the animal?

3. What do the currently available studies indicate regarding the relationship between exposures to Pb and health effects in those with preexisting diseases (e.g., renal diseases) compared to healthy individuals? What medical conditions are identified as increasing susceptibility to Pb effects? What is the nature and time-course of the development of effects in previously healthy persons and in persons with pre-existing disease (e.g., cardiovascular disease)? What are the pathways and mechanisms through which Pb may be acting for these groups?

Public Health Implications: The ISA will present concepts that integrate evidence on Pb-related health effects and consequent public health significance to assist in the assessment of the public health implications of exposure to Pb in ambient air. Development of these concepts may include consideration of estimates of the sizes of identified susceptible populations (e.g., adults with cardiovascular disease, children) and discussion of the public health significance of the magnitudes of change in health outcomes concluded to result from air-related Pb exposures.

### Ecological and Other Welfare Effects

The ISA will evaluate the current literature related to effects of Pb exposures in aquatic and terrestrial ecosystems at all scales, as available. Evidence related to any other welfare effects (e.g. visibility, climate, materials) will be considered, if available. Publications will be evaluated for causal relationships between Pb at ambient levels and ecological effects. Studies at higher than ambient Pb exposures will be evaluated to the extent they can inform the interpretation of the effects of exposures that are currently widespread in the environment. In the last review, EPA recognized the persistence of Pb in the environment, and concluded that the combination of Pb accumulated from past deposition, and much smaller ongoing deposition continue to cause ecological effects in terrestrial and aquatic ecosystems (U.S. EPA, 2006). If available, new studies pertaining to the recycling of Pb in aquatic and terrestrial ecosystems, and

to the role of previously sequestered Pb in current ecosystem processes, including its contribution to total loading, will be discussed. This discussion will include evaluation of the effect of Pb on ecosystem productivity and of the potential effects of Pb on ecosystem services. Sources of Pb that are not relevant to consideration of air-related Pb (e.g. Pb shot) were not considered. Some scientific questions that EPA will seek to address in the ISA follow, grouped by topic area.

Terrestrial Ecosystem Effects:

1. What new information is available about the nature of the effects of Pb on terrestrial ecosystems, especially Pb that is relevant to air-related pathways? Is there new evidence of effects at current ecosystem loads? Is there new evidence that, in combination with the previously existing evidence, supports the development of critical loads for terrestrial ecosystems?
2. Is there new information available for establishing specific exposure levels at which terrestrial ecological receptors are expected to experience effects?
3. Are there new empirical data or modeling results that would improve our understanding of the movement of Pb in or through terrestrial systems, or would improve our understanding of Pb bioavailability and pathways of exposure for terrestrial organisms?
4. Is there new evidence that contributes to a better understanding of the nature and magnitude of the potential effects of Pb on terrestrial ecosystem services?

Aquatic Ecosystem Effects:

1. What new information is available about the nature of the effects of Pb on aquatic ecosystems, especially Pb that is relevant to air-related pathways? Is there new evidence of effects at current ecosystem loads? Is there new evidence that, in combination with the previously existing evidence, supports the definition of critical loads for aquatic ecosystems?
2. Is there new information available for establishing specific exposure levels at which aquatic ecological receptors are expected to experience effects?
3. Are there new empirical data or modeling results that would improve our understanding of the movement of Pb in or through aquatic systems or would improve our understanding of Pb bioavailability and pathways of exposure for aquatic organisms?
4. Is there new evidence that contributes to a better understanding of the nature and magnitude of the potential effects of Pb on aquatic ecosystem services?

## 4.4 CAUSAL DETERMINATIONS

In evaluating and integrating the different types of evidence from recent studies with that available during the previous reviews, the ISA will draw conclusions regarding the strength of the evidence in describing causal relationships between relevant blood Pb, bone Pb or other exposure metrics and health effects and relevant Pb concentrations and environmental effects. Since the last Pb NAAQS review, EPA has developed a framework that is intended to provide a consistent and transparent basis for drawing such conclusions.[15] Briefly, the framework includes the following considerations for drawing conclusions of causality for specific endpoints: consistency of findings for an endpoint across studies in which it was examined, coherence of the results related to a specific endpoint among different study types or disciplines, the coherence of results with characterized mechanisms of action (biological plausibility), and evidence of a concentration- or dose-response relationship for an endpoint. In the ISA, in considering the strength of the evidence with regard to demonstrating that exposure to ambient air-related Pb, in particular, causes specific health effects, EPA will give particular attention to studies that examine Pb exposures relevant to those currently occurring in the U.S. population or ecosystems.

## 4.5 SUPPLEMENTARY MATERIALS

Previous science assessments conducted to support NAAQS reviews included supplementary materials, which were designed to provide detailed supporting information and more comprehensive coverage of the research areas summarized in the ISA. NCEA intends to change the form, while maintaining the relevant content, of the materials that were formerly contained within the Annexes to the ISA.

As discussed previously, studies included in the text of the ISA will be those deemed informative to the NAAQS review process (e.g. policy-relevant) and of adequate quality. The ISA text, tables and figures will highlight and summarize key study details that are needed to understand and interpret the results of a study. This information, which was described in the text as well as reiterated in the annex tables of previous documents, includes the air quality system (AQS) data; studies of fate and transport in air, water, and soil; human exposure and dosimetry studies; blood Pb, bone Pb or other exposure metrics corresponding to adverse health effects and dose and duration of exposure in toxicological studies; and, effect estimates, study location and time period, population, exposure metric and time window, as well as the characteristics of the exposure/dose distribution for epidemiologic studies. In addition, supplementary materials will be provided in the form of output from the Health and Environmental Research Online (HERO) database. A key function of the HERO output will be to document the base of evidence

[15] Use of this framework in the recent science assessment for particulate matter is described in chapter 1 of that ISA (EPA, 2009a).

containing publications evaluated for the Pb review, including any publications considered but not included in the ISA. This information will be presented as links to lists of references in the HERO database, which include bibliographic information and abstracts. In addition, certain study characteristics of epidemiologic studies, including location, ages investigated, outcomes, and health endpoints, will be summarized in tables developed from HERO extracted study data.

## 4.6 SCIENTIFIC AND PUBLIC REVIEW

Drafts of the ISA will be reviewed by the CASAC Pb Review Panel and made available for public comment, as indicated in Figure 4-1 above. The CASAC Pb Review Panel will review the first draft ISA and discuss their comments in a public meeting announced in the Federal Register. Based on CASAC's past practice, EPA anticipates that key CASAC advice and recommendations for revision of the first draft ISA will be summarized by the CASAC Review Panel in a letter to the EPA Administrator. In revising the first draft ISA, EPA will take into account any such recommendations. EPA will also consider comments received from CASAC or from the public at the meeting itself and any written public comments. Additionally, EPA has established a public docket for development of the ISA.[16] EPA will prepare a second draft ISA for CASAC review and public comment. The CASAC Pb Review Panel will review the second draft ISA and discuss their comments in a public meeting announced in the Federal Register. Again, based on CASAC's past practice, EPA anticipates that key CASAC advice and recommendations for revision of the second draft ISA will be summarized by the CASAC Pb Review Panel in a letter to the EPA Administrator. In finalizing the ISA, EPA will take into account any such recommendations. EPA will also consider comments received from CASAC or from the public at the meeting itself and any written public comments. After appropriate revision, the final document will be made publicly available on an EPA website and in hard copy. A notice announcing the availability of the final ISA will be published in the Federal Register.

[16] The ISA docket for the current Pb review is identified as EPA-HQ-ORD-2011-0051. The draft and final ISAs and CASAC letters will be placed into this docket by EPA and the public may submit materials to it for EPA consideration in development of the ISA. This docket and the rulemaking docket described in chapter 7 below are publicly accessible at www.regulations.gov.

# 5 QUANTITATIVE RISK AND EXPOSURE ASSESSMENTS

Quantitative risk and exposure assessments are generally designed to estimate human exposure and health risk, as well as environmental exposures and risks, when appropriate. Development of the risk/exposure assessments (REAs) draws upon the information presented in the ISA and its supplemental materials. This includes information on atmospheric chemistry, air quality, human and environmental exposures, including biokinetic information, and health and welfare effects of concern. In particular, the availability of concentration-response and dose-response data from the health and welfare effects literature influences the types of exposure assessment and risk characterization that are performed. The health and welfare assessments focus on exposures and dose metrics that are consistent with effects of concern, with available measurement and modeled data, where appropriate, used to generate estimates of exposure. Characterization of risks may include conducting air quality analyses to support quantitative exposure and risk assessments in specific locations to the extent warranted by new information, taking into consideration available resources. The results of such assessments are generally put into a broader public health and public welfare perspective, for example, with a particular emphasis on exposures and health risks in susceptible populations, such as children.

This phase generally begins with the preparation of a planning document. This document considers the extent to which newly available scientific evidence and tools/methodologies provide support for conducting quantitative risk and exposure assessments. To the extent warranted, the scope and methods for components of exposure/risk assessments are described. This document is the subject of a consultation with the CASAC Panel and is made available to the public for review and comment. If warranted, one or more drafts of an REA are then prepared and released for CASAC review and public comment prior to completion of a final REA subsequent to completion of the final ISA.

The information newly available in this review is considered in light of the comprehensive, complex and resource-intensive quantitative assessments of human exposure and health risks performed for the last review. This information is considered with regard to the extent to which it indicates the potential for development of an REA from which substantially different conclusions might be drawn with regard to the health risks associated with air-related Pb under conditions associated with the current standard. The REA planning document will describe this consideration of the available scientific evidence, tools and methodologies by EPA staff in light of areas of uncertainty in the REA prepared for the last review and of the potential for a new REA to provide notably different exposure and risk estimates, with lower associated

uncertainty. The timeline for collection of ambient air Pb data under the recently revised monitoring requirements is also recognized as a consideration for this document. Consultation with the CASAC Pb Panel and comments from the public on this draft IRP, as well as the availability of resources, will also inform development of the REA planning document.

## 5.1 OVERVIEW OF ASSESSMENTS IN LAST REVIEW

In the last review, EPA designed and developed a full-scale human exposure and health risk assessment as well as a screening-level ecological risk assessment. These assessments are summarized below.

### 5.1.1 Human Exposure and Health Risk Assessments

In the last review, EPA developed and applied models to estimate human exposures to air-related Pb and associated health risk. Estimates were developed for various air quality scenarios and alternative standards to provide additional information and insights that could help to put judgments about risk associated with exposure to air-related Pb in a broader public health context and inform decisions on the standards. The exposure and risk analyses to estimate blood Pb and associated IQ loss in children exposed to air-related Pb were conducted in the context of five 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 being evaluated, and (2) location-specific urban populations with a broader range of air-related exposures. The case studies representing the more highly air-pathway exposed children included a general urban case study and a primary Pb smelter case study. The three location-specific urban case studies focused on specific residential areas within three U.S. cities to provide representations of urban populations with a broader range of air-related exposures due to spatial gradients in both ambient air Pb levels and population density. The air quality scenarios assessed included (a) the current NAAQS (for all five case studies) ; (b) current conditions for the location-specific and general urban case studies (which are below the current NAAQS); and (c) a range of alternate standard levels (for all case studies).

Exposure and associated blood Pb levels were simulated using the Integrated Exposure and Uptake Biokinetic (IEUBK) model, as more fully described and presented in the Risk Assessment Report (USEPA, 2007a). The assessment incorporated a number of innovative design elements intended to support a probabilistic characterization of risk with consideration for the multi-pathway nature of lead exposure. In generating risk estimates, empirical data were combined with mechanistic modeling to increase the representativeness of the risk estimates generated. Some of the more important design elements included in the risk model were: (a) use of monitor data as the basis for characterizing Pb levels in ambient air for the case studies and in

outdoor soil, (b) use of a combination of empirically-derived ratios and more complex empirical-mechanistic hybrid modeling to predict indoor dust Pb levels associated with ambient (outdoor) air Pb levels and Pb levels in other related media such outdoor soil, (c) use of empirical data characterizing Pb exposure for some pathways such as dietary intake, (d) use of IEUBK to predict central tendency blood Pb (PbB) levels for study populations given pathway-specific intake rates (e) use of empirical PbB variability data combined with the IEUBK-based estimates of central-tendency PbB levels to generate population distributions of PbB levels and (f) use of epidemiological study-based concentration-response functions for IQ loss in children (given specified PbB levels) to generate risk distributions. The risk model that was developed allowed us to estimate IQ loss estimates for various percentiles of each study population and furthermore, to partition that risk between various pathways of interest (although with varying degrees of overall confidence, as noted below).

Although the assessment utilized a number of innovative modeling elements in order to generate representative estimates of risk for our study populations, like all risk models there was uncertainty associated with the model and its output. For example, because of the evidence for a nonlinear response of blood Pb to exposure and also the nonlinearity reflected in the C–R functions for estimation of IQ loss, the assessment first estimated total blood Pb levels and associated risk (i.e., for air- and nonair-related exposure pathways), and then separated out those estimates of blood Pb and associated risk associated with the pathways of interest in this review. We separated out the estimates of total (all-pathway) blood Pb and IQ loss into a background category and two air-related categories. However, significant limitations in our modeling tools and data resulted in an inability to parse specific risk estimates into specific pathways, such that we approximated estimates for the air-related and background categories. We believe these limitations led to slight overestimation of the risks in the one of the air-related categories and under representation of air-related pathways in the second category. Thus, we characterized the risk attributable to air-related exposure pathways to be bounded by the estimates developed for the two air-related categories.

Additional limitations, assumptions and uncertainties, which were recognized in various ways in the assessment and presentation of results, are listed below, beginning with those related to design of the assessment or case studies, followed by those related to estimation of Pb concentrations in ambient air, indoor dust, outdoor soil/dust, and blood, and estimation of Pb-related IQ loss.

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

- General Urban Case Study: The design for this case study employs assumptions regarding uniformity that are reasonable in the context of a small neighborhood population, but would contribute uncertainty to extrapolation of these estimates to a specific urban location, particularly a relatively large one.
- Location-specific Urban Case Studies: Limitations in the ambient air monitoring network limit characterization of spatial gradients of ambient air Pb in these case studies.
- Air Quality Simulation: The proportional roll-up and roll-down procedures used in some case studies to simulate the then-current NAAQS and alternate NAAQS levels, respectively, assume proportional changes in air concentrations across the study area in those scenarios for those case studies.
- Outdoor Soil/Dust Pb Concentrations: Uncertainty regarding soil/dust Pb levels and the inability to simulate the influence of changing air Pb levels related to lowering the NAAQS contributes uncertainty to air-related risk estimates.
- Indoor Dust Pb Concentrations: Limitations and uncertainty in modeling of indoor dust Pb levels, including the impact of reductions in ambient air Pb levels, contributes uncertainty to air-related risk estimates.
- Interindividual Variability in Blood Pb Levels: Uncertainty related to population variability in blood Pb levels, and limitations in our ability to model it, introduces uncertainty into blood Pb and IQ loss estimates for the 95$^{th}$ percentile of the population.
- Pathway Apportionment for Higher Percentile Blood Pb and IQ Loss: Limitations in data, modeling tools and assessment design introduce uncertainty into estimates of air-related blood Pb and IQ loss for the upper ends of population distribution.
- IQ Loss Concentration-response Functions: Specification of the quantitative relationship between blood Pb level and IQ loss is subject to significant uncertainty at lowest blood Pb levels (e.g., below 5 µg/dL concurrent blood Pb).

The assumptions, limitations and uncertainties noted above are areas for consideration as to any advances in available data and or risk characterization methods with regard to the extent to which they might substantially address areas of largest uncertainty with regard to estimation of health risks associated with ambient air-related Pb.

### 5.1.2 Ecological Risk Assessment

A screening level risk assessment was performed by EPA for the last review to estimate the potential for ecological risks associated with exposures to Pb emitted into ambient air.[17] This assessment built upon the environmental concentrations modeling performed for the human exposure and health risk assessment described above. A case study approach was used which included areas surrounding a primary Pb smelter and a secondary Pb smelter, as well as a location near a nonurban roadway. Soil, surface water, and/or sediment concentrations were estimated for each of the three initial case studies from available monitoring data or modeling analysis, and then compared to ecological screening benchmarks to assess the potential for ecological impacts from Pb that was emitted into the air. A national-scale screening assessment was also used to evaluate surface water and sediment monitoring locations across the United States for the potential for ecological impacts associated with atmospheric deposition of Pb. All three case studies and the national-scale assessment considered current or recent environmental conditions. In all cases but the primary Pb smelter case study, current air quality conditions were below the then-current NAAQS. The current air quality conditions for the primary Pb smelter case study exceeded the NAAQS. An additional case study was identified to look at gasoline-derived Pb effects on an ecologically vulnerable ecosystem but various limitations precluded any analyses.

Ecological screening values, developed from the Eco-SSLs methodology, EPA's recommended ambient water quality criteria, and sediment screening values developed by MacDonald and others (2000, 2003) were used to estimate the potential for ecological risk. A Hazard Quotient (HQ) was calculated for various receptors to determine the potential for risk to that receptor. The HQ was calculated as the ratio of the media concentration to the 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 were concluded to suggest that Pb concentrations in a specific medium were unlikely to pose significant risks to ecological receptors, while HQ values greater than 1.0 indicated that the expected exposure exceeded the ecotoxicity screening value, which was concluded to indicate a potential for adverse effects.

Several uncertainties that apply across case studies were identified:

[17] The assessment is described in detail in Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas, Pilot Phase (ICF, 2006). Various limitations precluded performance of a full-scale ecological risk assessment.

- The ecological risk screen was limited to specific case study locations and other locations for which Pb data were available. Efforts were made to ensure that the Pb exposures assessed were attributable to airborne Pb and not dominated by nonair sources. However, there was 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., 2006 AQCD, p. AX7–110).
- The methods and database from which the surface water screening values (i.e., EPA-recommended ambient water quality criteria 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 (2006 AQCD, sections X7.2.1.2 and AX7.2.1.3).
- No adjustments were made for sediment-specific characteristics that might affect the bioavailability of Pb in sediments in the derivation of the sediment quality criteria used for this ecological risk screen (2006 AQCD, 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).

For the case studies, the concentrations of Pb in soil and sediments in various locations exceeded screening values for these media indicating potential for adverse effects to terrestrial organisms (plants, birds and mammals) and to sediment dwelling organisms. While the assessment was limited in that it was not possible to dissect the contributions of air Pb emissions from other sources, it is likely that, at least for the primary smelter, that the air contribution is significant. For the other case studies, the contributions of current air emissions to the Pb burden, is less clear. The national-scale screen of surface water data initially identified 15 areas for which water column levels of dissolved Pb were greater than hardness adjusted chronic criteria for the protection of aquatic life indicating a potential for adverse effect if concentrations were persistent over chronic periods. Acute criteria were not exceeded at any of these locations. The extent to which air emissions of Pb had 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.

## 5.2 CONSIDERATION OF QUANTITATIVE ASSESSMENTS FOR THIS REVIEW

To the extent that new research and/or improved methodologies are identified to inform updates to the design of Pb exposure and risk assessments or new scientific evidence is available to substantially inform our ability to characterize and/or reduce uncertainties identified in the assessments performed for the last review, EPA may design and conduct quantitative assessments for this review. Drawing on the evaluation of evidence in the first draft ISA, a planning document will systematically discuss the available scientific evidence, tools and methodologies pertaining to each of the key aspects of an assessment, with particular attention to evidence and tools newly available in this review. This discussion will focus particularly on areas of uncertainty in the REA prepared for the last review and the potential for a new REA to provide notably different exposure and risk estimates, with lower associated uncertainty. Some key areas for staff analysis, including types of data, methodology and tools to be considered, are summarized below.

### 5.2.1 Human Exposure and Health Risk Assessments

#### 5.2.1.1 Air Quality and Environmental Media Concentrations

Generally speaking, and as addressed in the last review, Pb concentrations in air and indoor dust, and to some extent outdoor dust/soil, are particularly key components in the assessment of air-related Pb health risk. In the case studies included in the assessment for the last review, a mixture of modeling and monitoring approaches were used to estimate these concentrations. For example, in the location-specific urban case studies, air concentrations were estimated based on the assignment of ambient monitor concentrations to U.S. Census units according to proximity. The limited number of monitors in relation to sources contributed uncertainty to our characterization of spatial gradients in ambient air concentration. Limitations and uncertainty in modeling the associated Pb concentrations in indoor dust was another area of uncertainty. In considering the extent to which new information or insights might be gained from a new assessment, we will consider the availability of new information or methods in these areas.

To the extent more spatially detailed information on air Pb concentrations in the urban context is available, this could reduce this area of uncertainty in the risk assessment completed for the last review. Specifically, more spatially-refined air concentration estimates or measurements might allow us to more accurately define spatial gradients around ambient monitors, potentially differentiating gradients around source-oriented monitors from those associated with nonsource oriented monitors. This might in turn improve the representativeness of the characterization of ambient air Pb concentrations for exposed populations in urban study areas. If these types of more refined ambient data are available, an initial step to consider the impact of their inclusion in the assessment could be a sensitivity analysis-oriented calculation for one study area to determine the degree to which this type of refined ambient Pb spatial gradient data could impact exposure (and ultimately risk) estimates.

An additional area of uncertainty recognized in the last assessment concerned the procedures for simulating conditions for alternative NAAQS levels. The availability of more refined ambient air Pb data or other information providing insights into the spatial pattern associated with reductions in ambient Pb levels (i.e., spatial pattern of rollbacks in ambient air Pb levels) could address another important source of uncertainty with regard to estimation of air Pb concentrations in the previous risk assessment.

With regard to media related to indoor dust Pb modeling, any newly available urban residential datasets with matched measurements useful in evaluating the relationship between ambient outdoor air Pb and indoor dust Pb may be important to consider with regard to evaluation of this source of uncertainty in the risk assessment completed for the last review. Specifically, having outdoor ambient air Pb data matched to outdoor soil Pb, indoor ambient air Pb and indoor dust Pb data, for a set of residential locations, might improve our ability to evaluate and possibly further calibrate performance of the hybrid indoor dust Pb model developed and used in the last review. The availability of multiple matched media concentrations over an extended period (e.g., allowing for characterization of daily, weekly or monthly levels) would further improve their utility in this regard. This reflects the fact that the dust Pb model is a dynamic model which combines mechanistic and empirical elements to generate a near-steady state estimate of indoor dust Pb concentrations given various loading rates. Therefore, having data which are temporally refined would allow us to evaluate the degree to which the model tracks the temporal profile of these media concentrations.

The characterization of soil Pb levels and their relationship to air Pb levels, particularly in urban areas is another area contributing to the exposure characterization in which uncertainty might be reduced with new information or methods. For example, the identification of more current data characterizing Pb soil levels in the urban residential context which could be further differentiated to capture any regional trends and potentially more importantly, differences in

housing age (as a surrogate for information on leaded paint usage) might further reduce uncertainty associated with modeling this pathway, characterizing contributions from air-related and nonair-related sources, and potentially in modeling total exposure and total risk. Considering housing age in characterizing outdoor soil Pb levels is potentially important because in some cases (i.e., older houses with Pb exterior paint), soil Pb levels can be elevated due to historical loading from weathered exterior Pb paint. Furthermore, older houses are also more likely to have higher concentrations of indoor dust Pb contributed by older indoor Pb paint. Together these two factors mean that background (nonair) exposures to Pb can be elevated for residents of older houses, a factor important to reflect in our risk assessment to the extent that data allow.

An additional policy-relevant aspect of the environmental characterization component of the last assessment concerned the identification of air-related and nonair-related (background) environmental Pb concentrations. For example, as described in the documents prepared for the last review, while conceptually indoor Pb paint contributions to indoor dust Pb would be considered nonair or background, technical limitations precluded us from parsing out the indoor paint contributions from historic air-related Pb in indoor dust (73 FR 66980).[18] Similarly we were unable to separate the air contribution to dietary or drinking water Pb from the nonair contributions, such that Pb in these pathways was identified as "background" yet recognized qualitatively to also include air-related Pb. The availability of information and methods that might improve our characterization of distinctions between these air and nonair-related pathways will also be an important consideration with regard to the potential for impact on REA results.

#### 5.2.1.2 Human Exposure Assessment

The exposure assessment completed as part of the risk assessment for the last review focused on characterizing population-level distributions of blood Pb levels, including (a) estimates of high-end percentile estimates of that distribution and (b) estimation of the apportionment of total PbB levels associated with a given percentile among air- and nonair-related pathways of Pb. As noted in the last review and earlier in this section, there is considerable uncertainty associated with apportioning total Pb exposure (and hence total risk) to the air- and nonair-related pathways.

One aspect of the uncertainty in apportioning exposure and risk among exposure pathways concerns uncertainty regarding the specific contribution of different Pb exposure pathways to total exposure for individuals with widely differing total exposure. In the last assessment we applied the same relative contributions to all individuals in the population.

[18] Indoor dust Pb derived from lead recently emitted to the air was quantified separate from this combined historic Pb of paint or air origin.

Uncertainty in this area reflects the fact that we do not have comprehensive data on exposure levels matched with PbB measurements for a larger set of individuals, which prevents us from assessing how contributions of different Pb exposure pathways to total PbB may vary across percentiles in the population distribution (of total PbB). If such data are now available, we could be in a position to reduce this potentially important source of uncertainty. These types of data could take the form of matched data on PbB levels and dietary exposure (for a set of study subjects).

Furthermore, we plan to consider the extent to which data are now available that characterize key areas of variability in the inputs to modeling total PbB levels (e.g., soil Pb, outdoor and indoor dust Pb, dietary food Pb) which might support a probabilistic simulation of the full range of exposure and risk for a given study population. An important aspect to this consideration will be the availability of data characterizing the degree of correlation between these modeling inputs (e.g., degree to which indoor dust Pb levels and outdoor soil Pb levels are correlated). As available, the extent to which these types of data characterizing variability in pathway-specific Pb concentrations (and correlations between those distributions) might provide the basis for a Monte Carlo simulation-based estimation of population variability in PbB levels with pathway apportionment for the simulated PbB levels will also be considered, with regard to the ability to estimate, for example, the 95$^{th}$ population percentile PbB levels and the fractional contribution to that PbB level by the underlying Pb exposure pathways. Another area for consideration with regard to population variability will be the availability of more recent information on PbB variability in study populations relevant for an assessment (e.g., the availability of an updated estimate of population PbB variation such as geometric standard deviation, potentially differentiated by region and possibly by housing stock or by the SES attributes of the underlying study population).

#### 5.2.1.3 Health Risk Assessment

In analyzing newly available information pertaining to the health risk assessment step, we plan to consider newly available studies with regard to the support they might provide for assessment of health endpoints and risk metrics other than childhood IQ and, as available, the extent to which they indicate the potential to lead to risk estimates for notably different from those of the last assessment. Focusing specifically on the step of translating childhood exposure estimates into IQ loss estimates, as the risk metric, a key source of uncertainty in the last assessment was the specification of the IQ loss function, specifically, the portion of the function predicting IQ loss at lower exposure levels (e.g., below PbB levels of approximately 3-5 ug/dL). If we identify either new cohort studies, or pooled/meta analyses based on existing studies which describe the nature of the function at these lower exposure levels, then we might be in a position

to reduce uncertainty in the risk assessment. To the extent such newly available information is identified, we will consider the potential for it to impact REA results and the size and characterization of such impact. One other source of uncertainty that might be reduced with new information, involves the type of PbB metric to use (concurrent, lifetime averaged etc). For example, if newly available study data clearly point to the importance of a PbB metric other than the concurrent metric used in the last review, then, depending on the associated concentration-response function, this could impact the risk estimates generated.

### 5.2.2 Ecological Risk Assessment

In considering the extent to which the currently available information warrants development of an ecological risk assessment in this review, we will consider both the availability of new air quality data and data or estimates for other media that might inform consideration of the current Pb standards, as well as any newly available scientific evidence that indicates a more refined understanding of the direct and indirect effects of deposited ambient Pb on ecosystems and organisms. We intend to focus most specifically on 1) the ability of current data sets to characterize exposure of ecosystems to ambient Pb currently being deposited and 2) any new evidence that would allow the current review to arrive at different conclusions as to the causality or degree of effect than the last review.

In considering air quality information, availability of monitoring data from the newly designed Pb monitoring network, discussed below in chapter 6, will be considered. For example, available ambient data may be evaluated with regard to its adequacy for determining ambient concentrations of Pb in potentially vulnerable ecosystems. The availability of methods or models to estimate the amount of deposition occurring in those areas will also be considered. Additionally, it will be important to consider the available information with regard to its usefulness for apportioning sources of deposited Pb to ambient sources (as compared to nonair sources of Pb in ecosystems). A key consideration will be with regard to the extent to which information is available to support a quantitative analysis of ambient Pb-related effects associated with current ambient conditions or at conditions meeting the current standard.

In the last review, the scientific evidence of direct effect from current ambient levels of Pb to specific ecosystems or organisms was limited. In considering the scientific evidence on which a risk assessment might be based, staff plans to evaluate whether there is sufficient scientific evidence to causally link deposited atmospheric lead with adverse ecological effects under the current standard. Information relating to critical loads for Pb in ecosystems was lacking in the last review. Staff plans to evaluate the adequacy of any new scientific evidence on critical loads that might be used in assessing ecosystems potentially vulnerable to Pb on a national-scale. Staff also plans to look at any new scientific evidence that might be available to

apportion specific ecological effects to ambient air Pb as opposed to other sources of current and historic Pb in the environment, as well as to provide additional insight into the responsiveness of ecosystems to changes in Pb deposition.

## 5.3 SCIENTIFIC AND PUBLIC REVIEW

The REA planning document will be distributed to the CASAC Pb Panel for their consideration and provided to the public for review and comment. The document will be the subject of a consultation with the CASAC Pb Panel at a public meeting that will be announced in the Federal Register.

If upon consideration of CASAC and public comments, EPA concludes that development of a new REA, or updating or expanding the last assessment, is warranted, staff will take into account comments received from CASAC and the public in designing and conducting the assessments. In such a case, staff would prepare at least one draft of the assessments for CASAC review and public comment. Review would be conducted by the CASAC Pb Review Panel and discussed at public meetings that would be announced in the Federal Register. Based on past practice by CASAC, EPA expects that key advice and recommendations for revision of the document would be summarized in a letter to the EPA Administrator. In revising the draft REA document, EPA would take into account any such recommendations, and also consider comments received, from CASAC or from the public, at the meeting itself and any written comments received. A final document would then be made available on an EPA website, with its public availability announced in the Federal Register.

If upon consideration of CASAC and public comments on the REA planning document, EPA concludes that development of a new REA is not warranted, a REA will not be developed and the Policy Assessment for this review will draw from the REA developed in the last review in light of analyses or assessments made in the REA planning document with regard to the current evidence pertaining to exposure and risk, as well as the evidence presented in the ISA and other documents prepared for the review. Review steps for the PA are described in section 7.1 below.

# 6 AMBIENT AIR MONITORING CONSIDERATIONS

In the course of NAAQS reviews, aspects of the methods for sampling and analysis of the NAAQS pollutant are reviewed, and the current network of monitoring locations with the associated data is considered. The methods for sampling and analysis of each NAAQS pollutant are generally reviewed in conjunction with consideration of the indicator element for each NAAQS. Consideration of the ambient air monitoring network generally informs the interpretation of current data on ambient air concentrations, and helps identify if the monitoring network is adequate to determine compliance with a potentially revised Pb NAAQS. This chapter describes plans for considering these aspects of the ambient air monitoring program for Pb. [19]

## 6.1 CONSIDERATION OF SAMPLING AND ANALYSIS METHODS

In order to be used in attainment designations, ambient Pb concentration data must be obtained using either the Federal Reference Method (FRM) or a Federal Equivalent Method (FEM). As described in section 1.3 above, the indicator for the current Pb NAAQS is Pb-TSP. However, in some situations (described below), ambient Pb-$PM_{10}$ concentrations may be used in judging nonattainment. Accordingly, FRMs have been established for Pb-TSP and for Pb-$PM_{10}$.

The current FRM for the measurement of Pb-TSP is provided in 40 CFR part 50 Appendix G. This FRM includes sampling using a high-volume TSP sampler that meets the design criteria identified in 40 CFR part 50 Appendix B and sample analysis for Pb content using flame atomic adsorption. There are 24 FEMs currently approved for Pb-TSP.[20] All 24 FEMs are based on the use of high-volume TSP samplers and a variety of approved equivalent analysis methods.

During the review of the Pb NAAQS completed in 2008, CASAC noted the variability in high-volume TSP sample measurements associated with the effects of wind speed and wind direction on collection efficiency in their comments regarding the indicator. However, at the time of the 2008 review, no alternative TSP sampler designs were identified that had an adequate characterization of their collection efficiency over a wide range of particle sizes. The existing high volume sampler was retained as the sampling approach for the Pb-TSP FRM and FEMs.

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[19] The code of federal regulations (CFR) at parts 50, 53 and 58 specifies required aspects of the ambient monitoring program for NAAQS pollutants. The federal reference methods (FRMs) for sample collection and analysis are specified in 40 CFR part 50, the procedures for approval of FRMs and federal equivalent methods (FEMs) are specified in 40 CFR part 53 and the rules specifying requirements for the planning and operations of the ambient monitoring network are specified in 40 CFR part 58.

[20] A complete list of FEM can be found at the following webpage - http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf

Due to reduced availability of laboratories capable of performing flame atomic adsorption analyses and general advances in analysis methods, the EPA has initiated an effort to replace atomic adsorption with a more modern analysis method such as inductively coupled plasma mass spectroscopy (ICP-MS). A consultation with the CASAC Ambient Air Monitoring and Methods Subcommittee was held on September 15, 2010 and the EPA plans to propose a new FRM based on a more modern analysis method in the fall of 2011.

In addition to maintaining the existing FRM for Pb-TSP, a new FRM for Pb in $PM_{10}$ (Pb-$PM_{10}$) was promulgated as part of the 2008 review. This new FRM is based on the $PM_{10}$ sampler defined in 40 CFR part 50 Appendix J coupled with x-ray fluorescence (XRF) analysis. The Pb-$PM_{10}$ measurements may be used as an alternative to Pb-TSP measurements in certain conditions defined in 40 CFR part 58 Appendix D paragraph 2.10.1.2. These conditions include where Pb concentrations are not expected to equal or exceed 0.10 micrograms per cubic meter on an arithmetic 3-month mean and where the source of Pb emissions is expected to emit a substantial majority of its Pb in the $PM_{10}$ size fraction.

Sampling and analysis issues to be considered during this review include the following:

- Are new TSP samplers available and adequately characterized for use in Pb-TSP sampling?
- Are new data on Pb size distributions available that would better inform the need for Pb-TSP or the adequacy of Pb measurements in $PM_{10}$ or other size fractions (e.g., Pb-$PM_{15}$ or Pb-$PM_{20}$) in characterizing total Pb concentrations?
- If an alternative size fraction is identified that may adequately characterize total Pb concentrations, are there samplers for that size fraction that have been adequately characterized that can be used as the basis for a new FRM sampling method?

## 6.2 CONSIDERATION OF AIR MONITORING NETWORK REQUIREMENTS

The majority of data used to determine compliance with the Pb NAAQS are obtained from monitors operated by state, local, and tribal monitoring agencies ("monitoring agencies"). These monitors are either required due to federal regulations (40 CFR part 58, Appendix D) and state regulations, or are operated voluntarily by the monitoring agency. A review of the available lead monitoring data and then-existing Pb monitoring network was performed as part of the 2008 Pb NAAQS review (USEPA, 2007b). This review indicated that the Pb monitoring network existing at that time was inadequate to assess compliance and determine the extent of all the areas that may violate the revised NAAQS. Many states had no ambient air Pb monitors in place, such that there were large portions of the country with no data being collected on Pb concentrations in ambient air. In addition, many of the largest Pb emitting sources in the country

did not have nearby ambient Pb air monitors. Due to these findings, the EPA promulgated revised Pb monitoring network design requirements along with the revised Pb NAAQS (73 FR 66964). The Pb monitoring network design requirements were revised again in December 2010 as a result of EPA's decision to grant a petition to reconsider the prior network design requirements that was filed by several environmental and public health organizations (75 FR 81126).

The current Pb monitoring network design requirements (40 CFR part 58, Appendix D, paragraph 4.5) include two types of monitoring sites – source-oriented monitoring sites, and non-source-oriented monitoring sites. Source-oriented monitoring sites are required near sources of air Pb emissions which are expected to or have been shown to contribute to ambient air Pb concentrations in excess of the NAAQS. At a minimum, there must be one source-oriented site located to measure the maximum Pb concentration in ambient air resulting from each non-airport Pb source which emits 0.50 or more tons of Pb per year and from each airport which emits 1.0 or more tons of Pb per year.[21] In addition, one year of monitoring is required near 15 specific airports in order to gather additional information on the likelihood of NAAQS exceedances near airports due to the combustion of leaded aviation gasoline (75 FR 81126).

Monitoring agencies are required to conduct non-source-oriented Pb monitoring at the multipollutant monitoring sites (referred to as NCore sites, required under 40 CFR part 58 Appendix D, paragraph 3) in Core Based Statistical Areas (CBSA) with a population of 500,000 or more.[22] While non-source-oriented monitoring data can be used for designation purposes, the main objective for non-source-oriented monitoring is to gather information on neighborhood-scale lead concentrations that are typical in urban areas so to better understand ambient air-related Pb exposures for the general population.

Following the implementation of the December 2010 Pb network requirements, the Pb monitoring network will consist of approximately 270 required monitors including approximately 210 source-oriented monitors and 60 non-source-oriented monitors. Figure 6.1 shows the estimated geographic distribution of monitors associated with these new requirements.

[21] The Regional Administrator may waive the requirement in paragraph 4.5(a) for monitoring near Pb sources if the State or, where appropriate, local agency can demonstrate the Pb source will not contribute to a maximum Pb concentration in ambient air in excess of 50 percent of the NAAQS (based on historical monitoring data, modeling, or other means).

[22] Defined by the US Census Bureau - http://www.census.gov/population/www/metroareas/metroarea.html

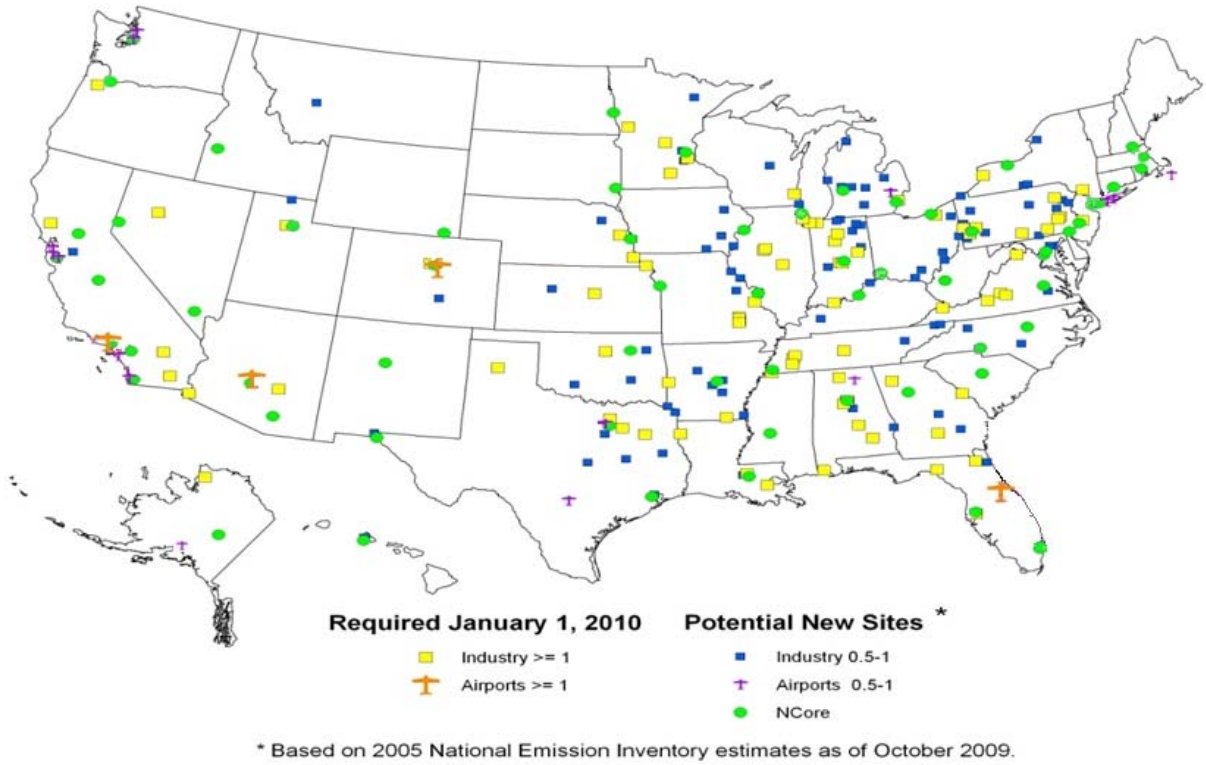


**Figure 6-1. Map of Required Lead Monitors based on 2005 National Emission Inventory Estimates.**

Sampling and analysis issues to be considered during this review include the following:

- Is the current emission threshold of 0.50 tons per year for industrial sources and 1.0 tons per year for airports appropriate and adequate for determining compliance with the current or alternative NAAQS considered?
- The current monitoring requirements specify source emissions thresholds intended to identify situations where these emissions may result in exceedances of the current NAAQS (e.g., near stationary sources or airports) and also provide for the identification of areas of historic industrial activity from which emissions may also result in exceedances. Is there recent, newly available information indicating other situations where exceedances to the current NAAQS are likely to occur? To the extent that revisions to the NAAQS are considered during this review, at what alternative levels and/or averaging times would other types of Pb sources be likely to cause exceedances to the alternative NAAQS considered?

# 7 POLICY ASSESSMENT AND RULEMAKING

## 7.1 POLICY ASSESSMENT

The PA, like the previous OAQPS Staff Paper, is a document that provides a transparent OAQPS staff analysis and staff conclusions regarding the adequacy of the current standards and potential alternatives that are appropriate to consider prior to the issuance of proposed and final rules. The PA integrates and interprets the information from the ISA and REA(s) to frame policy options for consideration by the Administrator. The PA is also intended to facilitate CASAC's advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the Clean Air Act. Staff conclusions will be based on the information contained in the ISA, and, as available, the REA[23], and any additional staff evaluations and assessments discussed in the PA. In so doing, the discussion in the PA will be framed by consideration of a series of the policy-relevant questions drawn from those outlined in chapter 3, including the fundamental questions associated with the adequacy of the current standards and, as appropriate, consideration of alternative standards in terms of the specific elements of the standards: indicator, averaging time, level, and form.

The PA will identify conceptual evidence-based and risk/exposure-based approaches for reaching public health and welfare policy judgments. It will discuss the implications of the science and quantitative assessments for the adequacy of the current standards, and for any alternative standards under consideration. The PA will also describe a broad range of policy options for standard setting, identifying the broadest range for which the staff identifies support within the available information. In so doing, the PA will describe the underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative policy options that could be considered by the Administrator in making decisions for the Pb standards.

In identifying a range of primary standard options for the Administrator to consider, it is recognized that the final decision will be largely a public health policy judgment. A final decision must draw upon scientific information and analyses about health effects and risks, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses. Staff's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum consisting of ambient levels at which scientists generally agree that health effects are likely to occur through

[23] The quantitative risk and exposure assessments from the last review may be considered in light of current air quality analyses if new quantitative risk and exposure assessments are not developed for this review.

lower levels at which the likelihood and magnitude of the response become increasingly uncertain. 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 are requisite to protect public health and are neither more nor less stringent than necessary for this purpose. The provisions do 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.[24]

In identifying a range of secondary standard options for the Administrator to consider, staff recognizes that the final decision will be largely a public policy judgment. A final decision must draw upon scientific evidence and analyses about effects on public welfare, as well as judgments about how to deal with the range of uncertainties that are inherent in the relevant information. 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 secondary standards that are requisite to protect 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 provisions do not require that secondary standards be set to eliminate all welfare effects, but rather at a level that protects public welfare from those effects that are judged to be adverse.

Staff will prepare at least one draft of the PA document for CASAC review and public comment. The draft PA document will be distributed to the CASAC Pb Panel for their consideration and provided to the public for review and comment. Review by the CASAC Pb Panel will be discussed at public meetings that will be announced in the Federal Register. Based on past practice by CASAC, EPA expects that key advice and recommendations for revision of the document would be summarized by the CASAC in a letter to the EPA Administrator. In revising the draft PA document, OAQPS will take into account any such recommendations, and also consider comments received, from CASAC and from the public, at the meeting itself, and any written comments received. The final document will be made available on an EPA website, with its public availability announced in the Federal Register.

[24] The sensitive population groups identified in a NAAQS review may be comprised of low income or minority groups. Where low income/minority groups are among the sensitive groups, the rulemaking decision will be based on providing protection for these and other sensitive population groups. To the extent that low income/minority groups are not among the sensitive groups, a decision based on providing protection of the sensitive groups would be expected to provide protection for the low income/minority groups (as well as any other less sensitive population groups).

## 7.2 RULEMAKING

Following issuance of the final PA and EPA management consideration of staff analyses and conclusions presented therein, and taking into consideration of CASAC advice and recommendations, the Agency will develop a notice of proposed rulemaking. The proposed rulemaking notice conveys the Administrator's proposed conclusions regarding the adequacy of the current standards and any revision that may be appropriate. A draft notice of proposed rulemaking will be submitted to the Office of Management and Budget (OMB) for interagency review, in which OMB and other federal agencies are provided the opportunity for review and comment. After the completion of interagency review, EPA will publish the notice of proposed rulemaking in the Federal Register. Monitoring rule changes associated with review of the Pb standards, and drawing from considerations outlined in chapter 6 above, will be developed and proposed, as appropriate, in conjunction with this NAAQS rulemaking.

At the time of publication of the notice of proposed rulemaking, all materials on which the proposal is based are made available in the public docket for the rulemaking.[25] Publication of the proposal notice is followed by a public comment period, generally lasting 60 to 90 days, during which the public is invited to submit comments on the proposal to the rulemaking docket. Taking into account comments received on the proposed rule, the Agency will then develop a notice of final rulemaking, which again undergoes OMB-coordinated interagency review prior to issuance by EPA of the final rule. In the notice of final rulemaking, and generally also through the use of an accompanying document, the Agency responds to all significant comments on the proposed rule.[26] Publication of the final rule in the Federal Register completes the rulemaking process.

[25] The rulemaking docket for the current Pb review is identified as EPA-HQ-OAR-2010-0108. This docket has incorporated the ISA docket (EPA-HQ-ORD-2011-0051) by reference. Both dockets are publicly accessible at www.regulations.gov.

[26] For example, Agency responses to all substantive comments on the 2008 notice of proposed rulemaking in the last review were provided in the preamble to the final rule and in a document titled "Response to Responses to Significant Comments on the 2008 Proposed Rule on the National Ambient Air Quality Standards for Lead (May 20, 2008; 73 FR 29184)", which is available at: http://www.epa.gov/ttn/naaqs/standards/pb/data/20081015_responsetocomments.pdf.

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# Appendix A

# Integrated Science Assessment for Lead – Outline

# Integrated Science Assessment for Lead


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