



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

**External Review Draft**

*[This page intentionally left blank.]*

# **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.

## TABLE OF CONTENTS

1.	INTRODUCTION .....	1-1
1.1	LEGISLATIVE REQUIREMENTS .....	1-1
1.2	OVERVIEW OF THE NAAQS REVIEW PROCESS.....	1-3
1.3	REVIEW OF AIR QUALITY CRITERIA AND STANDARDS FOR LEAD ....	1-8
1.4	SCOPE OF THE CURRENT REVIEW.....	1-10
2.	REVIEW SCHEDULE .....	2-1
3.	KEY POLICY-RELEVANT ISSUES .....	3-1
3.1	ISSUES RELATED TO THE PRIMARY NAAQS.....	3-1
3.2	ISSUES RELATED TO THE SECONDARY NAAQS.....	3-2
4.	SCIENCE ASSESSMENT .....	4-1
4.1	SCOPE AND ORGANIZATION .....	4-1
4.2	ASSESSMENT APPROACH.....	4-2
4.2.1	Introduction.....	4-2
4.2.2	Literature Search and Identification of Relevant Studies .....	4-4
4.2.3	Criteria for Study Selection .....	4-4
4.2.4	Quality Assurance.....	4-6
4.3	CONTENT AND ORGANIZATION OF THE ISA .....	4-7
4.4	CAUSAL DETERMINATIONS .....	4-15
4.5	SUPPLEMENTARY MATERIALS .....	4-15
4.6	SCIENTIFIC AND PUBLIC REVIEW.....	4-16
5.	QUANTITATIVE RISK AND EXPOSURE ASSESSMENT.....	5-1
5.1	OVERVIEW OF ASSESSMENTS IN LAST REVIEW.....	5-2
5.1.1	Human Exposure and Health Risk Assessments .....	5-2
5.1.2	Ecological Risk Assessment .....	5-5
5.2	CONSIDERATION OF QUANTITATIVE ASSESSMENTS FOR THIS REVIEW .....	5-7
5.2.1	Human Exposure and Health Risk Assessment.....	5-7
5.2.2	Ecological Risk Assessment .....	5-11
5.3	SCIENTIFIC AND PUBLIC REVIEW.....	5-12
6.	AMBIENT AIR MONITORING.....	6-1
6.1	Consideration of Sampling and Analysis Methods.....	6-1
6.2	Consideration of Air Monitoring Network Requirements .....	6-2
7.	POLICY ASSESSMENT AND RULEMAKING .....	7-1
7.1	Policy Assessment .....	7-1
7.2	Rulemaking.....	7-3
8.	REFERENCES .....	8-1
	APPENDIX A. INTEGRATED SCIENCE ASSESSMENT FOR LEAD – OUTLINE.....	A-1

# 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,<sup>1</sup> averaging time, form,<sup>2</sup> 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 . . .

---

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

<sup>2</sup> 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<sub>2.5</sub> NAAQS is the 3-year average of the weighted annual mean PM<sub>2.5</sub> 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.

1 [the Administrator] plans to issue air quality criteria...” Air quality criteria are intended to  
2 “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all  
3 identifiable effects on public health or welfare which may be expected from the presence of [a]  
4 pollutant in the ambient air . . .” 42 U.S.C. § 7408(b). Section 109 (42 U.S.C. 7409) directs the  
5 Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants for  
6 which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one “the  
7 attainment and maintenance of which in the judgment of the Administrator, based on such  
8 criteria and allowing an adequate margin of safety, are requisite to protect the public health.”<sup>3</sup> A  
9 secondary standard, as defined in section 109(b)(2), must “specify a level of air quality the  
10 attainment and maintenance of which, in the judgment of the Administrator, based on such  
11 criteria, is requisite to protect the public welfare from any known or anticipated adverse effects  
12 associated with the presence of [the] pollutant in the ambient air.”<sup>4</sup>

13 The requirement that primary standards provide an adequate margin of safety was  
14 intended to address uncertainties associated with inconclusive scientific and technical  
15 information available at the time of standard setting. It was also intended to provide a reasonable  
16 degree of protection against hazards that research has not yet identified. See *Lead Industries*  
17 *Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied*, 449 U.S. 1042 (1980);  
18 *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied*, 455  
19 U.S. 1034 (1982); *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 533 (D.C. Cir.  
20 2009); *Association of Battery Recyclers v. EPA*, 604 F. 3d 613, 617-18 (D.C. Cir. 2010). Both  
21 kinds of uncertainties are components of the risk associated with pollution at levels below those  
22 at which human health effects can be said to occur with reasonable scientific certainty. Thus, in  
23 selecting primary standards that provide an adequate margin of safety, the Administrator is  
24 seeking not only to prevent pollution levels that have been demonstrated to be harmful but also  
25 to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is  
26 not precisely identified as to nature or degree. The CAA does not require the Administrator to  
27 establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead*  
28 *Industries v. EPA*, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as  
29 to protect public health with an adequate margin of safety.

---

<sup>3</sup> 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).

<sup>4</sup> 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.”

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

7 In setting primary and secondary standards that are “requisite” to protect public health  
8 and welfare, respectively, as provided in section 109(b), EPA’s task is to establish standards that  
9 are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not  
10 consider the costs of implementing the standards. See generally, *Whitman v. American Trucking*  
11 *Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, “[a]ttainability and  
12 technological feasibility are not relevant considerations in the promulgation of national ambient  
13 air quality standards.” *American Petroleum Institute v. Costle*, 665 F. 2d at 1185.

14 Section 109(d)(1) requires that “not later than December 31, 1980, and at 5-year  
15 intervals thereafter, the Administrator shall complete a thorough review of the criteria  
16 published under section 108 and the national ambient air quality standards . . . and shall make  
17 such revisions in such criteria and standards and promulgate such new standards as may be  
18 appropriate . . . .” Section 109(d)(2) requires that an independent scientific review committee  
19 “shall complete a review of the criteria . . . and the national primary and secondary ambient air  
20 quality standards . . . and shall recommend to the Administrator any new . . . standards and  
21 revisions of existing criteria and standards as may be appropriate . . . .” Since the early 1980’s,  
22 this independent review function has been performed by the Clean Air Scientific Advisory  
23 Committee (CASAC).<sup>5</sup>

## 24 **1.2 OVERVIEW OF THE NAAQS REVIEW PROCESS**

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

---

<sup>5</sup> 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>.

<sup>6</sup> 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>.



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

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

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

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

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

30 Following issuance of the final PA and consideration of conclusions presented therein,  
31 the Agency develops and publishes a notice of proposed rulemaking that communicates the  
32 Administrator’s proposed decisions regarding the standards review. A draft notice undergoes  
33 interagency review involving other federal agencies prior to publication.<sup>7</sup> Materials upon which

---

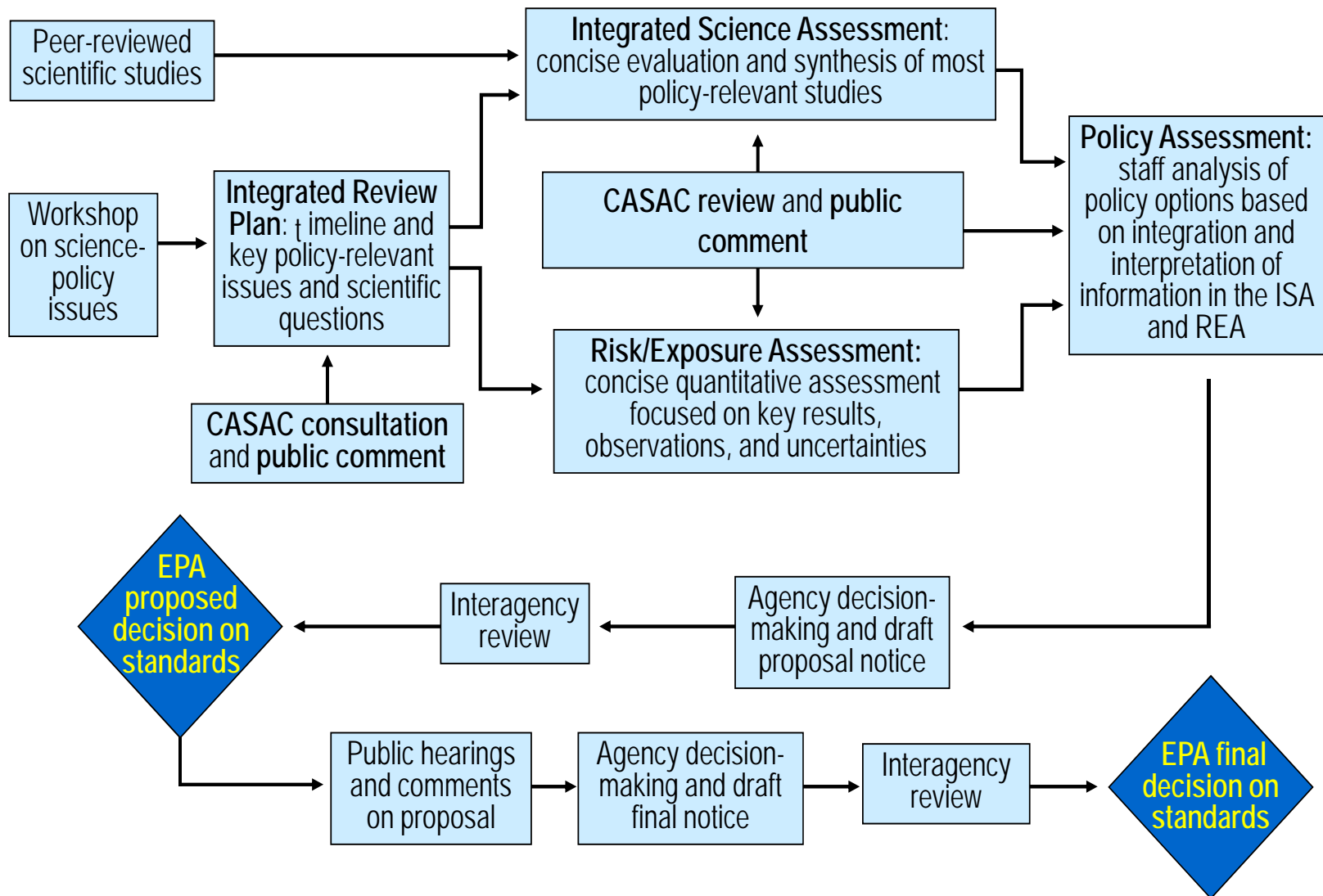
<sup>7</sup> Where implementation of the proposed decision would have an annual effect on the economy of \$100 million or more, e.g., by necessitating the implementation of emissions controls, EPA develops and releases a draft regulatory impact analysis (RIA) concurrent with the notice of proposed rulemaking.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

1 this decision is based, including the documents described above, are made available to the public  
2 in the regulatory docket for the review. A public comment period, during which public hearings  
3 are generally held, follows publication of the notice of proposed rulemaking. Taking into  
4 account comments received on the proposed rule,<sup>8</sup> the Agency develops a final rule which  
5 undergoes interagency review prior to publication to complete the rulemaking process. Chapter  
6 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.

<sup>8</sup>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 **1.3 REVIEW OF AIR QUALITY CRITERIA AND STANDARDS FOR** 2 **LEAD**

3 On October 5, 1978, EPA initially promulgated primary and secondary NAAQS for Pb  
4 under section 109 of the Act (43 FR 46246). Both primary and secondary standards were set at a  
5 level of 1.5 micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ), measured as Pb in total suspended particles  
6 (Pb-TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a  
7 calendar quarter. These standards were based on the 1977 Air Quality Criteria for Lead (USEPA,  
8 1977).

9 The first review of the Pb standards was initiated in the mid-1980s. The scientific  
10 assessment for that review is described in the 1986 Air Quality Criteria for Lead (USEPA,  
11 1986a), the associated Addendum (USEPA, 1986b) and the 1990 Supplement (USEPA, 1990a).  
12 As part of the review, the Agency designed and performed human exposure and health risk  
13 analyses (USEPA, 1989), the results of which were presented in a 1990 Staff Paper (USEPA,  
14 1990b). Based on the scientific assessment and the human exposure and health risk analyses, the  
15 1990 Staff Paper presented recommendations for consideration by the Administrator (USEPA,  
16 1990b). After consideration of the documents developed during the review and the significantly  
17 changed circumstances since Pb was listed in 1976, the Agency did not propose any revisions to  
18 the 1978 Pb NAAQS. In a parallel effort, the Agency developed the broad, multi-program,  
19 multimedia, integrated U.S. Strategy for Reducing Lead Exposure (USEPA, 1991). As part of  
20 implementing this strategy, the Agency focused efforts primarily on regulatory and remedial  
21 clean-up actions aimed at reducing Pb exposures from a variety of nonair sources judged to pose  
22 more extensive public health risks to U.S. populations, as well as on actions to reduce Pb  
23 emissions to air, such as bringing more areas into compliance with the existing Pb NAAQS  
24 (USEPA, 1991).

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

---

<sup>9</sup> In the current review, these two documents have been combined into an integrated plan (this document).

1           The scientific assessment for the review is described in the 2006 Air Quality Criteria for  
2 Lead (USEPA, 2006b), multiple drafts of which received review by CASAC and the public.  
3 EPA also conducted human exposure and health risk assessments and a pilot ecological risk  
4 assessment for the review, after consultation with CASAC and receiving public comment on a  
5 draft analysis plan (USEPA, 2006c). Drafts of these quantitative assessments were reviewed by  
6 CASAC and the public. The pilot ecological risk assessment was released in December 2006  
7 (ICF, 2006) and the final health risk assessment report was released in November 2007 (USEPA,  
8 2007a). The policy assessment based on both of these assessments, air quality analyses and key  
9 evidence from the AQCD was presented in the Staff Paper (USEPA, 2007b), a draft of which  
10 also received CASAC and public review. The final Staff Paper presented OAQPS staff's  
11 evaluation of the public health and welfare policy implications of the key studies and scientific  
12 information contained in the Criteria Document and presented and interpreted results from the  
13 quantitative risk/exposure analyses conducted for this review. Based on this evaluation, the Staff  
14 Paper presented OAQPS staff recommendations that the Administrator give consideration to  
15 substantially revising the primary and secondary standards to a range of levels at or below 0.2  
16 micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ).

17           Immediately subsequent to completion of the Staff Paper, EPA issued an advance notice  
18 of proposed rulemaking (ANPR) that was signed by the Administrator on December 5, 2007 (72  
19 FR 71488).<sup>10</sup> CASAC provided advice and recommendations to the Administrator with regard to  
20 the Pb NAAQS based on its review of the ANPR and the previously released final Staff Paper  
21 and Risk Assessment Report. The proposed decision on revisions to the Pb NAAQS was signed  
22 on May 1, 2008 and published in the Federal Register on May 20, 2008 (73 FR 29184). In  
23 addition to public comments on the proposal received during the public comment period, both  
24 written and oral at two public hearings, the CASAC Pb Panel provided advice and  
25 recommendations to the Administrator based on its review of the proposal notice. The final  
26 decision on revisions to the Pb NAAQS was signed on October 15, 2008 and published in the  
27 Federal Register on November 12, 2008 (73 FR 66964).

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

---

<sup>10</sup> 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).

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

15 Revisions to the NAAQS were accompanied by revisions to the data handling  
16 procedures, the treatment of exceptional events and the ambient air monitoring and reporting  
17 requirements, as well as emissions inventory reporting requirements.<sup>12</sup> As described in chapter 6  
18 below, one aspect of the new data handling requirements is the allowance for the use of Pb-PM<sub>10</sub>  
19 monitoring for Pb NAAQS attainment purposes in certain limited circumstances at non-source-  
20 oriented sites. Subsequent to the 2008 rulemaking, additional revisions were made to the  
21 monitoring network requirements as described in chapter 6 below.

## 22 **1.4 SCOPE OF THE CURRENT REVIEW**

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

---

<sup>11</sup> The current NAAQS for Pb are specified at 40 CFR 50.16.

<sup>12</sup> 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).

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

- 3 • Lead emitted into the air is predominantly in particulate form, which can be transported  
4 long or short distances depending on particle size.
- 5 • Once deposited out of the air, Pb can subsequently be resuspended in the ambient air and,  
6 because of the persistence of Pb, Pb emissions contribute to media concentrations for  
7 some years into the future.
- 8 • Exposure to Pb emitted into the ambient air (air-related Pb) can occur directly by  
9 inhalation, or indirectly by ingestion of Pb-contaminated food, water or other materials  
10 including dust and soil.<sup>13</sup> These exposures occur as Pb emitted into the ambient air is  
11 distributed to other environmental media and can contribute to human exposures via  
12 indoor and outdoor dusts, outdoor soil, food and drinking water, as well as inhalation of  
13 air.
- 14 • Air-related exposure pathways are affected by changes to air quality, including changes  
15 in concentrations of Pb in air and changes in atmospheric deposition of Pb. Further,  
16 because of its persistence in the environment, Pb deposited from the air may contribute to  
17 human and ecological exposures for years into the future. Thus, the roles of both air  
18 concentration and air deposition in human exposure pathways, and the persistence of Pb  
19 once deposited, influence the dynamics of the response of the various Pb exposure  
20 pathways to changes in air quality.

21  
22 The current review of the Pb standards builds on the substantial body of work done  
23 during the course of the last review. In addition to a comprehensive Air Quality Criteria  
24 Document, EPA staff designed and conducted a complex multimedia, multipathway health risk  
25 assessment involving case studies represented different ambient air Pb exposure circumstances,  
26 and an assessment of the available information on ecological impacts of Pb, including the  
27 consideration of potentially vulnerable ecosystems. These different types of information were  
28 evaluated in a Staff Paper and provided the basis for the notice of proposed rulemaking and for  
29 the substantial revisions made to the Pb NAAQS. In light of the extensive and detailed  
30 quantitative analysis of health risks in the last review, as well as the substantial revisions made to  
31 the standard and the period of time elapsed since then in which new data may have been  
32 collected, the information newly available in the current review will be considered with regard to  
33 the extent to which an update or expansion to the last quantitative risk assessment is warranted.

---

<sup>13</sup> 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.**

<b>Stage of Review</b>	<b>Major Milestone</b>	<b>Draft Target Dates</b>
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

1  
2

### 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)?

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

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

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

### 29 **3.2 ISSUES RELATED TO THE SECONDARY NAAQS**

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

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

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

- 28 • Does the available information provide support for considering different Pb exposure  
29 indices?
- 30 • Does the available information provide support for considering different averaging times?
- 31 • What range of levels and forms of alternative standards is supported by the information,  
32 and what are the uncertainties and limitations in that information?
- 33 • To what extent do specific levels and forms of alternative standards reduce adverse  
34 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.

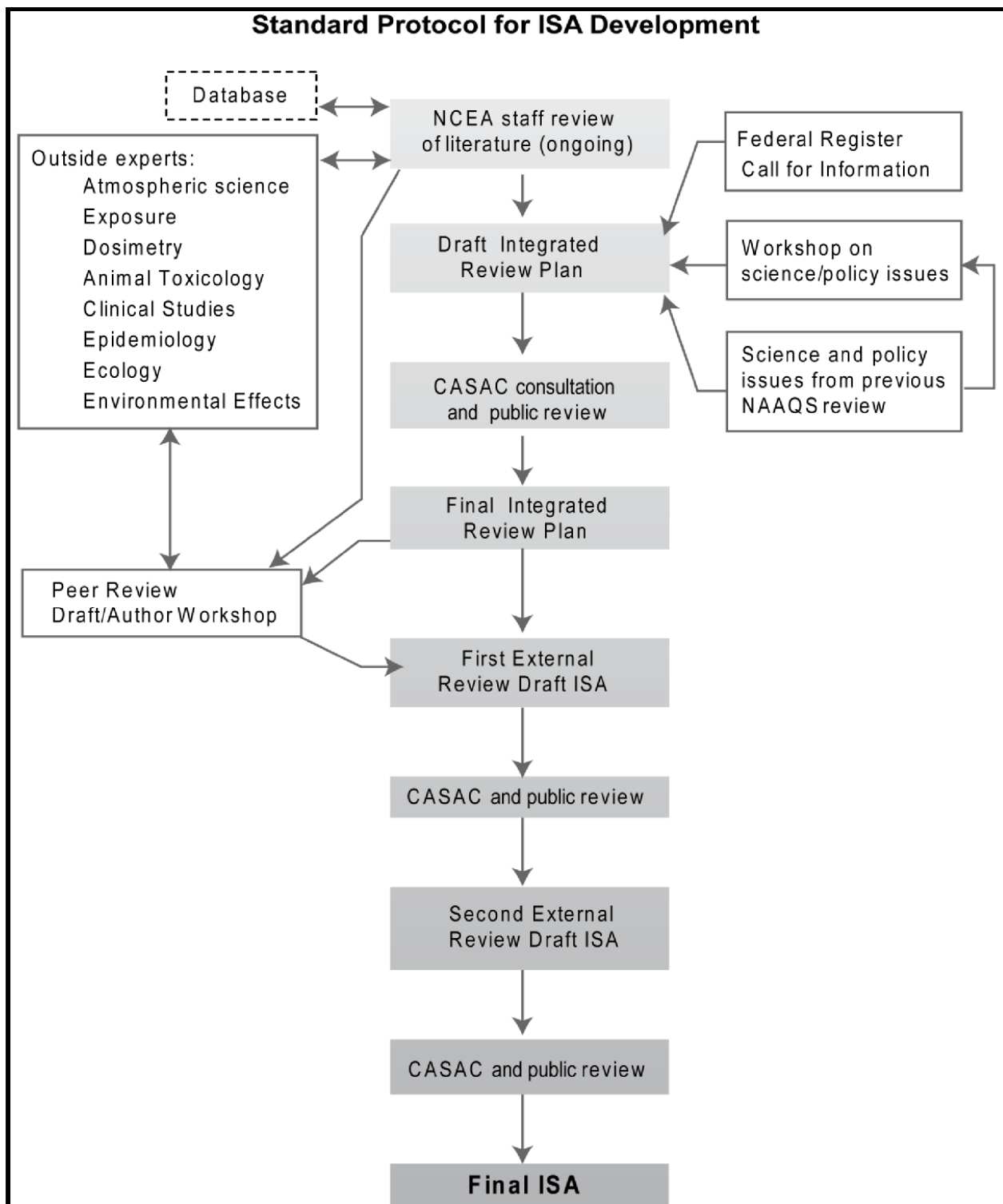
The ISA will build on the conclusions of the last review of the air quality criteria for Pb, presented in the 2006 air quality criteria document (AQCD) (U.S. EPA, 2006), and focus on peer reviewed literature published thereafter and on any new interpretations of previous literature. The 2006 AQCD (U.S. 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

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

## 3 **4.2 ASSESSMENT APPROACH**

### 4 **4.2.1 Introduction**

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



1  
2 **Figure 4-1. Standard steps in the development of Integrated Science Assessments (ISAs).**  
3



## 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?

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

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

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

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

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

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

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

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

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

#### 26 **4.2.4 Quality Assurance**

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

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

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

### 10 **4.3 CONTENT AND ORGANIZATION OF THE ISA**

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

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

#### **Source to Exposure**

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

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

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

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

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

- 35 1. What new evidence is available on exposure to Pb through air-related pathways? Can air-  
36 related pathways be disentangled from water- and soil-related pathways using available  
37 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<sup>14</sup> 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?

---

<sup>14</sup> The phrase toxicokinetics refers generally to the quantitative aspects and timing of absorption, distribution, biotransformation and excretion of xenobiotic chemicals in the body.

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

### **Human Health Effects**

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

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

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

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

- 1 Do recent studies expand the current understanding of concentration-response  
2 relationships pertinent to the range of Pb exposures currently experienced by the U.S.  
3 population?
- 4 2. How do different indicators of Pb body burdens (e.g., Pb in blood or bone) compare  
5 in terms of their associations with adverse health outcomes? What do these findings  
6 contribute to the understanding of how effects may differ for more recent and  
7 cumulative lifetime exposure?
- 8 3. What new epidemiological evidence is available on health outcomes associated with  
9 measures of Pb exposure in the elderly (e.g., total mortality and cardiovascular  
10 mortality)? What does such evidence indicate regarding the potential for different  
11 impacts of early-life, current, and cumulative lifetime Pb exposures?
- 12 4. Within the epidemiologic literature, is there consistency between associations  
13 observed in children and adults and between related health outcomes (e.g.,  
14 cardiovascular and renal)?
- 15 5. Does new evidence from the literature on effects observed in adult animals in  
16 response to experimental exposures to Pb during development inform the  
17 understanding of populations and life stages that are susceptible to Pb exposure (e.g.,  
18 children, elderly, obese)? Within the sensitive in utero period of development, is there  
19 evidence of Pb causing epigenetic changes or evidence of Pb effects differing  
20 between the sexes or genetic variants?
- 21 6. For what Pb-induced health effects, is there sufficient evidence in multiple species to  
22 support a quantitative comparison of exposures that induce the effects?
- 23 7. To what extent does exposure to Pb contribute to health effects in organ systems other  
24 than the neurological, cardiovascular, and renal systems (e.g., hepatic,  
25 gastrointestinal, skeletal)? Is there epidemiological evidence that Pb exposure is  
26 associated with new biological markers of effect (e.g. cortisol, brain imaging  
27 endpoints, glomerular filtration) that combined with mechanistic evidence may  
28 support conclusions regarding biological plausibility?
- 29 8. What new evidence has become available to help discern how the effects of Pb  
30 exposure on a health outcome are modified when it occurs within mixtures that  
31 include other toxic metals, ambient pollutants, or other environmental exposures  
32 versus Pb alone (e.g., additive, synergistic, or antagonistic effects)?

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

- 37 1. To what extent are the health effects observed in epidemiological studies attributable  
38 to exposure to Pb rather than co-exposures to other toxic metals or environmental  
39 contaminants?
- 40 2. In epidemiologic studies, what are the uncertainties in Pb effect estimates due to  
41 potential confounding factors (e.g., demographic and lifestyle attributes,



- 1 socioeconomic status [SES], genetic susceptibility factors, occupational exposure,  
2 and access to medical care)?
- 3 3. Based on the new body of evidence, what uncertainties remain regarding the nature  
4 and shape of concentration-response relationships (e.g., threshold, linear, nonlinear)?  
5 What evidence is newly available on the uncertainties related to other aspects of  
6 statistical model specification and how can it be used to assess the influence of these  
7 uncertainties on the results of epidemiologic studies? What evidence is available  
8 from toxicological studies of dose-response relationships?
- 9 4. What uncertainties surround the evidence for long-term effects such as those that  
10 shorten life duration and/or affect the development or progression of disease?

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

- 14 1. To what extent is evidence now available regarding mechanisms for neurological  
15 effects associated with “lower” ( $< 10 \mu\text{g/dL}$  or  $< 5 \mu\text{g/dL}$ ) blood Pb levels (e.g.,  
16 oxidative stress)? What toxicological evidence is available on mechanisms and dose-  
17 response relationships for other health outcomes (e.g., cardiovascular, renal, or  
18 immunological effects) or dose metrics, and is there coherence between this and  
19 epidemiologic findings for these endpoints?
- 20 2. To what extent is key evidence now available regarding mechanisms of action and  
21 concentration-response relationships at various ages and developmental stages,  
22 including critical windows of exposure that result in different effects and/or effects at  
23 lower exposures? Are new animal models available to better characterize  
24 mechanisms of action at various lifestages?
- 25 3. What mechanistic evidence is available on common modes of action that would help  
26 our understanding of health effects of exposure to Pb when it occurs within mixtures  
27 versus alone (e.g., evidence for additive, synergistic, or antagonistic effects)?

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

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

- 1 a. Is there evidence from new animal models of susceptibility factors that improves  
2 our characterization of susceptible populations and is there coherence between  
3 findings for these models and epidemiologic findings?
- 4 2. To what extent is key evidence now available to inform our understanding of  
5 developmental lifestages that are particularly susceptible to Pb exposures? What is  
6 known about critical windows of exposure for Pb with regard to their impact on  
7 concentration-response relationships and/or effects elicited?
  - 8 a. To what extent is susceptibility to the effects of early life Pb exposure associated  
9 with the development and or persistence/progression of Pb effects in adults? Are  
10 there new animal models that follow these windows of susceptibility?
  - 11 b. Are new animal models available that may help us to characterize the critical  
12 windows of exposure to Pb and, is there coherence between findings from these  
13 models and epidemiologic findings? Do any of these models show differential  
14 responses by sex of the animal?
- 15 3. What do the currently available studies indicate regarding the relationship between  
16 exposures to Pb and health effects in those with preexisting diseases (e.g., renal diseases)  
17 compared to healthy individuals? What medical conditions are identified as increasing  
18 susceptibility to Pb effects? What is the nature and time-course of the development of  
19 effects in previously healthy persons and in persons with pre-existing disease (e.g.,  
20 cardiovascular disease)? What are the pathways and mechanisms through which Pb may  
21 be acting for these groups?

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

### 28 **Ecological and Other Welfare Effects**

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

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

7 Terrestrial Ecosystem Effects:

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

21 Aquatic Ecosystem Effects:

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

35

#### 1 **4.4 CAUSAL DETERMINATIONS**

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

#### 16 **4.5 SUPPLEMENTARY MATERIALS**

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

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

---

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

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

#### 6 **4.6 SCIENTIFIC AND PUBLIC REVIEW**

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

---

<sup>16</sup> 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](http://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

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

## 5 **5.1 OVERVIEW OF ASSESSMENTS IN LAST REVIEW**

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

### 9 **5.1.1 Human Exposure and Health Risk Assessments**

10 In the last review, EPA developed and applied models to estimate human exposures to  
11 air-related Pb and associated health risk. Estimates were developed for various air quality  
12 scenarios and alternative standards to provide additional information and insights that could help  
13 to put judgments about risk associated with exposure to air-related Pb in a broader public health  
14 context and inform decisions on the standards. The exposure and risk analyses to estimate blood  
15 Pb and associated IQ loss in children exposed to air-related Pb were conducted in the context of  
16 five case studies that generally represent two types of population exposures: (1) more highly air-  
17 pathway exposed children (as described below) residing in small neighborhoods or localized  
18 residential areas with air concentrations somewhat near the standard being evaluated, and (2)  
19 location-specific urban populations with a broader range of air-related exposures. The case  
20 studies representing the more highly air-pathway exposed children included a general urban case  
21 study and a primary Pb smelter case study. The three location-specific urban case studies  
22 focused on specific residential areas within three U.S. cities to provide representations of urban  
23 populations with a broader range of air-related exposures due to spatial gradients in both ambient  
24 air Pb levels and population density. The air quality scenarios assessed included (a) the current  
25 NAAQS (for all five case studies); (b) current conditions for the location-specific and general  
26 urban case studies (which are below the current NAAQS); and (c) a range of alternate standard  
27 levels (for all case studies).

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

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

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

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

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



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

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

30

## 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.<sup>17</sup> 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:

---

<sup>17</sup> 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.

- 1 • The ecological risk screen was limited to specific case study locations and other locations  
2 for which Pb data were available. Efforts were made to ensure that the Pb exposures  
3 assessed were attributable to airborne Pb and not dominated by nonair sources. However,  
4 there was uncertainty as to whether other sources might have actually contributed to the  
5 Pb exposure estimates.
- 6 • A limitation to using the selected ecotoxicity screening values is that they might not be  
7 sufficient to identify risks to some threatened or endangered species or unusually  
8 sensitive aquatic ecosystems (e.g., 2006 AQCD, p. AX7–110).
- 9 • The methods and database from which the surface water screening values (i.e., EPA-  
10 recommended ambient water quality criteria for Pb) were derived is somewhat dated.  
11 New data and approaches (e.g., use of pH as indicator of bioavailability) may now be  
12 available to estimated the aquatic toxicity of Pb (2006 AQCD, sections X7.2.1.2 and  
13 AX7.2.1.3).
- 14 • No adjustments were made for sediment-specific characteristics that might affect the  
15 bioavailability of Pb in sediments in the derivation of the sediment quality criteria used  
16 for this ecological risk screen (2006 AQCD, sections 7.2.1 and AX7.2.1.4; Appendix M,  
17 ICF, 2006). Similarly, characteristics of soils for the case study locations were not  
18 evaluated for measures of bioavailability.
- 19 • Although the screening value for birds used in this analysis is based on reasonable  
20 estimates for diet composition and assimilation efficiency parameters, it was based on a  
21 conservative estimate of the relative bioavailability of Pb in soil and natural diets  
22 compared with water soluble Pb added to an experimental pellet diet (Appendix L, ICF,  
23 2006).

24 For the case studies, the concentrations of Pb in soil and sediments in various locations  
25 exceeded screening values for these media indicating potential for adverse effects to terrestrial  
26 organisms (plants, birds and mammals) and to sediment dwelling organisms. While the  
27 assessment was limited in that it was not possible to dissect the contributions of air Pb emissions  
28 from other sources, it is likely that, at least for the primary smelter, that the air contribution is  
29 significant. For the other case studies, the contributions of current air emissions to the Pb  
30 burden, is less clear. The national-scale screen of surface water data initially identified 15 areas  
31 for which water column levels of dissolved Pb were greater than hardness adjusted chronic  
32 criteria for the protection of aquatic life indicating a potential for adverse effect if concentrations  
33 were persistent over chronic periods. Acute criteria were not exceeded at any of these locations.  
34 The extent to which air emissions of Pb had contributed to these surface water Pb concentrations  
35 is unclear. In the national-scale screen of sediment data associated with the 15 surface water  
36 sites described above, threshold effect concentration-based HQs at nine of these sites exceeded

1 1.0. Additionally, HQs based on probable effect concentrations exceeded 1.0 at five of the sites,  
2 indicating probable adverse effects to sediment dwelling organisms. Thus, sediment Pb  
3 concentrations at some sites are high enough that there is a likelihood that they would cause  
4 adverse effects to sediment dwelling organisms. However, the contribution of air emissions to  
5 these concentrations is unknown.

## 6 **5.2 CONSIDERATION OF QUANTITATIVE ASSESSMENTS FOR THIS** 7 **REVIEW**

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

### 20 **5.2.1 Human Exposure and Health Risk Assessments**

#### 21 **5.2.1.1 Air Quality and Environmental Media Concentrations**

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

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

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

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

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

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

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

#### 22 **5.2.1.2 Human Exposure Assessment**

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

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

---

<sup>18</sup> Indoor dust Pb derived from lead recently emitted to the air was quantified separate from this combined historic Pb of paint or air origin.

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

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

### 25 **5.2.1.3 Health Risk Assessment**

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

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

## 8 **5.2.2 Ecological Risk Assessment**

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

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

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



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

### 4 **5.3 SCIENTIFIC AND PUBLIC REVIEW**

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

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

21 If upon consideration of CASAC and public comments on the REA planning document,  
22 EPA concludes that development of a new REA is not warranted, a REA will not be developed  
23 and the Policy Assessment for this review will draw from the REA developed in the last review  
24 in light of analyses or assessments made in the REA planning document with regard to the  
25 current evidence pertaining to exposure and risk, as well as the evidence presented in the ISA  
26 and other documents prepared for the review. Review steps for the PA are described in section  
27 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.<sup>19</sup>

## 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<sub>10</sub> concentrations may be used in judging nonattainment. Accordingly, FRMs have been established for Pb-TSP and for Pb-PM<sub>10</sub>.

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.<sup>20</sup> 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.

---

<sup>19</sup> 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.

<sup>20</sup> 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>

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

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

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

- 16 • Are new TSP samplers available and adequately characterized for use in Pb-TSP  
17 sampling?
- 18 • Are new data on Pb size distributions available that would better inform the need for Pb-  
19 TSP or the adequacy of Pb measurements in PM<sub>10</sub> or other size fractions (e.g., Pb-PM<sub>15</sub>  
20 or Pb-PM<sub>20</sub>) in characterizing total Pb concentrations?
- 21 • If an alternative size fraction is identified that may adequately characterize total Pb  
22 concentrations, are there samplers for that size fraction that have been adequately  
23 characterized that can be used as the basis for a new FRM sampling method?

## 24

## 25 **6.2 CONSIDERATION OF AIR MONITORING NETWORK**

## 26 **REQUIREMENTS**

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

1 did not have nearby ambient Pb air monitors. Due to these findings, the EPA promulgated  
2 revised Pb monitoring network design requirements along with the revised Pb NAAQS (73 FR  
3 66964). The Pb monitoring network design requirements were revised again in December 2010  
4 as a result of EPA’s decision to grant a petition to reconsider the prior network design  
5 requirements that was filed by several environmental and public health organizations (75 FR  
6 81126).

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

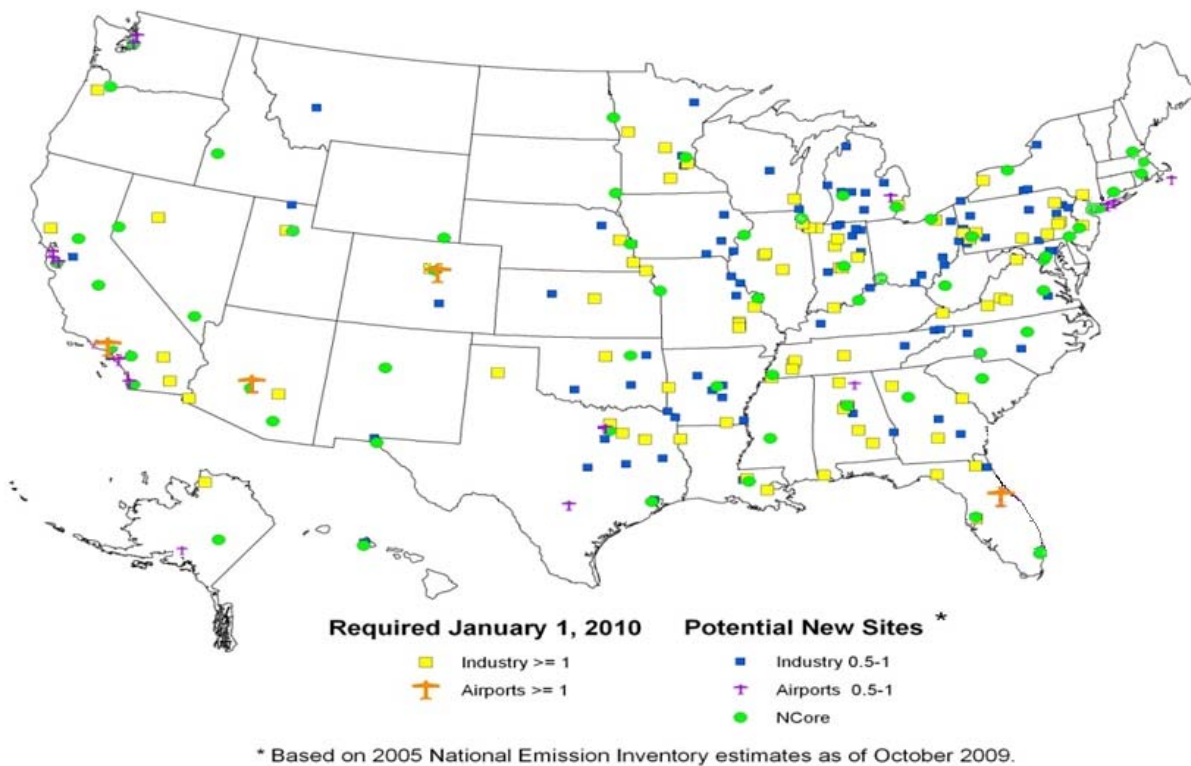
17 Monitoring agencies are required to conduct non-source-oriented Pb monitoring at the  
18 multipollutant monitoring sites (referred to as NCore sites, required under 40 CFR part 58  
19 Appendix D, paragraph 3) in Core Based Statistical Areas (CBSA) with a population of 500,000  
20 or more.<sup>22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

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

---

<sup>21</sup> 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).

<sup>22</sup> Defined by the US Census Bureau - <http://www.census.gov/population/www/metroareas/metroarea.html>



1

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

2

3

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

4

- 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?

6

7

- 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?

16

17

# 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<sup>23</sup>, 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

---

<sup>23</sup> 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.

1 lower levels at which the likelihood and magnitude of the response become increasingly  
2 uncertain. This approach is consistent with the requirements of the NAAQS provisions of the  
3 Act and with how EPA and the courts have historically interpreted the Act. These provisions  
4 require the Administrator to establish primary standards that are requisite to protect public health  
5 and are neither more nor less stringent than necessary for this purpose. The provisions do not  
6 require that primary standards be set at a zero-risk level, but rather at a level that avoids  
7 unacceptable risks to public health, including the health of sensitive groups.<sup>24</sup>

8 In identifying a range of secondary standard options for the Administrator to consider,  
9 staff recognizes that the final decision will be largely a public policy judgment. A final decision  
10 must draw upon scientific evidence and analyses about effects on public welfare, as well as  
11 judgments about how to deal with the range of uncertainties that are inherent in the relevant  
12 information. This approach is consistent with the requirements of the NAAQS provisions of the  
13 Act and with how EPA and the courts have historically interpreted the Act. These provisions  
14 require the Administrator to establish secondary standards that are requisite to protect public  
15 welfare from any known or anticipated adverse effects associated with the presence of the  
16 pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are  
17 neither more nor less stringent than necessary for this purpose. The provisions do not require  
18 that secondary standards be set to eliminate all welfare effects, but rather at a level that protects  
19 public welfare from those effects that are judged to be adverse.

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

---

<sup>24</sup> 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).

1 **7.2 RULEMAKING**

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

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

---

<sup>25</sup> 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](http://www.regulations.gov).

<sup>26</sup> 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](http://www.epa.gov/ttn/naaqs/standards/pb/data/20081015_responsetocomments.pdf).



## 8 REFERENCES

- 1
- 2 ICF International. (2006) Lead Human Exposure and Health Risk Assessments and Ecological Risk  
3 Assessment for Selected Areas. Pilot Phase. Draft Technical Report. Prepared for the U.S.  
4 EPA's Office of Air Quality Planning and Standards, Research Triangle Park, NC.  
5 December.
- 6 Jackson, L. (2009) Memorandum from Administrator Lisa Jackson, Subject: Development of  
7 regulations and policies. September 11, 2009. Available at:  
8 <http://www.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf>
- 9 MacDonald, D.D., Ingersoll, C.G., and Berger, T.A. (2000) Development and evaluation of  
10 consensus-based sediment quality guidelines for freshwater ecosystems. Archives of  
11 Environmental Contamination and Toxicology. 39:20-31.
- 12 MacDonald, D.D., Ingersoll, C.G., Smorong, D.E., Lindskoog, R.A., Sloane, G., and Biernacki, T.  
13 (2003) Development and Evaluation of Numerical Sediment Quality Assessment Guidelines  
14 for Florida Inland Waters. British Columbia: MacDonald Environmental Sciences, Lt.  
15 Columbia, MO: U.S. Geological Survey. Prepared for: Florida Department of  
16 Environmental Protection, Tallahassee, FL. January.
- 17 U.S. Environmental Protection Agency. (1977) Air quality criteria for lead. Research Triangle Park,  
18 NC: Health Effects Research Laboratory, Criteria and Special Studies Office; EPA report  
19 no. EPA-600/8-77-017. Available from: NTIS, Springfield, VA; PB-280411.
- 20 U.S. Environmental Protection Agency. (1986a) Air quality criteria for lead. Research Triangle  
21 Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and  
22 Assessment Office; EPA report no. EPA-600/8-83/028aF-dF. 4v. Available from: NTIS,  
23 Springfield, VA; PB87-142378.
- 24 U.S. Environmental Protection Agency. (1986b) Lead effects on cardiovascular function, early  
25 development, and stature: an addendum to U.S. EPA Air Quality Criteria for Lead (1986).  
26 In: Air quality criteria for lead, v. 1. Research Triangle Park, NC: Office of Health and  
27 Environmental Assessment, Environmental Criteria and Assessment Office; pp. A1-A67;  
28 EPA report no. EPA-600/8-83/028aF. Available from: NTIS, Springfield, VA; PB87-  
29 142378.
- 30 U.S. Environmental Protection Agency. (1989) Review of the national ambient air quality standards  
31 for lead: Exposure analysis methodology and validation: OAQPS staff report. Research  
32 Triangle Park, NC: Office of Air Quality Planning and Standards; report no. EPA-450/2-  
33 89/011. Available on the web:  
34 [http://www.epa.gov/ttn/naaqs/standards/pb/data/rnaaqsl\\_eamv.pdf](http://www.epa.gov/ttn/naaqs/standards/pb/data/rnaaqsl_eamv.pdf)
- 35 U.S. Environmental Protection Agency. (1990a) Air quality criteria for lead: supplement to the 1986  
36 addendum. Research Triangle Park, NC: Office of Health and Environmental Assessment,  
37 Environmental Criteria and Assessment Office; report no. EPA/600/8-89/049F. Available  
38 from: NTIS, Springfield, VA; PB91-138420.

- 1 U.S. Environmental Protection Agency. (1990b) Review of the national ambient air quality  
2 standards for lead: assessment of scientific and technical information: OAQPS staff paper.  
3 Research Triangle Park, NC: Office of Air Quality Planning and Standards; report no. EPA-  
4 450/2-89/022. Available from: NTIS, Springfield, VA; PB91-206185. Available on the  
5 web: [http://www.epa.gov/ttn/naaqs/standards/pb/data/rnaaqsl\\_asti.pdf](http://www.epa.gov/ttn/naaqs/standards/pb/data/rnaaqsl_asti.pdf)
- 6 U.S. Environmental Protection Agency. (1991) U.S. EPA Strategy for Reducing Lead Exposure.  
7 Available from U.S. EPA Headquarters Library/Washington, D.C. (Library Code EJBD;  
8 Item Call Number: EAP 100/1991.6; OCLC Number 2346675)..
- 9 U.S. Environmental Protection Agency. (2005) Project Work Plan for Revised Air Quality Criteria  
10 for Lead. Research Triangle Park, NC: National Center for Environmental Assessment-RTP  
11 Report no. NCEA-R-1465. CASAC Review Draft.
- 12 U.S. Environmental Protection Agency. (2006a) Plan for Review of the National Ambient Air  
13 Quality Standards for Lead. Office of Air Quality Planning and Standards, Research  
14 Triangle Park, NC. Available online at:  
15 [http://www.epa.gov/ttn/naaqs/standards/pb/s\\_pb\\_cr\\_pd.html](http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_pd.html)
- 16 U.S. Environmental Protection Agency. (2006b) Air Quality Criteria for Lead. Washington, DC,  
17 EPA/600/R-5/144aF. Available online at: [www.epa.gov/ncea/](http://www.epa.gov/ncea/)
- 18 U.S. Environmental Protection Agency. (2006c) Analysis Plan for Human Health and Ecological  
19 Risk Assessment for the Review of the Lead National Ambient Air Quality Standards.  
20 Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available online  
21 at: [http://www.epa.gov/ttn/naaqs/standards/pb/s\\_pb\\_cr\\_pd.html](http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_pd.html)
- 22 U.S. Environmental Protection Agency. (2007a) Lead: Human Exposure and Health Risk  
23 Assessments for Selected Case Studies, Volume I. Human Exposure and Health Risk  
24 Assessments – Full-Scale and Volume II. Appendices. Office of Air Quality Planning and  
25 Standards, Research Triangle Park, NC. EPA-452/R-07-014a and EPA-452/R-07-014b.
- 26 U.S. Environmental Protection Agency. (2007b) Review of the National Ambient Air Quality  
27 Standards for Lead: Policy Assessment of Scientific and Technical Information, OAQPS  
28 Staff Paper. EPA-452/R-07-013. Office of Air Quality Planning and Standards, Research  
29 Triangle Park, NC.
- 30 U.S. Environmental Protection Agency. (2010) Integrated Science Assessment for Carbon  
31 Monoxide. EPA/600/R-09/019F. National Center for Environmental Assessment-RTP  
32 Division, Research Triangle Park, NC.

## **Appendix A**

### **Integrated Science Assessment for Lead – Outline**

# Integrated Science Assessment for Lead

## **Chapter 1 Introduction**

- 1.1 Legislative Requirements
- 1.2 History of Reviews of the NAAQS for Pb
- 1.3 ISA Development
- 1.4 Document Organization
- 1.5 Document Scope
- 1.6 EPA Framework for Causal Determination
- 1.7 Summary

## **Chapter 2 Integrative Overview**

- 2.1 Ambient Pb Sources and Concentrations
- 2.2 Exposure to Ambient Pb
- 2.3 Kinetics, Biomarkers, and Models Relating Pb Exposure to Dose Metrics
- 2.4 Mode of Action
- 2.5 Pb Health Effects
- 2.6 Policy Relevant Considerations
- 2.7 Ecological and Other Welfare Effects
- 2.8 Integration of Health and Ecosystem Effects of Pb

## **Chapter 3 Ambient Pb Source to Concentration**

- 3.1 Introduction
- 3.2 Sources of Atmospheric Pb
- 3.3 Fate and Transport of Pb
- 3.4 Monitoring of Ambient Pb
- 3.5 Ambient Pb Air Pb Concentrations
- 3.6 Ambient Pb Concentrations in Non-Air Media and Biota
- 3.7 Summary

## **Chapter 4 Toxicokinetics, Biomarkers and Models of Pb Burden in Humans**

- 4.1 Pb Exposure Assessment
- 4.2 Kinetics of Pb
- 4.3 Biomarkers of Pb
- 4.4 Empirical Models of Pb Exposure-Blood Pb Relationships
- 4.5 Biokinetic Models of Pb Exposure-Blood Pb Relationships

## **Chapter 5 Integrated Health Effects of Pb Exposure**

- 5.1 Introduction
- 5.2 Modes of Action
- 5.3 Neurotoxic Effects of Pb
- 5.4 Cardiovascular Effects of Pb
  - 5.4.1 Mortality Effects
- 5.5 Renal Effects
- 5.6 Effects of Pb on the Immune System
- 5.7 Carcinogenic and Genotoxic Potential of Pb

- 5.8 Effects of Pb on Heme Synthesis and RBC Function
- 5.9 Effects of Pb on the Reproductive System
- 5.10 Effects of Pb on Other Organ Systems
- 5.11 Summary

**Chapter 6 Susceptible Populations**

- 6.1 Susceptibility Factors and Biomarkers of Pb Exposure
- 6.2 Susceptibility Factors Related to Pb-induced Health Effects
- 6.3 Summary

**Chapter 7 Ecological Effects and Other Welfare Effects of Pb**

- 7.1 Introduction to Ecological Concepts
- 7.2 Terrestrial Ecosystem Effects
- 7.3 Aquatic Ecosystem Effects
- 7.4 Summary

United States  
Environmental Protection  
Agency

Office of Air Quality Planning and Standards  
Health and Environmental Impacts Division  
Research Triangle Park, NC

Publication No. EPA-452/D-11-001  
March 2011

---