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

Volume 1: Background Document

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U.S. Environmental Protection Agency

Office of Air Quality Planning and Standards
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and
Center for Public Health and Environmental Assessment
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This document serves as a public information document and as a management tool for the U.S. Environmental Protection Agency's Center for Public Health and Environmental Assessment and the Office of Air Quality Planning and Standards in conducting the review of the national ambient air quality standards for lead. It does not represent and should not be construed to represent an Agency determination or policy. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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PREFACE

The planning phase of the U.S. Environmental Protection Agency's (EPA's) reviews of the national ambient air quality standards (NAAQS) includes development of an integrated review plan (IRP) which is made available for public comment and provided to the Clean Air Scientific Advisory Committee (CASAC) for review or consultation. As a result of recent efforts to improve the efficiency of the planning phase and to facilitate the receipt of timely input from the CASAC and the public, the IRP for the current review of the lead NAAQS is comprised of three volumes. Volume 1 (this document) provides background information on the air quality criteria and standards for Pb, and may serve as a reference for the public and the CASAC in their consideration of the subsequent two volumes. Volume 2 addresses the general approach for the review and planning for the integrated science assessment (ISA), and will be the subject of a consultation with the CASAC. Volume 2 identifies policy-relevant issues in the review and describes key considerations in EPA's development of the ISA. Volume 3 is the planning document for quantitative analyses to be considered in the policy assessment (PA), including exposure and risk analyses. It will describe key considerations in EPA's development of the PA and planning with regard to any quantitative exposure/risk analyses to inform the review. In order that consideration of the availability of new evidence in the review can inform these plans, the development and public availability of Volume 3 will generally coincide with that of the draft ISA and it will be the subject of a consultation with the CASAC at that time.

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. 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 pollutants "emissions of which, in his 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 he "plans to issue air quality criteria…." (42 U.S.C. § 7408(a)(1)). Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air…." (42 U.S.C. § 7408(a)(2)).

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria are issued (42 U.S.C. § 7409(a)). Section 109(b)(1) defines primary standards as ones "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[1] Under section 109(b)(2), a secondary standard must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[2]

In setting primary and secondary standards that are "requisite" to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally, *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 465–472, 475–76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." See *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); accord *Murray Energy Corp. v. EPA*, 936 F.3d 597, 623–24 (D.C. Cir. 2019). At the same time, courts have

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

[2] Under CAA section 302(h) (42 U.S.C. § 7602(h)), effects on welfare include, but are not limited to, "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

clarified the EPA may consider "relative proximity to peak background … concentrations" as a factor in deciding how to revise the NAAQS in the context of considering standard levels within the range of reasonable values supported by the air quality criteria and judgments of the Administrator. See *American Trucking Ass'ns, v. EPA*, 283 F.3d 355, 379 (D.C. Cir. 2002), hereafter referred to as "*ATA III*."

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980); *American Petroleum Institute v. Costle*, 665 F.2d at 1186; *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi v. EPA*, 744 F.3d 1334, 1353 (D.C. Cir. 2013). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels (see *Lead Industries Ass'n v. EPA*, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 744 F.3d at 1351), but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s),[3] and the kind and degree of uncertainties. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Ass'n v. EPA*, 647 F.2d at 1161–62; *Mississippi v. EPA*, 744 F.3d at 1353.

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge concerning the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to

[3] As used here and similarly throughout this document, the term population (or group) refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or life stage. Identification of such sensitive groups (called at-risk groups or at-risk populations) involves consideration of susceptibility and vulnerability.

periodically review and, if appropriate, revise the NAAQS, based on the revised air quality criteria.[4]

Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of "seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." Section 109(d)(2)(B) provides that the independent scientific review committee "shall complete a review of the criteria...and the national primary and secondary ambient air quality standards…and shall recommend to the Administrator any new…standards and revisions of existing criteria and standards as may be appropriate …" Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board. A number of other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

> Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

As previously noted, the Supreme Court has held that section 109(b) "unambiguously bars cost considerations from the NAAQS-setting process," in *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 471 (2001). Accordingly, while some of the issues listed in section 109(d)(2)(C) as those on which Congress has directed the CASAC to advise the Administrator are ones that are relevant to the standard setting process, others are not. Issues that are not relevant to standard setting may be relevant to implementation of the NAAQS once they are established.[5]

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[4] This section of the Act requires the Administrator to complete these reviews and make any revisions that may be appropriate "at five-year intervals."

[5] Because some of these issues are not relevant to standard setting, some aspects of CASAC advice may not be relevant to EPA's process of setting primary and secondary standards that are requisite to protect public health and welfare. Indeed, were the EPA to consider costs of implementation when reviewing and revising the standards "it would be grounds for vacating the NAAQS." Whitman v. American Trucking Ass'ns, 531 U.S. 457, 471 n.4 (2001). At the same time, the CAA directs CASAC to provide advice on "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of the NAAQS to the Administrator under section 109(d)(2)(C)(iv). In Whitman, the Court clarified that most of that advice would be relevant to implementation but not standard setting, as it "enable[s] the Administrator to assist the States in carrying out their statutory role as primary implementers of the NAAQS" (id.

at 470 [emphasis in original]). However, the Court also noted that CASAC's "advice concerning certain aspects of 'adverse public health…effects' from various attainment strategies is unquestionably pertinent" to the NAAQS rulemaking record and relevant to the standard setting process (id. at 470 n.2).

2 NAAQS REVIEW PROCESS AND DOCUMENTS

Each review of ambient air quality criteria and standards begins with a Call for Information for the Agency to consider in the review. This Call for Information, published in the *Federal Register*, generally is focused on scientific information pertinent to the criteria review but may also solicit comments from the public on policy-relevant issues important to address in the criteria and/or standards reviews. The Call for Information kicks off the first of the three phases in NAAQS reviews, the planning phase. The other two phases are assessment and regulatory (Figure 2-1). The documents prepared in these three phases, summarized below, are available to the public on an Agency web site maintained for this purpose (http://www.epa.gov/ttn/naaqs/).

The Agency plans for the review are presented to the public in an integrated review plan (IRP).[6] The IRP is prepared jointly by EPA's Center for Public Health and Environmental Assessment (CPHEA), within the Office of Research and Development (ORD), and EPA's Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation (OAR). In general, the IRP contains background material, both generic across reviews (e.g., presentation of legislative requirements) and specific to the pollutant for the review (e.g., history of existing criteria and standards, current monitoring methods and network, and the review timeline), as well as key scientific, technical or policy aspects of plans for the new review. The IRP also presents the current plan and specifies the schedule and process for conducting the review and the key policy-relevant science issues that will guide the review. All are made available to the public, and the key aspects of plans for the new review are the subject of consultation with the CASAC and public comment.

As a result of recent efforts to improve the efficiency of the planning phase and to facilitate the receipt of timely input from the CASAC and the public on key aspects of the review, the IRP for the current review of the lead NAAQS is comprised of three volumes. Volume 1 (this document) provides background information, and may serve as a reference for the public and the CASAC in their consideration of the subsequent two volumes. Volume 2 addresses the general approach for the review, identifying policy-relevant issues in the review, and also addresses planning for the integrated science assessment (ISA), including key considerations in its development. Volume 2 will be the subject of a consultation with the CASAC. Volume 3 is the planning document for quantitative analyses to be considered in the policy assessment (PA), including exposure and risk analyses. It will describe key considerations

[6] Development of the IRP for some NAAQS reviews may be informed by a science policy workshop to help the Agency identify issues and questions to frame the review.

in EPA's development of the PA and planning with regard to any quantitative exposure/risk analyses to inform the review. In order that consideration of the availability of new evidence in the review can inform these plans, the development and public availability of Volume 3 will generally coincide with that of the draft ISA and it will be the subject of a consultation with the CASAC at that time.

In the assessment phase, the EPA prepares the ISA[7] and any supplementary materials; quantitative air quality, exposure and risk analyses, as warranted; and a PA. The ISA, prepared by the CPHEA, provides a concise review, synthesis, and evaluation of the most policy-relevant science, including key science judgments that are important to the design and scope of air quality, exposure and risk analyses, as well as other aspects of the NAAQS review. The ISA and its supplementary materials provide a comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of the pollutant in the ambient air, emphasizing information that has become available since the last air quality criteria review in order to reflect the current state of knowledge. In this way, the ISA forms the scientific foundation for each NAAQS review. Section 2.1 summarizes key aspects of the ISA.

Based on the updated scientific information available in the review and considered in the ISA, along with ISA conclusions, OAQPS staff considers the support provided for development of quantitative assessments of air quality, exposures and/or risks of health and/or welfare effects. As warranted in a given review, the EPA develops relevant quantitative analyses, the details of which, in recent reviews, are presented in appendices to the PA. These appendices provide concise presentations of methods, key results, observations, and related uncertainties.

The PA, like the OAQPS Staff Paper in earlier reviews, is a document that provides a transparent OAQPS staff analysis and conclusions regarding the adequacy of the current standards and potential alternatives that are appropriate to consider prior to the issuance of proposed and final decisions. This evaluation of policy implications is intended to help ''bridge the gap'' between the Agency's scientific and technical assessments in the ISA and the quantitative exposure and risk analyses, and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS. In this way, the PA integrates and interprets the information from the ISA and quantitative exposure and risk analyses to frame policy options for consideration by the Administrator. Development of the PA is also intended to facilitate CASAC's advice to the Agency and recommendations to the

[7] The ISA and its associated materials function in the NAAQS review process today, as the Air Quality Criteria Document (AQCD) did in reviews of the past.

Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the CAA.

In the regulatory phase of the review process, which generally follows issuance of the final PA and consideration of conclusions presented therein, the Agency develops and publishes a notice of proposed decision to communicate the Administrator's proposed decisions regarding the standards review. To the extent the proposed decision is to revise the existing NAAQS or establish new NAAQS, the notice presents the proposed regulatory changes. Prior to publication of a draft notice, it generally undergoes interagency review involving other federal agencies.[8] Materials upon which the proposed decision is based, including the documents described above, are made available to the public in the regulatory docket for the review. A public comment period, during which public hearings are generally held, follows publication of the proposed decision. Taking into account comments received on the proposed decision,[9] the Agency develops a notice of final decision, including any regulatory revision, which undergoes interagency review prior to publication to complete the regulatory process. Section 2.3 summarizes the regulatory steps in a review.

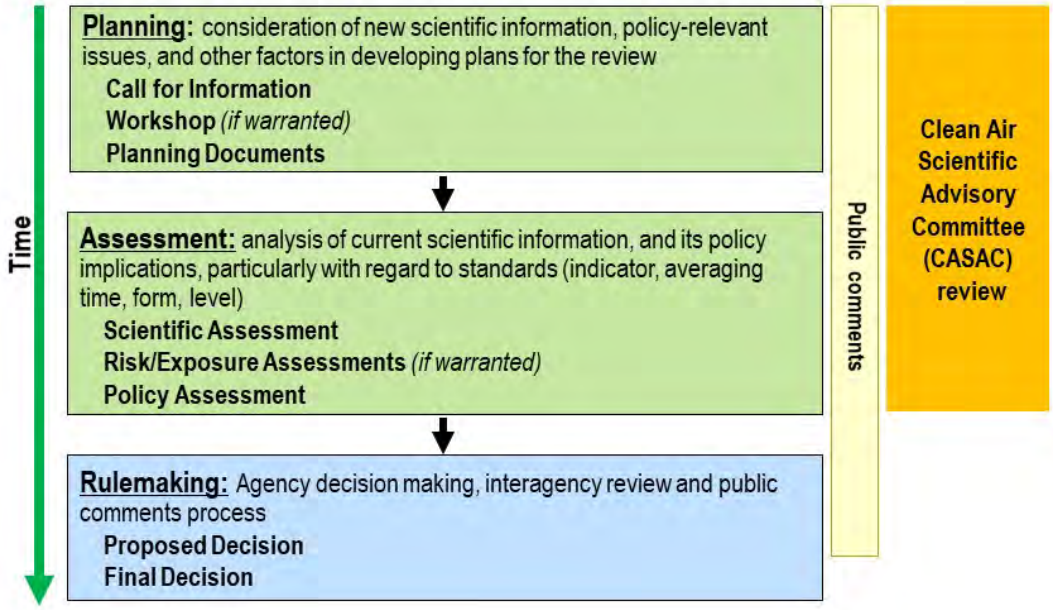

Figure 2-1. Overview of the NAAQS review process.

[8] 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 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.

[9] When issuing the final rulemaking decision, the Agency responds to all significant comments on the proposal.

2.1 INTEGRATED SCIENCE ASSESSMENT

The purpose of the ISA is to draw upon the existing body of evidence to synthesize and provide a critical evaluation of the current state of scientific knowledge on the most relevant issues pertinent to the review of the NAAQS; to identify changes in the scientific evidence bases since the previous review; and to describe remaining or newly identified uncertainties. The ISA identifies, critically evaluates and synthesizes the most policy-relevant current scientific literature (e.g., epidemiology, controlled human exposure, animal toxicology, atmospheric science, exposure science, environmental science, and ecology). In doing so, it presents a concise policy-relevant evaluation of the current scientific information along with the EPA's conclusions on the health and welfare effects of lead and associated key science findings that are important to inform the development of risk and exposure analyses (as warranted) and the PA, as well as other aspects of the NAAQS review process.

The ISA provides a focused assessment of the scientific evidence to address specific scientific questions and inform the overall policy-relevant questions for the PA. Through periodic reviews of the available scientific evidence, ISAs build on the data and conclusions of previous assessments. The ISA for a NAAQS review identifies and evaluates studies published since the literature cutoff date for inclusion of studies in the prior ISA, synthesizing and integrating the new evidence in the context of the conclusions from the previous review. Important older studies may be discussed to reinforce key concepts and conclusions. Older studies also may be the primary focus in some subject areas or scientific disciplines where research efforts have subsided and/or where these older studies remain the definitive works available in the literature. The general process for developing the ISA, including the scientific and public review aspects, is summarized in Appendix A, while details and the specific science issues to be addressed in the Pb ISA are presented in Volume 2 of the IRP.

2.2 POLICY ASSESSMENT

The PA is a document that provides an evaluation of the currently available information with regard to the adequacy of the current standards and potential alternatives, if any are appropriate to consider in the current review. In so doing, the PA integrates and interprets the current scientific evidence from the ISA and available information from quantitative exposure/risk analysis, together with related limitations and uncertainties, to frame policy options for consideration by the Administrator. This evaluation of policy implications is intended to "bridge the gap" between the Agency's scientific assessments and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS.

Quantitative risk and exposure assessments (REAs), a term used in several past NAAQS reviews, referred to assessments presented in a stand-alone REA document. More recently, we

have also used this term or the phrase “REA analyses” to simply refer to the air quality, exposure and/or risk analyses which we intend to present in appendices or as supplemental materials to the PA. These quantitative REAs are generally designed to assess human exposure and health risk, as well as ecological exposures and risks to public welfare, for air quality conditions associated with the existing standards and, as appropriate, for conditions associated with potential alternative standards. The objective for such assessments is generally to provide quantitative estimates of impacts that can inform the Administrator’s judgments on the public health and public welfare significance of exposures likely to occur under air quality conditions reflective of the current NAAQS and, as appropriate, any alternative standards under consideration. Accordingly, the assessments are also intended to provide a basis for judgments as to the extent of public health and public welfare protection afforded by such standards. The development of REAs in each NAAQS review draws upon the currently available evidence that is characterized in the ISA and on current methods and tools. In considering whether new analyses are warranted for particular types of assessments in each review, we evaluate the availability of new scientific evidence and technical information, as well as improved methods and tools, that may provide support for conducting updates to address key limitations or uncertainties in analyses from the last review or to provide additional insight beyond those provided by the prior REA. Thus, we focus on identifying the new analyses that are warranted in consideration of factors such as those raised here, while also bearing in mind practical and logistical considerations such as available resources and timeline for the review. The details of any new analyses are documented with the PA (e.g., in appendices or associated volumes) and the findings presented and discussed within the main body of the PA.

The PA includes pertinent background information, such as information on current air quality and the decisions in the last NAAQS review, as well as discussion of the currently available health and welfare effects evidence and exposure/risk information. These discussions focus on policy-relevant aspects important for the Agency to consider in reviewing the existing standards. The policy evaluation in the PA of the current scientific evidence from the ISA and the current exposure/risk information is generally framed by consideration of a series of the policy-relevant questions, including the fundamental overarching questions associated with the adequacy of the current standards and, as appropriate, consideration of alternative standards that involve revision to any of the specific elements of the standards: indicator, averaging time, level, and form. To the extent it is concluded to be appropriate to consider potential alternative standards, the PA will also describe policy options for such revisions that are supported by the available information. Key considerations in development of the exposure/risk information and those related to the policy-relevant questions for the PA evaluation will be discussed in the planning document for the PA (IRP, Volume 3).

The draft PA, inclusive of the current air quality, exposure and risk information, whether newly developed in this review or drawn from previously developed assessments, is distributed to the CASAC for its consideration and released to the public for review and comment. Review of the draft PA by the CASAC also facilitates 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. The CASAC discusses its review of the draft PA at public meetings that are announced in the *Federal Register*. Based on past practice by the CASAC, the EPA expects that key advice and recommendations for revision of the document would be summarized by the CASAC in a letter to the EPA Administrator. In revising the draft PA document, any such advice and recommendations are taken into account, and comments received from the public are also considered. The final document is made available on an EPA website, with its public availability announced in the *Federal Register*.

2.3 REGULATORY DECISION MAKING

Following issuance of the final PA and consideration of analyses and conclusions presented therein, and taking into consideration CASAC advice and recommendations, the Agency develops a notice of proposed decisions. This notice conveys the Administrator's proposed conclusions, reached in consideration of the analyses and conclusions in the documents developed in the review (e.g., as described in the preceding sections) and advice and recommendations from the CASAC, regarding the adequacy of the current standards and any revision(s) that may be appropriate. As appropriate, a draft notice of proposed decision is submitted to the Office of Management and Budget (OMB) for its review and comment. In this interagency review step, the OMB also provides to other federal agencies the opportunity for review and comment. After the completion of interagency review, the notice of proposed action is published in the *Federal Register*.

At the time of publication of the notice of the proposed action, all materials on which the proposal is based are made available in the public docket for the review.[10] Publication of the proposal notice is followed by a public comment period, generally lasting 45 to 90 days, during which the public is invited to submit comments on the proposal to the docket and one or more public hearings may be held. Taking into account comments received on the proposed action, the Agency then develops a notice of final action, which communicates the Administrator's decisions regarding this review and which may again undergo OMB-coordinated interagency review prior to issuance by the EPA. At the time of the final action, the Agency responds to all

[10] The docket for the current Pb NAAQS review is identified as EPA-HQ-OAR-2020-0312. This docket has incorporated the ISA docket (EPA-HQ-ORD-2020-0701) by reference. Both dockets are publicly accessible at www.regulations.gov.

significant comments on the proposal.[11] Publication of the notice of the final action in the *Federal Register* will complete the review process.

The final decisions on the primary and secondary standards are largely public health or welfare policy judgments by the Administrator. Final decisions must draw upon scientific information and analyses about health or welfare 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. Consistent with the Agency's approach across all NAAQS reviews, the approach of the PA to inform these judgments is based on a recognition that the available evidence generally reflects continuums that include ambient air exposures for which scientists generally agree that effects are likely to occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Act and with how the EPA and the courts have historically interpreted the Act.

With regard to primary standards, these provisions require the Administrator to establish standards that are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The provisions do not require that standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups[12].

With regard to the secondary standard, the CAA provisions require the Administrator to establish secondary standards that are requisite to protect public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The provisions do not require that secondary standards be set to eliminate all welfare effects, but rather to protect public welfare from those effects that are judged to be adverse.

[11] For example, Agency responses to all substantive comments on the 2015 proposed decision notice in the last review were provided in the final decision notice. In some reviews, responses are additionally provided in a separate document (e.g., "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)").

[12] More than one population group may be identified as sensitive or at-risk in a NAAQS review. The decision in the review will reflect consideration of the degree to which protection is provided for these sensitive population groups. To the extent that any particular population group is not among the identified sensitive groups, a decision that provides protection for the sensitive groups would be expected to also provide protection for other population groups.

3 BACKGROUND ON THE LEAD NAAQS

3.1 HISTORY OF AIR QUALITY CRITERIA AND STANDARDS FOR LEAD

Unlike pollutants such as particulate matter and carbon monoxide, air quality criteria had not been issued for Pb as of the enactment of the Clean Air Act of 1970, which first set forth the requirement to set NAAQS based on air quality criteria. In the years just after enactment of the CAA, the EPA did not intend to issue air quality criteria for Pb and accordingly had not listed Pb under Section 108 of the Act. The EPA had determined to control Pb air pollution through regulations to phase out the use of Pb additives in gasoline, and the EPA viewed those controls, and possibly additional federal controls, as the best approach to controlling Pb emissions (e.g., 41 FR 14921, April 8, 1976). However, the decision not to list Pb under Section 108 was challenged by environmental and public health groups, and the U.S. District Court for the Southern District of New York concluded that the EPA was required to list Pb under Section 108. *Natural Resources Defense Council v. EPA*, 411 F. Supp. 864 21 (S.D. N.Y. 1976), aff'd, 545 F.2d 320 (2d Cir. 1978).

Accordingly, on April 8, 1976, the EPA published a notice in the *Federal Register* that Pb had been listed under Section 108 as a criteria pollutant (41 FR 14921), and on October 5, 1978, the EPA promulgated primary and secondary NAAQS for Pb under Section 109 of the Act (43 FR 46246). Both primary and secondary standards were set at a level of 1.5 micrograms per cubic meter ($\mu g/m^3$), measured as Pb in total suspended particles (Pb-TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. These standards were based on the 1977 Air Quality Criteria for Lead (U.S. EPA, 1977).

The first review of the Pb standards was initiated in the mid-1980s. The scientific assessment for that review is described in the 1986 Air Quality Criteria for Lead (U.S. EPA, 1986a), the associated Addendum (U.S. EPA, 1986b) and the 1990 Supplement (U.S. EPA, 1990a). As part of the review, the Agency designed and performed human exposure and health risk analyses (U.S. EPA, 1989), the results of which were presented in a 1990 Staff Paper (U.S. EPA, 1990b). Based on the scientific assessment and the human exposure and health risk analyses, the 1990 Staff Paper presented recommendations for consideration by the Administrator (U.S. EPA, 1990b). After consideration of the documents developed during the review and the significantly changed circumstances since Pb was listed in 1976, the Agency did not propose any revisions to the 1978 Pb NAAQS. In a parallel effort, the Agency developed the broad, multi-program, multimedia, integrated U.S. Strategy for Reducing Lead Exposure (U.S. EPA, 1991). As part of implementing this strategy, the Agency focused efforts primarily on

regulatory and remedial clean-up actions aimed at reducing Pb exposures from a variety of nonair sources judged to pose more extensive public health risks to U.S. populations, as well as on actions to reduce Pb emissions to air, such as bringing more areas into compliance with the existing Pb NAAQS (U.S. EPA, 1991). EPA continues this broad, multi-program, multimedia approach to reducing Pb exposures today.

The second review of the Pb air quality criteria and standards was initiated in November 2004 (69 FR 64926, November 9, 2004), and the Agency's plans for preparation of the Air Quality Criteria Document and conduct of the NAAQS review were presented in documents completed in 2005 and early 2006 (U.S. EPA, 2005; U.S. EPA, 2006a). The schedule for completion of the review was governed by a judicial order in *Missouri Coalition for the Environment v. EPA* (No. 4:04CV00660 ERW, Sept. 14, 2005; and amended on April 29, 2008 and July 1, 2008), which specified a schedule for the review of duration shorter than five years.

The scientific assessment for the second review is described in the 2006 Air Quality Criteria for Lead (U.S. EPA, 2006b; henceforth referred to as the 2006 AQCD), multiple drafts of which received review by CASAC and the public. The EPA also conducted human exposure and health risk assessments and a pilot ecological risk assessment for the review, after consultation with CASAC and receiving public comment on a draft analysis plan (U.S. EPA, 2006c; 71 FR 34129, June 13, 2006). Drafts of these quantitative assessments were reviewed by CASAC and the public. The pilot ecological risk assessment was released in December 2006 (ICF, 2006, hereafter 2006 REA), and the final health risk assessment report was released in November 2007 (U.S. EPA, 2007a, hereafter 2007 REA). The policy assessment, based on both of these assessments, air quality analyses and key evidence from the 2006 AQCD, was presented in the Staff Paper (U.S. EPA, 2007b, hereafter 2007 Staff Paper), a draft of which also received CASAC and public review. The Staff Paper presented OAQPS staff recommendations that the Administrator give consideration to substantially revising the primary and secondary standards to a range of levels at or below 0.2 $\mu g/m^3$. Immediately subsequent to completion of the 2007 Staff Paper, the EPA issued an advance notice of proposed rulemaking (ANPR; 72 FR 71488, December 17, 2007), which the CASAC reviewed along with the final PA.

The proposed and final decisions on revisions to the Pb NAAQS were published in 2008 (73 FR 29184, May 20, 2008; 73 FR 66964, November 12, 2008). In consideration of the much-expanded health effects evidence on neurocognitive effects of Pb in children, the EPA substantially revised the primary standard from a level of 1.5 $\mu g/m^3$ to a level of 0.15 $\mu g/m^3$. The averaging time was revised to a rolling three-month period with a maximum (not-to-be exceeded) form, evaluated over a three-year period. The indicator of Pb-TSP was retained, reflecting the evidence that Pb particles of all sizes pose health risks. The secondary standard was revised to be identical in all respects to the revised primary standards. Revisions to the

NAAQS were accompanied by revisions to the data handling procedures, the treatment of exceptional events and the ambient air monitoring and reporting requirements, as well as emissions inventory reporting requirements. One aspect of the new data handling requirements is the allowance for the use of Pb-PM_{10} monitoring for Pb NAAQS attainment purposes in certain limited circumstances at non-source-oriented sites. Additional revisions to the monitoring network requirements, subsequent to the 2008 rulemaking, are described in Appendix B.

In 2010, the EPA initiated the third periodic review of the air quality criteria and the Pb NAAQS with a call for information in the *Federal Register*, followed by a workshop to discuss the policy-relevant science, which informed the identification of key policy issues and questions to frame the review (75 FR 8934, February 26, 2010; 75 FR 20843, April 21, 2010). Drawing from the workshop discussions and after consultation with CASAC (76 FR 21346, April 15, 2011) and the public on a draft IRP, the EPA released a final IRP in November 2011 (U.S. EPA, 2011a). In developing the ISA for this review, the EPA held a workshop in December 2010 to discuss with invited scientific experts preliminary draft materials (75 FR 69078, November 10, 2010). Following several drafts, which received review by CASAC and the public, the final ISA was released in June 2013 (Frey and Samet, 2011; Samet and Frey, 2012; Frey, 2013a; U.S. EPA, 2013).

Based on the current scientific evidence assessed in the ISA and current exposure and risk information,[13] the OAQPS developed a draft PA, which was reviewed by the CASAC and the public (78 FR 938, January 7, 2013; 78 FR 2394, January 11, 2013; Frey 2013b) The final PA, was completed in 2014 (U.S. EPA, 2014, hereafter 2014 PA). Subsequently that year, the EPA proposed to retain the existing 2008 standards (80 FR 278, January 5, 2015). After consideration of public comment on the proposal, the EPA announced its decision to retain the existing standards, without revision (81 FR 71906, October 18, 2016).

3.2 MULTIMEDIA PATHWAY CONSIDERATIONS FOR AMBIENT AIR LEAD

Unlike the other pollutants for which NAAQS are established, Pb is a multimedia and persistent pollutant that contributes complexities to the review of the Pb NAAQS. Lead emitted into ambient air may subsequently occur in multiple environmental media, contributing to

[13] The REA Planning Document, on which the CASAC Pb review Panel provided consultative advice, and general concurrence, concluded that the information newly available in the review, related to assessment of human and ecological exposure and risk of Pb, did not provide a basis for developing new quantitative risk and exposure assessments likely to substantially improve utility for informing the EPA's evaluation of the adequacy of the primary and secondary standards (76 FR 36120, June 21, 2011; Frey, 2011; U.S. EPA, 2011b). Accordingly, new exposure/risk analyses were not developed, and the prior review assessments and findings for human exposure and health risk (U.S. EPA, 2007a) and ecological risk (ICF International, 2006) comprised the exposure/risk information considered in the review (U.S. EPA, 2014).

multiple pathways of exposure for humans and ecological receptors. This multimedia distribution of and multipathway exposure to air-related Pb has a key role in the Agency's consideration of the Pb NAAQS. Some associated considerations include the following:

- Lead emitted into the air is predominantly in particulate form, which can be transported long or short distances depending on particle size.
- Once deposited out of the air, Pb can subsequently be resuspended in the ambient air and, because of the persistence of Pb, Pb emissions can contribute to media concentrations for years into the future. The timeline and extent of this contribution, however, varies with the type and location of media and Pb deposition characteristics.
- Exposure to Pb emitted into the ambient air (air-related Pb) can occur directly by inhalation or indirectly by ingestion of Pb-contaminated food, water or other materials including dust and soil.[14] These exposures occur as Pb emitted into the ambient air is distributed to other environmental media and can contribute to human exposures via indoor and outdoor dusts, outdoor soil, food and drinking water, as well as inhalation of air.
- Air-related exposure pathways are affected by changes to air quality, including changes in concentrations of Pb in air and changes in atmospheric deposition of Pb. Further, because of its persistence in the environment, Pb deposited from the air may contribute to human and ecological exposures for years into the future. Thus, the roles of both air concentration and air deposition in human exposure pathways, and the persistence of Pb once deposited, influence the dynamics of the response of the various Pb exposure pathways to changes in air quality.

Given the distribution of Pb from air to other media and its persistence, reviews of the NAAQS for Pb consider the protection provided against such effects associated both with exposures to Pb in ambient air and with exposures to Pb that makes its way into other media from ambient air. Additionally, in assessing the adequacy of protection afforded by the current NAAQS, we are mindful of the long history of greater and more widespread atmospheric emissions that occurred in previous years (both before and after establishment of the 1978 NAAQS) and that contributed to the Pb that exists in human populations and ecosystems today.

Human and environmental exposure pathways pertaining to the environmental distribution of Pb emitted in the ambient air are illustrated in Figure 3-1 below. As shown in this figure, the multimedia distribution of Pb emitted into ambient air (air-related Pb) contributes to multiple air-related pathways of human and ecosystem exposure (2013 ISA, sections 3.1.1 and 3.7.1).[15] Figure 3-1 additionally illustrates that air-related pathways may involve media other

[14] 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.

[15] The exposure assessment for children performed for the review completed in 2008 employed available data and methods to develop estimates intended to inform a characterization of these pathways, as described in the

than air, including indoor and outdoor dust, soil, surface water and sediments, vegetation, and biota. As recognized by the figure, Pb occurring in indoor and outdoor environments that has not passed through ambient air (non-air Pb) may complicate our evaluation of ambient air related Pb exposures. Further, the persistence of Pb and the associated environmental legacy of historical releases pose an additional complication with regard to consideration of exposures associated with current Pb emissions.

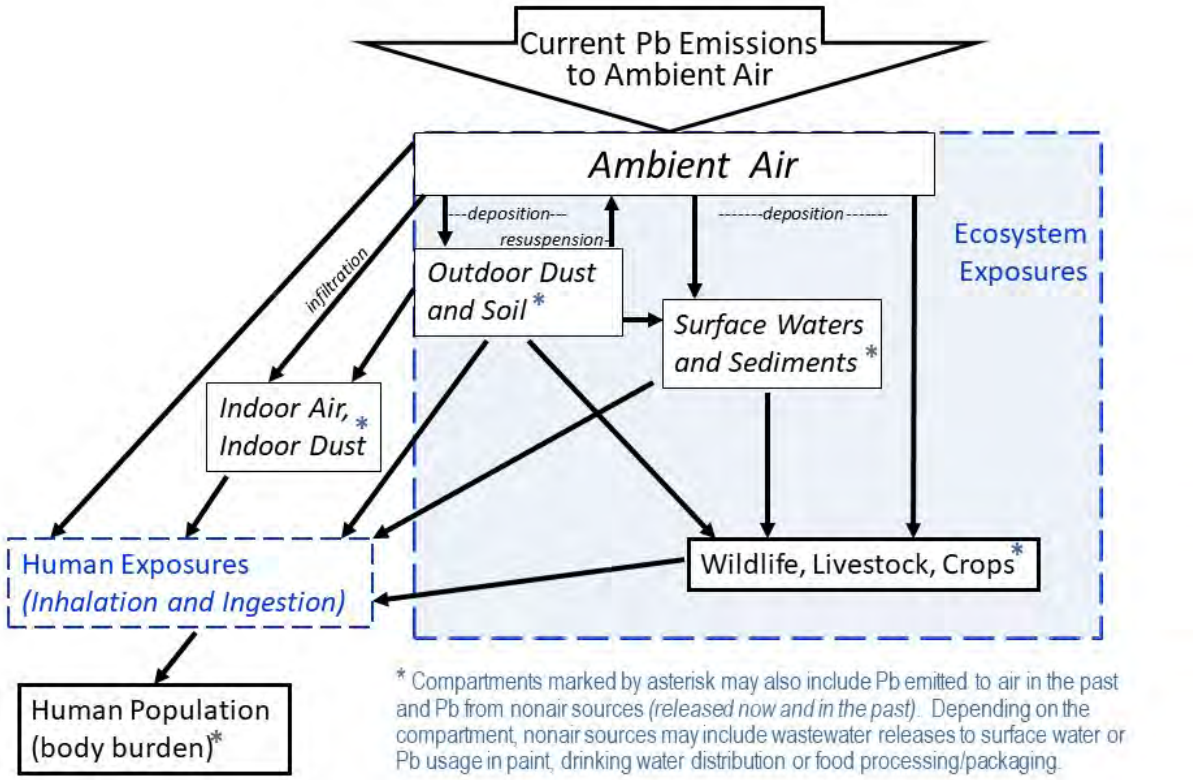

Figure 3-1. Pathways of human and ecosystem exposure to lead from ambient air.

rulemaking notices for that review (73 FR 29184, May 20, 2008; 73 FR 66964, November 12, 2008) and the associated health risk assessment report (U.S. EPA, 2007a).

3.3 THE PRIMARY STANDARD

The current primary Pb standard of 0.15μg/m^3 was established in 2008 and retained, without revision, in 2016 (73 FR 66964, November 12, 2008; 81 FR 71906, October 18, 2016). The 2008 decision, which substantially revised the primary standard – to a level that is one-tenth the level of the prior standard - was based on the extensive body of scientific evidence published over almost three decades, from the time the prior standard was set in 1978 through 2005–2006. In addition to the finding that Pb has been demonstrated to exert ‘‘a broad array of deleterious effects on multiple organ systems,’’ the 2008 review documented effects at appreciably lower exposures than previously established and the general scientific consensus that the developing nervous system in children is among the most sensitive health endpoints associated with Pb exposure, if not the most sensitive one (73 FR 66975, November 12, 2008).

Accordingly, in focusing on the effects most pertinent to recent ambient air exposures, the 2008 review considered those effects related to relatively lower exposures and associated blood Pb levels, with primary attention given to consideration of nervous system effects, including neurocognitive and neurobehavioral effects, in children (73 FR 66975-76, November 12, 2008). The large body of scientific evidence available in the review included significant new evidence of effects at blood Pb concentrations substantially below those previously identified (73 FR 66987, November 12, 2008; 43 FR 46246, October 5, 1978). In its consideration of the robust evidence of neurotoxic effects of Pb exposure in children, the 2008 decision recognized: (1) that, while blood Pb levels in U.S. children had decreased notably since the late 1970s, newer epidemiological studies had investigated and reported associations of effects on the neurodevelopment of children with those more recent lower blood Pb levels, and (2) that the toxicological evidence included extensive experimental laboratory animal evidence substantiating well the plausibility of the epidemiological findings observed in human children and expanding our understanding of likely mechanisms underlying the neurotoxic effects (73 FR 66987, November 12, 2008). Additionally, within the range of blood Pb levels investigated for such effects - mean blood Pb levels below 10 μg/dL in variously aged children, extending from 8 down to 2 μg/dL (73 FR 66976, November 12, 2008) - a threshold level for neurocognitive effects was not identified (73 FR 66984, November 12, 2008; 2006 AQCD, p. 8–67). Further, the evidence indicated a steeper concentration-response (C–R) relationship for effects on cognitive function at those lower blood Pb levels than at higher blood Pb levels that were more common in the past, ‘‘indicating the potential for greater incremental impact associated with exposure at these lower levels’’ (73 FR 66987, November 12, 2008).

The Administrator’s judgment in 2008 was based primarily on consideration of the health effects evidence, supported by the quantitative risk analyses, with a focus on the public health implications of effects of air-related Pb on cognitive function (e.g., IQ). In the review concluded

in 2016, the Agency considered the available evidence and exposure/risk information, including that newly available since the 2008 decision, and reaffirmed the judgments associated with establishment of the different elements of the standard, and the Administrator concluded that the existing standard, set in 2008, continued to provide the requisite public health protection with an adequate margin of safety (81 FR 71906, October 18, 2016). Key aspects of the health effects evidence and exposure risk information available in the 2016 review, as well as the associated judgments reflecting consideration of associated limitations and uncertainties, are summarized below for each of the four basic elements of the NAAQS (indicator, averaging time, form, and level) in turn.

The indicator of the current standard is Pb-TSP. Although Pb monitoring methods based on a specific size fraction such as PM_{10} have been considered (both in setting the standard in 2008 and in the last review), the EPA retained Pb-TSP as the indicator based on several factors. First, the difference in particulate Pb captured by the TSP and PM_{10} monitors may be a factor of two in some areas, and all particle sizes contribute to Pb in blood and associated health effects. Further, ultra-coarse particles (those larger than those captured by PM_{10}) may have a greater presence in areas where Pb concentrations are highest contributing to uncertainty with regard to whether a Pb-PM_{10}-based standard would also effectively control ultra-coarse Pb particle size (81 FR 71906, October 18, 2016; 73 FR 66991, November 12, 2008). Accordingly, the Pb-TSP was retained as the indicator in order to provide sufficient public health protection from the broad range of particle sizes of ambient air Pb, including ultra-coarse particles (73 FR 66991, November 12, 2008; 81 FR 71906, October 18, 2016).[16]

The current averaging time and form is a rolling 3-month average, with a maximum (not-to-be-exceeded) form, evaluated over a 3-year period (73 FR 66996, November 12, 2008). This averaging time (established in 2008) gives equal weight to all 3-month periods and includes a method for deriving the 3-month average that provides equal weighting to each month.[17] The 2008 decision recognized the complexity inherent in this aspect of the standard which is greater for Pb than in the case of other criteria pollutants due to the multimedia nature of Pb and its multiple pathways of human exposure. In this situation for Pb, the Administrator emphasized the

[16] However, in order to take advantage of the increased precision of Pb-PM_{10} measurements and decreased spatial variation of Pb-PM_{10} concentrations without raising the same concerns over a lack of protection against health risks from all particulate Pb emitted to the ambient air that support retention of Pb-TSP as the indicator (*versus* revision to Pb-PM_{10}), a role is provided for Pb-PM_{10} measurements in the monitoring required fora Pb-TSP standard at sites not influenced by sources of ultra-coarse Pb, and where Pb concentrations are well below the standard (73 FR 66991, November 12, 2008).

[17] Both of these changes to the averaging time from the prior (1978) standard afford greater weight to each individual month than did the calendar quarter form of the 1978 standard, thus tending to control both the likelihood that any month will exceed the level of the standard and the magnitude of any such exceedance.

importance of considering in an integrated manner all of the relevant factors, both those pertaining to the human physiological response to changes in Pb exposures and those pertaining to the response of air-related Pb exposure pathways to changes in airborne Pb, recognizing that some factors might imply support for a period as short as a month for averaging time, and others supporting use of a longer time, with all having associated uncertainty. Thus, the current averaging time is based on such an integrated consideration of the range of relevant factors. This was retained without revision in the 2016 decision (81 FR 71906, October 18, 2016).

The level of the current standard is primarily based on consideration of the evidence using a very specifically defined framework referred to as an air-related IQ loss evidence-based framework (73 FR 67004, November 12, 2008). In the 2008 review, the Administrator's decision on a standard he judged requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety, relied on this framework in combination with the specified choice of indicator, averaging time, and form. This framework integrates evidence for the relationship between Pb in air and Pb in young children's blood with evidence for the relationship between Pb in young children's blood and IQ loss (73 FR 66987, November 12, 2008). The 2008 decision on level was based on consideration of the available health effects evidence in the context of this framework, and with support from the exposure/risk information,[18] recognizing the uncertainties attendant in both, as well as the increasing uncertainty of risk estimates for lower air Pb concentrations.

In the review completed in 2016, the EPA adopted an approach to considering the primary standard that built upon the general approach used in the 2008 Pb review and reflected the broader body of evidence and information that was available. In this context, the Administrator concluded that the evidence-based framework used in 2008 to inform selection of the standard level remained an appropriate tool for considering and integrating the evidence and informing her decision on the adequacy of the primary standard. She additionally took note of the ISA and PA findings that the evidence base, while somewhat expanded since the prior review, was not appreciably expanded or supportive of appreciably different conclusions with regard to air-to-blood ratios or C-R functions for neurocognitive decrements in young children. Thus, based on consideration of the available health effects evidence in the context of this

[18] A detailed exposure and risk assessment was performed in the 2008 review and augmented in the 2016 review. The assessment estimated blood Pb levels and associated IQ decrements in young children in the context of several case studies. Limitations in the assessment design, data and modeling tools contributed uncertainty to the results (80 FR 303, January 5, 2015). In the 2016 review, the EPA concluded that the "resultant, approximate, air-related risk bounds, however, encompass estimates drawn from the air-related IQ loss evidence-based framework, providing a rough consistency and general support, as was the case in the last review (73 FR 67004, November 12, 2008)" (81 FR 71925, October 18, 2016). To inform consideration of quantitative human exposure and health risk analyses in the current review, this prior assessment will be summarized in Volume 3 of the IRP.

framework, and support from the exposure/risk information, recognizing the uncertainties attendant in both, as well as the increasing uncertainty of risk estimates for lower air Pb concentrations, the Administrator concluded that the existing standard provided the requisite protection of public health with an adequate margin of safety, including protection of at-risk populations, and that the standard should be retained. (73 FR 66964, November 12, 2008; 81 FR 71906, October 18, 2016). Key considerations related to the evidence-based framework, including the context for its application and interpretation of the associated estimates, are summarized below.

The evidence-based approach applied in the last two reviews considers air-related effects on neurocognitive function (using the quantitative metric of IQ loss) associated with exposure in those areas with elevated air concentrations equal to potential alternative levels for the Pb standard. In simplest terms, the framework focuses on children exposed to air-related Pb in those areas with elevated air Pb concentrations equal to specific potential standard levels, providing for estimation of a mean air-related IQ decrement for young children with air-related exposures that are in the high end of the national distribution of such exposures. Thus, the conceptual context for the framework is that it provides estimates of air-related IQ loss for the subset of U.S. children living in close proximity to air Pb sources that contribute to such elevated air Pb concentrations. Consideration of this framework additionally recognizes that in such cases when a standard of a particular level is just met at a monitor sited to record the highest source-oriented concentration in an area, the large majority of children in the larger surrounding area would likely experience exposures to concentrations well below that level (73 FR 66964, November 12, 2008; 81 FR 71906, October 18, 2016).

The two primary inputs to the air-related IQ loss evidence-based framework are air-to-blood ratios[19] and C–R functions for the relationship between blood Pb concentration and IQ response in young children (73 FR 67004, November 12, 2008; 81 FR 71933-71935, October 18, 2016). In applying and drawing conclusions from the framework – both in 2008 and in 2016- the Administrator additionally took into consideration the uncertainties inherent in these two inputs. Application of the framework also entailed consideration of an appropriate level of protection from air-related IQ loss to be used in conjunction with the framework. The framework estimates of mean air-related IQ loss are derived through multiplication of the following factors: standard level ($\mu g/m^3$), air-to-blood ratio (in terms of μg/dL blood Pb per $\mu g/m^3$ air concentration), and slope for the C–R function in terms of points of IQ decrement per μg/dL blood Pb. In light of the

[19] The term ‘‘air-to-blood ratio’’ describes the increase in blood Pb (in μg/dL) estimated to be associated with each unit increase of air Pb (in $\mu g/m^3$). Ratios are presented in the form of 1:x, with the 1 representing air Pb (in $\mu g/m^3$) and x representing blood Pb (in μg/dL). Description of ratios as higher or lower refers to the values for x (i.e., the change in blood Pb per unit of air Pb).

uncertainties and limitations associated with the evidence on these relationships, and other considerations, application of the air-related IQ loss evidence-based framework was recognized to provide ‘‘no evidence- or risk-based bright line that indicates a single appropriate level’’ for the standard (73 FR 67005–67006, November 12, 2008). Rather, the framework was seen as a useful guide, in the context of the specified averaging time and form, for consideration of health risk estimates for exposure to levels of Pb in the ambient air to inform the Administrator's decision on a level for a revised NAAQS that provides public health protection that is sufficient but not more than necessary under the Act (73 FR 67004, November 12, 2008).

Use of the air-related IQ loss evidence-based framework involved consideration of the evidence for the two primary input parameters mentioned above. With regard to air-to-blood ratio estimates, the evidence, both in the 2008 and 2016 reviews, indicated a broad range of estimates, each with limitations and associated uncertainties. Based on this evidence, 1:5 to 1:10 was concluded to represent a reasonable range to consider, and focus has been on 1:7 as a generally central value (81 FR 71906, October 18, 2016; 73 FR 67004, November 12, 2008). With regard to C–R functions, in light of the evidence of nonlinearity and of steeper slopes at lower blood Pb levels, focus was on C–R analyses of children with blood Pb levels that most closely reflect the population of young children in the U.S.[20] In this context, the EPA identified four such analyses and gave weight to the central estimate or median of the resultant linear C–R functions (73 FR 67003, November 12, 2008, Table 3; 73 FR 67004, November 12, 2008). The median estimate for the four C–R slopes of -1.75 IQ points decrement per μg/dL blood Pb was selected for use with the framework.

In using the framework, potential alternative standard levels (μg/m^3) are multiplied by estimates of air-to-blood ratio (μg/dL blood Pb per μg/m^3 air Pb) and the median slope for the C–R function (points IQ decrement per μg/dL blood Pb), yielding estimates of a mean air-related IQ decrement for a specific subset of young children (i.e., those children exposed to air-related Pb in areas with elevated air Pb concentrations equal to specified alternative levels). As such, the application of the framework is focused on the subset of children expected to experience air-related Pb exposures at the high end of the distribution of such exposures. The associated mean IQ loss estimate is an estimate, with associated uncertainties and limitations, of the average for

[20] The geometric mean blood Pb level for U.S. children aged 5 years and below, reported for NHANES in 2003–04 (the most recent years for which such an estimate was available at the time of the 2008 decision) was 1.8 μg/dL and the 5th and 95th percentiles were 0.7 μg/dL and 5.1 μg/dL, respectively (73 FR 67002). Using the air-to-blood ratio 1:7, the estimated air-related blood Pb level associated with the final standard level is approximately 1 μg/dL. In the 2008 decision, the EPA noted that even if it assumed, as an extreme hypothetical example, that the mean for the general population of U.S. children included zero contribution from air-related sources and added that to the estimate of air-related Pb, the result would still be below the lowest mean blood Pb level among the set of C–R analyses (73 FR 67002). Blood Pb levels in U.S. children aged 5 years and below, at the time of the 2016 review were lower still, with a geometric mean level of 1.17 μg/dL (81 FR 71909, October 18, 2016).

this highly exposed subset and is not an estimate of the average air-related IQ loss projected for the entire U.S. population of children. The EPA, in its use of the framework to inform the Agency's decisions, has recognized uncertainties and limitations in the use of the framework and in the resultant estimates (73 FR 67000, November 12, 2008; 81 FR 71906; October 18, 2016).

In considering the use of the air-related IQ loss evidence-based framework to inform the Administrator's judgment as to the appropriate degree of public health protection that should be afforded by the NAAQS to provide requisite protection against risk of neurocognitive effects in sensitive populations, such as IQ loss in children, the Administrator, both in the 2008 and in 2016 reviews, recognized a lack of commonly accepted guidelines or criteria within the public health community that would provide a clear basis for such a judgment. During the 2008 review, CASAC commented regarding the significance from a public health perspective of a 1–2 point IQ loss in the entire population of children and, along with some public commenters, emphasized that the NAAQS should prevent air-related IQ loss of a significant magnitude, such as on the order of 1–2 IQ points, in all but a small percentile of the population. Similarly, the Administrator, both at that time and in the 2016 review, stated that ''ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur'' (81 FR 71933, October 18, 2016; 73 FR 66998, November 12, 2008). The decisions in both reviews further recognized that, in the case of setting a national ambient air quality standard, the Administrator was required to make a judgment as to what degree of protection is requisite to protect public health with an adequate margin of safety (73 FR 66998, November 12, 2008). This reflects the understanding that the NAAQS must be sufficient but not more stringent than necessary to achieve that result, and the Act does not require a zero-risk standard (73 FR 66998, November 12, 2008). Further, the Administrators, in both reviews, additionally recognized that their judgments on the degree of protection against IQ impacts that should be afforded by the primary standard was particularly focused on consideration of impacts in the at-risk population and was not addressing a specific quantitative public health policy goal for air-related decrements in IQ that would be acceptable or unacceptable for the entire population children of in the U.S. Rather, the at-risk population to which the Administrator was giving particular attention in making such a judgment was the small subset of U.S. children living in close proximity to air Pb sources that contribute to elevated air Pb concentrations that equal the level of the standard (81 FR 71934, October 18, 2016). As noted in the 2016 decision, "[a]ccordingly, [the Administrator] is considering IQ impacts in this small subset of U.S. children that is expected to experience air-related Pb exposures at the high end of the national distribution of such exposures … and not a projection of the average air-related IQ loss for the entire U.S. population of children" (81 FR 71934, October 18, 2016). The evidence-based

framework estimates with which there are associated uncertainties and limitations relate to this small subset of children exposed at the level of the standard (81 FR 71934, October 18, 2016).

In reaching a judgment as to the appropriate degree of protection, the Administrator, both in the 2008 and in 2016 reviews, considered advice and recommendations from CASAC and public comments and recognized the uncertainties in the health effects evidence and related information as well as the role of, and context for, a selected air-related IQ loss in the application of the framework, as described above. In the context of the use of the framework as a tool to inform the Administrator's decision on the adequacy of the primary standard (and its four elements), the EPA took note of the complexity associated with consideration of health effects caused by different ambient air concentrations of Pb and with uncertainties with regard to the relationships between air concentrations, exposures, and health effects. For example, selection of a maximum, not to be exceeded, form in conjunction with a rolling 3-month averaging time over a 3-year span was expected to have the effect that the at-risk population of children would be exposed below the standard most of the time (81 FR 71906, October 18, 2016; 73 FR 67005, November 12, 2008)[21]. The EPA additionally noted that "[i]n light of this and the uncertainty in the relationship between time period of ambient level, exposure, and occurrence of a health effect, the air related IQ loss considered for the current standard in applying the framework should not be interpreted to mean that a specific level of air-related IQ loss will occur in fact in areas where the standard is just met or that such a loss has been determined as acceptable if it were to occur" (81 FR 71934, October 18, 2016). Rather, it was recognized that "judgment regarding such an air-related IQ loss is one of the judgments that need to be made in using the evidence-based framework to provide useful guidance in the context of public health policy judgment on the degree of protection from risk to public health that is sufficient but not more than necessary, taking into consideration the patterns of air quality that would likely occur upon just meeting the standard and uncertainties in relating those patterns to exposures and effects" (81 FR 71934, October 18, 2016).

In the 2016 review, the Administrator additionally recognized the generally lower blood Pb levels of U.S. children as compared to 2008. In so doing, she "recognized the degree to which IQ loss estimates drawn from the air-related IQ loss evidence-based framework reflect mean

[21] The Administrator additionally considered the provision of an adequate margin of safety in making decisions on each of the elements of the standard, including, for example ''selection of TSP as the indicator and the rejection of the use of PM10 scaling factors; selection of a maximum, not to be exceeded form, in conjunction with a 3-month averaging time that employs a rolling average, with the requirement that each month in the 3-month period be weighted equally (rather than being averaged by individual data) and that a 3-year span be used for comparison to the standard; and the use of a range of inputs for the evidence-based framework, that includes a focus on higher air-to-blood ratios than the lowest ratio considered to be supportable, and steeper rather than shallower C–R functions, and the consideration of these inputs in selection of 0.15 $\mu g/m^3$ as the level of the standard'' (73 FR 67007, November 12, 2008).

blood Pb levels that are below those represented in the currently available evidence for young children," and while she viewed such an extension reasonable given the limitation of the evidence base and the need for the NAAQS to provide a margin of safety, she also recognized the "increasing uncertainty with regard to likelihood of response and magnitude of the estimates at levels extending below the current standard" (81 FR 71934, October 18, 2016). The Administrator's 2016 conclusion that the existing standard provides the requisite protection and that a more restrictive standard would not be requisite additionally further recognized that "the uncertainties and limitations associated with the many aspects of the estimated relationships between air Pb concentrations and blood Pb levels and associated health effects are amplified with consideration of increasingly lower air concentrations" and took note of the PA conclusion with which the CASAC agreed "that based on the current evidence, there is appreciable uncertainty associated with drawing conclusions regarding whether there would be reductions in blood Pb levels and risk to public health from alternative lower levels of the standard as compared to the level of the current standard" (81 FR 71934, October 18, 2016). The Administrator judged that this uncertainty was too great to provide a basis for revising the standard. Thus, the Administrator concluded, based on the evidence, the public health policy judgments summarized above, including weight given to uncertainties in the evidence, and advice from the CASAC, that the standards set in 2008 were requisite and should be retained, without revision (81 FR 71935, October 18, 2016).

3.4 THE SECONDARY STANDARD

The current secondary standard of 0.15 $\mu g/m^3$ of Pb in total suspended particles, as the average of three consecutive monthly averages, was established in 2008 and retained, without revision, in 2016 (73 FR 66964, November 12, 2008; 81 FR 71906, October 18, 2016). These decisions were based on the array of evidence then available about the effects of Pb in the environment and on the very limited evidence to relate specific ecosystem effects with ambient air concentrations of Pb related to a specific secondary standard through deposition to terrestrial and aquatic ecosystems and subsequent movement of deposited Pb through the environment (e.g., soil, sediment, water, organisms).

In establishing the standard in 2008, the EPA first decided that the then-existing standard (set in 1978) did not provide the requisite protection of public welfare from known or anticipated adverse effects. That decision was based on evidence- and exposure/risk-based considerations in the 2007 Staff Paper, drawn on the evidence in the 2006 AQCD and the 2006 REA, views of public commenters, and advice from the CASAC (73 FR 67010-67011, November 12, 2008). In identifying the appropriate revision of the standard in 2008, the Administrator then concluded, in concurrence with the CASAC, that the secondary standard should be set at least as low as the

level of the primary standard. Further, he observed that the Agency lacked the relevant data to provide a clear quantitative basis for setting a secondary standard that differs from the primary in indicator, averaging time, level, or form. Thus, taking into account the then-available evidence, exposure/risk information, public comments and advice from the CASAC, the Administrator revised the standard to be identical in all respects to the primary standard.

In the 2016 decision on review of the 2008 standard, the EPA found there to still be limitations and uncertainties affecting the availability of a clear quantitative basis to support specific or precise judgments regarding the protection of the public welfare provided by the current secondary standard (81 FR 71935-71940, October 18, 2016). For example, the potential for ecosystem effects of Pb from atmospheric sources under conditions meeting the existing standard was recognized to be difficult to assess due to limitations on the availability of information to fully characterize the distribution of Pb from the atmosphere into ecosystems over the long term, as well as limitations on information on the bioavailability of atmospherically deposited Pb (as affected by the specific characteristics of the receiving ecosystem). As stated in the 2013 ISA "the connection between air concentration and ecosystem exposure and associated potential for welfare effects continues to be poorly characterized for Pb" (2013 ISA, section 6.4), and the EPA concluded such a connection to be even harder to characterize with respect to the existing standard than it was in 2008 with respect to the previous, much higher standard. While the 2013 ISA recognized the appreciable influence of site-specific environmental characteristics on the bioavailability and toxicity of environmental Pb, there was a lack of studies conducted under conditions closely reflecting the natural environment such that there continued to be significant difficulties in relating effects evidence from laboratory studies to the natural environment and linking those effects to ambient air Pb concentrations. Thus, while new research added to the understanding of Pb biogeochemistry and expanded the list of organisms for which Pb effects have been described, there remained a significant lack of knowledge about the potential for adverse effects on public welfare from ambient air Pb in the environment and the exposures that occur from such air-derived Pb, particularly under conditions meeting the existing standard (2014 PA, section 6.2.1; 81 FR 71935-71940, October 18, 2016).

With respect to the exposure/risk-based information available in the 2016 review, while the previous assessment was consistent with and generally supportive of the evidence-based conclusions about Pb in the environment, the limitations on the ability to apportion Pb between past and present air contributions and between air and non-air sources remained significant. Thus, the risk and exposure information available in the 2016 review, when considered with regard to air-related ecosystem exposures likely to occur with air Pb levels that just meet the now-current standard, was concluded to not provide evidence of adverse effects under the current standard (81 FR 71937-39, October 18, 2016).

In summary, the existing secondary standard for Pb was set in 2008 to be identical to the primary standard based on a conclusion that the prior standard was not requisite and a lack of information to support an alternative standard. Such limitations and uncertainties remained in the evidence available in the subsequent 2016 review, and the Administrator, with concurrence from the CASAC, judged that the information available did not call into question the adequacy of the standard to provide the requisite protection for public welfare. Accordingly, the Administrator concluded the existing standard to be requisite, and it was retained, without revision (81 FR 71939-71940, October 18, 2016).

4 THE CURRENT LEAD NAAQS REVIEW: MILESTONES AND TIMELINE

In July 2020, EPA 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* (85 FR 40641 July 7, 2020). The current review of the Pb standards builds on the substantial body of work done during the course of prior reviews, represented both in comprehensive science assessments (e.g., 2006 AQCD; U.S, EPA, 2013) and past quantitative exposure and risk analyses.[22] These different types of information, evaluated in past policy assessments, provided the basis for decisions on the existing Pb NAAQS.

The timeline projected for the current review is presented in Table 4-1. Concurrent with the release of this background document (Volume 1 of the IRP), the EPA is releasing the planning document for the review and the ISA, as Volume 2 of the IRP (U.S. EPA, 2022). Volume 2 identifies policy-relevant science issues important to guiding the evaluation of the air quality criteria for Pb and the reviews of the primary and secondary Pb NAAQS. It will be subject of a consultation with CASAC. Based on consideration of input received during this consultation, EPA will develop a draft ISA for external review.

With consideration of the newly available evidence identified in the draft ISA, the EPA will develop the planning document for quantitative analyses, including exposure/risk analyses, that might be warranted to inform decisions in the current review. This planning document for quantitative analyses will comprise the third volume of the IRP. With consideration of the CASAC review of the draft ISA and consultation discussion on Volume 3 of the IRP, the EPA will develop a draft of the PA (with associated policy evaluations and quantitative analyses) for public and CASAC review. Completion of the final ISA and PA are projected in late 2023 and mid 2024, respectively. These will be followed by proposed and final decisions for the review in early 2025 and early 2026, respectively .

[22] For example, in the 2008 review, EPA staff designed and conducted a complex multimedia, multipathway health risk assessment involving case studies represented different ambient air Pb exposure circumstances, and an assessment of the available information on ecological impacts of Pb, including the consideration of potentially vulnerable ecosystems.

Table 4-1. Schedule for the review of ambient air quality criteria and NAAQS for Pb.

Stage of Review	Major Milestone	Target Dates
Planning	Federal Register Call for Information	July 7, 2020
	Integrated Review Plan (IRP), volumes 1 and 2	March 2022
	CASAC consultation on IRP, volume 2	April 2022
	IRP, volume 3	Early 2023
	CASAC consultation on IRP, volume 3	Early 2023
Science Assessment	External review draft of ISA	Early 2023
	CASAC public meeting for review of draft ISA	Early 2023
	Final ISA	Late 2023
Quantitative Exposure/Risk Analyses and Policy Assessment	External draft of PA (including quantitative air quality, exposure and/or risk analyses, as warranted)	Fall 2023
	CASAC public meeting for review of draft PA	Late 2023
	Final PA	Spring 2024
Regulatory Process	Notice of proposed decision	Early 2025
	Notice of final decision	Early 2026

5 REFERENCES

Frey, H.C. (2011). Letter from Dr. H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee Lead Review Panel, to Administrator Lisa P. Jackson. Re: Consultation on EPA's Review of the National Ambient Air Quality Standards for Lead: Risk and Exposure Assessment Planning Document. October 14, 2011.

Frey, H.C. and Samet, J.M. (2011). Letter from Drs. H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee Lead Review Panel, and Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee, to Administrator Lisa P. Jackson. Re: CASAC Review of the EPA's Integrated Science Assessment for Lead (First External Review Draft—May 2011). December 9, 2011.

Frey, H.C. (2013a). Letter from Dr. H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee and Clean Air Scientific Advisory Committee Lead Review Panel, to Acting Administrator Bob Perciasepe. Re: CASAC Review of the EPA's Integrated Science Assessment for Lead (Third External Review Draft— November 2012). June 4, 2013.

Frey, H.C. (2013b). Letter from Dr. H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee and Clean Air Scientific Advisory Committee Lead Review Panel, to Acting Administrator Bob Perciasepe. Re: CASAC Review of the EPA's Policy Assessment for Lead (External Review Draft—January 2013). June 4, 2013.

ICF International. (2006) Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas. Pilot Phase. Draft Technical Report. Prepared for the U.S. EPA's Office of Air Quality Planning and Standards, Research Triangle Park, NC. December.

Samet, J.M. and Frey, H.C. (2012) Letter from Drs. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee and H. Christopher Frey, Chair, Clean Air Scientific Advisory Committee Lead Review Panel, to Administrator Lisa P. Jackson. Re: CASAC Review of the EPA's Integrated Science Assessment for Lead (Second External Review Draft – February 2012). July 20, 2012.

U.S. EPA. (1977) Air Quality Criteria for Lead. U.S. EPA, Office of Research and Development, Washington, DC. EPA-600/8-77-017. Available at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=45706.

U.S. EPA. (1986a) Air Quality Criteria for Lead. Volumes 1-IV. U.S. EPA, Washington, DC. EPA-600/8-83/028aF-dF. Available at: https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=NCEA&dirEntryID=32647.

U.S. EPA. (1986b) Lead Effects on Cardiovascular Function, Early Development, and Stature: An Addendum to U.S. EPA Air Quality Criteria for Lead (1986). In: Air Quality Criteria for Lead, V. 1. pp. A1-A67. U.S. EPA, Washington, DC. EPA-600/8-83/028aF. Available at: https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=94002C16.TXT.

U.S. EPA. (1989) Review of the National Ambient Air Quality Standards for Lead: Exposure Analysis Methodology and Validation: OAQPS Staff Report. Office of Air Quality Planning and Standards. Research Triangle Park, NC. EPA-450/289/011. Available at: https://www.epa.gov/sites/production/files/2020-07/documents/rnaaqsl_eamv1.pdf.

U.S. EPA. (1990a) Air Quality Criteria for Lead: Supplement to the 1986 Addendum. U.S. EPA, Washington, DC. EPA/600/8-89/049F. Available at: https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=45189.

U.S. EPA. (1990b) Review of the National Ambient Air Quality Standards for Lead: Assessment of Scientific and Technical Information: OAQPS Staff Paper. Office of Air Quality Planning and Standards. Research Triangle Park, NC. EPA450/2-89/022. Available at: https://www.epa.gov/sites/production/files/2020-07/documents/rnaaqsl_asti1.pdf.

U.S. EPA. (1991) U.S. EPA Strategy for Reducing Lead Exposure. Available at: https://www.epa.gov/sites/production/files/2020-07/documents/lead_strategy_1991.pdf.

U.S. EPA. (2005) Project Work Plan for Revised Air Quality Criteria for Lead. CASAC Review Draft. National Center for Environmental Assessment, Research Triangle Park, NC. NCEA-R-1465. Available at: https://www.regulations.gov/document/EPA-HQ-ORD-2004-0018-0014

U.S. EPA. (2006a) Plan for Review of the National Ambient Air Quality Standards for Lead. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available at: https://www.regulations.gov/document/EPA-HQ-OAR-2006-0735-5235

U.S. EPA. (2006b) Air Quality Criteria for Lead. U.S. EPA, Washington, DC. EPA/600/R-5/144aF-bF. Available at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=158823

U.S. EPA. (2006c) Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available at: https://www.regulations.gov/document/EPA-HQ-OAR-2006-0735-5510

U.S. EPA. (2007a) Lead: Human Exposure and Health Risk Assessments for Selected Case Studies, Volume I. Human Exposure and Health Risk Assessments – Full-Scale and Volume II. Appendices. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA-452/R-07-014a and EPA-452/R-07-014b. Available at: https://www.regulations.gov/document/EPA-HQ-OAR-2006-0735-5233 and https://www.regulations.gov/document/EPA-HQ-OAR-2006-0735-5234.

U.S. EPA. (2007b) Review of the National Ambient Air Quality Standards for Lead: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA-452/R-07-013. Available at: https://www.epa.gov/sites/production/files/2020-07/documents/20071101_pb_staff1.pdf

U.S. EPA. (2009a) Integrated Science Assessment for Particulate Matter (Final Report). U.S. EPA, Washington, DC. EPA/600/R-08/139F. Available at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=216546

U.S. EPA. (2011a). Integrated Review Plan for the National Ambient Air Quality Standards for Lead. Research Triangle, NC. EPA–452/ R–11–008. Available online at: https://www.epa.gov/sites/production/files/2020-07/documents/20111117pbirpfinal.pdf

U.S. EPA. (2011b) Review of the National Ambient Air Quality Standards for Lead: Risk and Exposure Assessment Planning Document. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA/452/P-11-003. Available at: https://www.epa.gov/sites/production/files/2020-07/documents/20110628pbplanningdoc.pdf

U.S. EPA. (2013) Integrated Science Assessment for Lead. Washington, DC, EPA/600/R-10/075F. Available online at: https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=255721

U.S. EPA. (2014). Policy Assessment for the National Ambient Air Quality Standards for Lead. Research Triangle Park, NC. EPA–452/R–14–001. Available at: https://www.epa.gov/sites/production/files/2020-07/documents/140501_pa_pb_fin.pdf

U.S. EPA. (2022). Integrated Review Plan for the National Ambient Air Quality Standards for Lead: Volume 2. Planning for the Review and the Integrated Science Assessment. Research Triangle, NC. EPA–452/R-22-003b. Available online at: https://www.epa.gov/naaqs/lead-pb-air-quality-standards

Appendices

APPENDIX A ISA DEVELOPMENT PROCESS

A.1. INTRODUCTION

In developing ISAs, the EPA employs systematic review methodologies to identify, critically evaluate, and synthesize relevant scientific information and produces summary text and figures to communicate the state of the science to varied audiences. The major steps in the ISA development process are generally presented in Figure A-1 and are described in greater detail in the Preamble to the ISAs (U.S. EPA, 2015a). The development of an ISA builds upon knowledge and experience gained from prior ISAs and is refined with each subsequent review of the science for each of the criteria air pollutants.

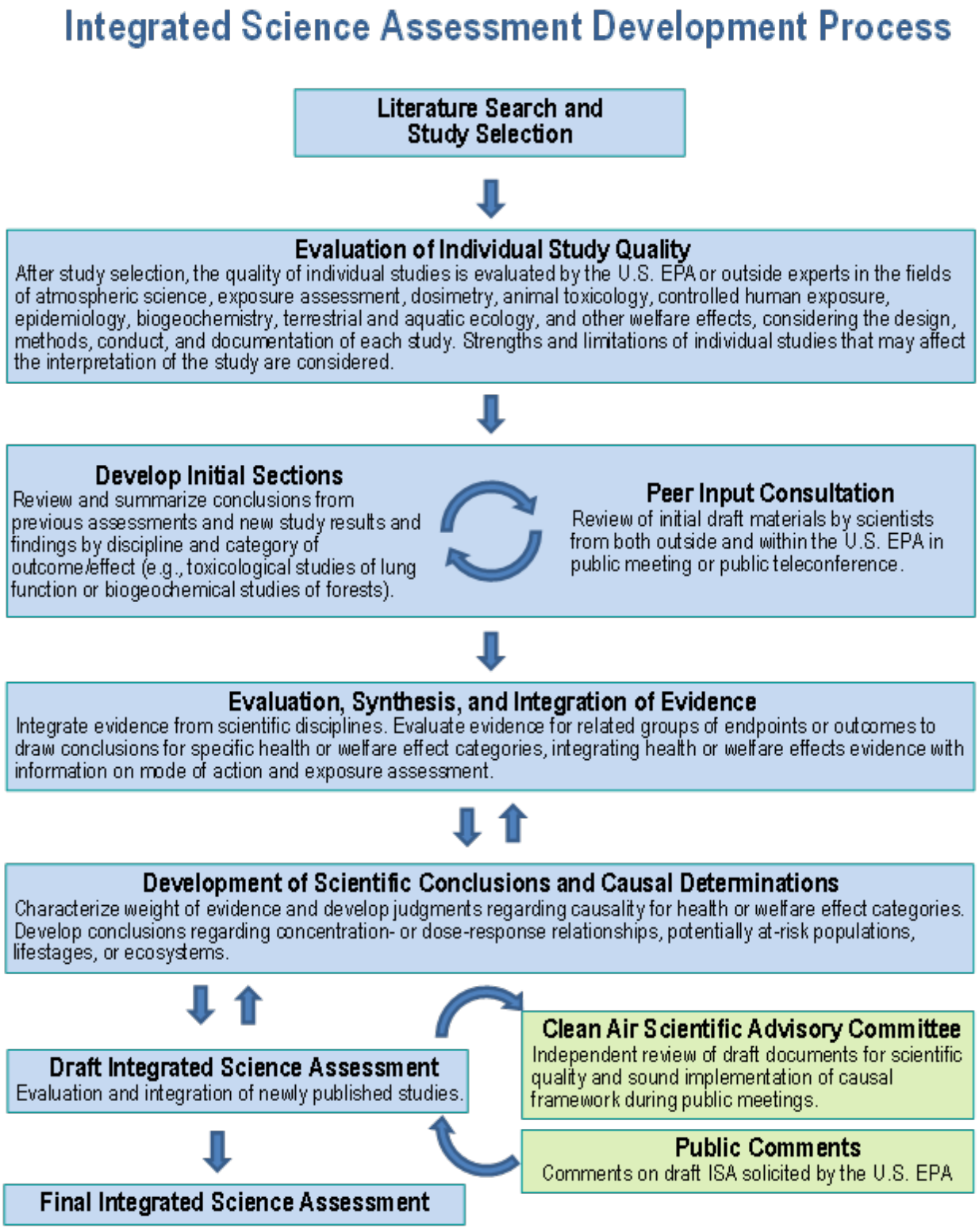

Figure A-1. General steps of the ISA development process from the initial literature search to final assessment (blue boxes), and including the CASAC and public review steps for the draft ISA (green boxes).

The ISA process begins with a "Call for Information" published in the *Federal Register* that announces the start of a NAAQS review and invites the public to assist in this process through the submission of research studies in identified subject areas. For the current Pb NAAQS review, this notice was published on July 7, 2020 (85 FR 40641). This appendix provides an overview of the process steps that follow the Call for Information, including literature search steps and identification of relevant studies (Section A.2), evaluation of individual study quality (Section A.3), evidence integration and determination of causality (A.4), quality management (A.5), and scientific and public review (A.6).

A.2. LITERATURE SEARCH AND IDENTIFICATION OF RELEVANT STUDIES

A.2.1. Systematic Literature Search

The EPA uses a structured approach to identify relevant studies for consideration and inclusion in the ISAs. The search for relevant literature in this review of the criteria and standards for Pb began with publication of the Call for Information in the *Federal Register* announcing the initiation of this Pb review and requesting information from the public including relevant literature (85 FR 40641 July 7, 2020). In addition, the EPA identifies publications by conducting a multi-tiered systematic literature search that includes extensive mining of literature databases on specific topics in a variety of disciplines. The search strategies are designed *a priori* to optimize identification of pertinent published papers. Studies identified in the literature search will be documented in the Health and Environmental Research Online (HERO) database (http://hero.epa.gov). For this ISA, discipline-specific approaches are used to identify literature. In each case, careful consideration is given to literature search strategies used in the development of previous assessments and the methods that resulted in the best precision and recall for each of the disciplines, including atmospheric science, exposure assessment, experimental health studies, epidemiology, and ecology. As has been done for past ISAs, a series of discipline-specific keyword searches (i.e. Pb sources, atmospheric science, water and soil research, exposure assessment, toxicokinetics, experimental health studies, epidemiology, Pb effects in terrestrial ecosystems, Pb effects in aquatic ecosystems) was developed as a starting point to capture literature pertinent to the pollutant of interest in citation databases (i.e., PubMed, Web of Science). Following the broad keyword search, automatic topic classification is applied, where relevant, to categorize references by discipline (e.g., epidemiology and toxicology). This step employs machine learning where positive and negative seed references for a particular discipline are used to train an algorithm to identify discipline-specific references based on word use and frequency in titles and abstracts. This method varies in effectiveness across disciplines due to the

broad range of topics and variability in term usage in some evidence bases. However, it is invaluable when effective and has been used in several prior ISAs.

Another approach used in past ISAs that is employed in this review is citation mapping, or relational reference searching. In this approach, a set of relevant published references are identified as a seed set and then more recent literature that has cited any of the references in the seed set are collected. References from the previous ISA for each broad topic area comprise the seed set for the new ISA. Because the seed set is highly relevant to the topic of interest, this targeted approach to reference identification is more precise than keyword searches, and it further allows for relevance ranking based on the number of references in a bibliography that match references in the seed set. References may be identified for inclusion in several additional ways including the following: identification of relevant literature by expert scientists within the US EPA Center for Public Health and Environmental Assessment (CPHEA); recommendations received in response to the call for information and the external review process for the ISA; and review of citations included in previous assessments. All these search methods will be used to identify recent research published or accepted for publication starting in 2011, providing some overlap with the September 2011 cutoff date from the last review. Additional studies may also be considered in subsequent phases of the NAAQS review (e.g., studies identified by CASAC members during review of the draft ISA). Such a consideration will include the extent to which they provide new information that impacts key scientific conclusions.

A.2.2. Initial (Level 1) and Full Text (Level 2) Screening of Studies from Literature Search

Once studies are identified, ISA authors (EPA staff and extramural scientists) review the studies for relevance. With regard to human exposure and health related topic areas, relevant studies include epidemiologic and toxicological studies, including studies of dosimetry and mode of action, or those that examine human exposure to Pb through various pathways, atmospheric chemistry, sources, and emissions. For ecological exposure and effects, relevant studies are those that examine ecological effects of Pb in terrestrial and aquatic ecosystems. As described above, the literature search methods are targeted for discipline-relevant references to the extent possible, and the subsequent screening results in a further refined list of references to be included in the ISA. References for each discipline first undergo title and abstract screening using SWIFT-ActiveScreener (SWIFT-AS), which is referred to as Level 1 screening. Level 1 screening criteria for inclusion will be broad and err on the side of inclusion. For each health discipline (i.e., epidemiology and toxicology), title and abstracts are selected for further screening if there is indication that the reference meets the criteria developed by CPHEA subject matter experts. For other disciplines, title and abstracts are selected for further screening if there is a measure of Pb and a quantifiable effect relevant to that discipline or if a study potentially addresses

uncertainties identified in the last review. SWIFT-AS is a software application that employs machine learning in real-time to identify relevant literature. The machine learning feature builds a model to predict relevant references based on inclusion/exclusion screening decisions in real-time as scientists screen each reference. As title/abstract screening is conducted, references are queued based on the predicted relevance, and SWIFT-AS further predicts when a 95% recall threshold has been reached, a level often used to evaluate the performance of machine learning applications and considered comparable to human error rates (Cohen et al. 2006, Howard et al. 2016). The application of SWIFT-AS is tailored for each discipline. This includes using a specific seed set of relevant references from the 2013 ISA to train the SWIFT-AS algorithm and developing specific screening questions for each discipline to allow for the categorization of references based on the information available in the title and abstract. An understanding of the volume and topics of the recent literature on Pb is important to consider in refining the scope of the ISA.

Following Level 1 screening, references identified for inclusion are acquired and compiled in HERO for full-text Level 2 screening conducted by CPHEA subject matter experts. References are tracked for both relevance to the broad ISA and for the defined scope for each topic area (e.g., outcome category).

A.2.3. Criteria of In-Scope Studies

To be included in the ISA, relevant studies and reports must have undergone scientific peer review and have been published or accepted for publication before the cutoff date. Some publications retrieved from the literature search are excluded as not being relevant in Level 1 screening based on the title/abstract or the type of publication (e.g., conference abstract, review articles, commentaries). For other publications, decisions about relevance are made in Level 2 screening as they require reading beyond the title/abstract. These publications are labeled as "considered" for inclusion in the ISA. Inclusion and exclusion decisions are documented in the HERO database (http://hero.epa.gov).

A.3. EVALUATION OF INDIVIDUAL STUDY QUALITY

After selecting studies for inclusion, individual study quality is evaluated by considering the design, methods, conduct, and documentation of each study, but not the study results. Conclusions about the strength of inference from study results are made by independently evaluating the overall quality of each study (U.S. EPA, 2015a). This uniform approach aims to consider the strengths, limitations, and possible roles of chance, confounding, and other biases

that may affect the interpretation of individual studies and the strength of inference from the results of the study.

In general, in assessing the scientific quality of studies on health and welfare effects, the following questions are considered.

- Were the study design, study groups, methods, data, and results clearly presented in relation to the study objectives to allow for study evaluation? Were limitations and any underlying assumptions of the design and other aspects of the study stated?
- Were the ecosystems, study site(s), study populations, subjects, or organism models adequately selected, and are they sufficiently well-defined to allow for meaningful comparisons between study or exposure groups?
- Are the air quality, exposure, or dose metrics of adequate quality, and are they sufficiently representative of or pertinent to ambient air?
- Are the health or welfare effect measurements meaningful, valid, and reliable?
- Were likely covariates or modifying factors adequately controlled or taken into account in the study design and statistical analysis?
- Do the analytical methods provide adequate sensitivity and precision to support conclusions?
- Were the statistical analyses appropriate, properly performed, and properly interpreted?

Additional aspects that are considered in evaluating individual study quality specific to particular scientific disciplines are discussed in detail in the Preamble to the ISAs (U.S. EPA, 2015a).

A.4. INTEGRATION OF EVIDENCE AND DETERMINATION OF CAUSALITY

As described in the Preamble to the ISAs (U.S. EPA, 2015a), the EPA uses a structured framework to provide a consistent and transparent basis for classifying the weight of available evidence for health and welfare effects according to a five-level hierarchy: (1) causal relationship; (2) likely to be a causal relationship; (3) suggestive of, but not sufficient to infer, a causal relationship; (4) inadequate to infer a causal relationship; and (5) not likely to be a causal relationship (Table A-1).

Table A-1. Weight of evidence for causality determinations (Source: U.S. EPA, 2015a)**.**

	Health Effects	Welfare Effects
Causal relationship	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures (e.g., doses or exposures generally within one to two orders of magnitude of recent concentrations). That is, the pollutant has been shown to result in health effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. For example: (1) controlled human exposure studies that demonstrate consistent effects, or (2) observational studies that cannot be explained by plausible alternatives or that are supported by other lines of evidence (e.g., animal studies or mode of action information). Generally, the determination is based on multiple high-quality studies conducted by multiple research groups.	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures. That is, the pollutant has been shown to result in effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. Controlled exposure studies (laboratory or small- to medium-scale field studies) provide the strongest evidence for causality, but the scope of inference may be limited. Generally, the determination is based on multiple studies conducted by multiple research groups, and evidence that is considered sufficient to infer a causal relationship is usually obtained from the joint consideration of many lines of evidence that reinforce each other.
Likely to be a causal relationship	Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall. For example: (1) observational studies show an association, but copollutant exposures are difficult to address and/or other lines of evidence (controlled human exposure, animal, or mode of action information) are limited or inconsistent, or (2) animal toxicological evidence from multiple studies from different laboratories demonstrate effects, but limited or no human data are available. Generally, the determination is based on multiple high-quality studies.	Evidence is sufficient to conclude that there is a likely causal association with relevant pollutant exposures. That is, an association has been observed between the pollutant and the outcome in studies in which chance, confounding, and other biases are minimized but uncertainties remain. For example, field studies show a relationship, but suspected interacting factors cannot be controlled, and other lines of evidence are limited or inconsistent. Generally, the determination is based on multiple studies by multiple research groups.
Suggestive of, but not sufficient to infer, a causal relationship	Evidence is suggestive of a causal relationship with relevant pollutant exposures but is limited, and chance, confounding, and other biases cannot be ruled out. For example: (1) when the body of evidence is relatively small, at least one high-quality epidemiologic study shows an association with a given health outcome and/or at least one high-quality toxicological study shows effects relevant to humans in animal species, or (2) when the body of evidence is relatively large, evidence from studies of varying quality is generally supportive but not entirely consistent, and there may be coherence across lines of evidence (e.g., animal studies or mode of action information) to support the determination.	Evidence is suggestive of a causal relationship with relevant pollutant exposures, but chance, confounding, and other biases cannot be ruled out. For example, at least one high-quality study shows an effect, but the results of other studies are inconsistent.
Inadequate to infer a causal relationship	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quantity, quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.
Not likely to be a causal relationship	Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies, covering the full range of levels of exposure that human beings are known to encounter and considering at-risk populations and lifestages, are mutually consistent in not showing an effect at any level of exposure.	Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies examining relationships with relevant exposures are consistent in failing to show an effect at any level of exposure.

Determination of causality involves evaluating and integrating evidence for different types of health or welfare effects associated with short- and long-term exposure periods. Key considerations in drawing conclusions about causality include consistency of findings for an endpoint across studies, coherence of the evidence across disciplines and across related endpoints, and biological plausibility. As judged by these parameters, studies in which chance, confounding, and other biases could be ruled out with reasonable confidence are sufficient to infer a causal relationship. Increasing uncertainty due to limited available information, inconsistency across the body of evidence, and/or limited coherence and biological plausibility may lead to conclusions lower in the causality hierarchy. Causality determinations are based on the confidence in the integrated body of evidence, considering study design and quality and strengths and weaknesses in the overall collection of previous and recent studies across disciplines. In discussing each determination of causality, the EPA characterizes the evidence upon which the judgment is based, including the extent of and weight of evidence for individual endpoints within the health or welfare effect category or group of related endpoints.

For evaluation of human health effects, determinations of causality are made for major health effect categories and for the range of doses (e.g., blood Pb concentration) that are defined to be relevant to ambient concentrations. The main lines of evidence for use in causality determinations for human health are epidemiologic and animal toxicological studies. Evidence is integrated from previous and recent studies. Other information including mechanistic evidence, toxicokinetics, and exposure assessment may be drawn upon if relevant to the evaluation of health effects and if of sufficient importance to affect the overall evaluation. The relative importance of different sources of evidence to the conclusions varies by pollutant or assessment, as does the availability of different sources of evidence when making a causality determination. In forming judgments of causality, CPHEA scientists will also evaluate uncertainty in the scientific evidence, considering issues such as extrapolations of observed pollutant-induced pathophysiological alterations from laboratory animals to humans; confounding by co-exposure to other ambient pollutants, meteorological factors, or other factors; the potential for effects to be due to exposure to pollutant mixtures; and the influence of exposure measurement error on epidemiologic study findings. Judgments of causality also are informed by the extent to which uncertainty in one line of evidence (e.g., potential copollutant confounding in epidemiologic results) is addressed by another line of evidence (e.g., coherence of effects observed in epidemiologic studies with experimental findings, mode of action information). Thus, evidence integration is not a unidirectional process but occurs iteratively within and across scientific disciplines and related outcomes.

A similar process is used for the integration of evidence and determination of causality for welfare-related effects. For ecological effects this includes evaluating evidence relevant to quantitative relationships between pollutant exposures and ecological effects. This also includes reviewing concentration-response relationships and, to the extent possible, drawing conclusions on the levels at which effects are observed. Also evaluated are effects of Pb on biological levels of organization from species to populations to biological communities and ecosystems. Both laboratory and field studies (including field experiments and observational studies) can provide useful data for causality determination. Generally, a causality determination is made based on many lines of evidence that reinforce each other and are based on integrating evidence from both previous and recent studies.

A.5. QUALITY MANAGEMENT WITHIN THE EPA

Quality Management Plans (QMP) are developed to ensure that all Agency materials meet a high standard for quality. CPHEA participates in the Agency-wide Quality Management System, which requires the development of a QMP. Implementation of the CPHEA QMP ensures that all information disseminated by CPHEA adheres to a high standard for quality including objectivity, utility, and integrity. Quality assurance (QA) measures detailed in the QMP will be employed for the development of the ISA. CPHEA QA staff will be responsible for the review and approval of quality-related documentation. CPHEA scientists will be responsible for the evaluation of all inputs to the ISA, including primary (new) and secondary (existing) data, to ensure their quality is appropriate for their intended purpose. CPHEA adheres to Data Quality Objectives, which identify the most appropriate inputs to the science assessment and provide QA instruction for researchers citing secondary information. The approaches utilized to search the literature and criteria applied to select and evaluate studies were detailed in the two preceding subsections. Generally, CPHEA scientists rely on scientific information found in peer-reviewed journal articles, books, and government reports. The ISA also can include information that is integrated or summarized from multiple sources to create new figures, tables, or summation, which is subject to rigorous quality assurance measures to ensure their accuracy.

A.6. SCIENTIFIC AND PUBLIC REVIEW

A.6.1. Peer Input Workshop

During the development of the ISA, EPA holds a preliminary peer input meeting. This meeting brings together subject matter experts from a variety of disciplines to review initial draft materials for the ISA. This workshop generally spans multiple days, covering a different topic area each day. This workshop occurs prior to the integration of evidence across scientific disciplines and the consideration of the collective body of evidence for the purposes of making

causality determinations. Therefore, the peer input review is different from what is provided by the Clean Air Scientific Advisory Committee (CASAC) and the public following the release of the draft ISAs. During the peer input meeting, expert panelists are asked to address the following overarching questions: a. Do the initial draft materials capture the key new studies from the peer-reviewed literature that have been published since the completion of the prior ISA? Are there additional studies published since the last ISA that should be included? b. Are there specific issues that should be considered or highlighted that will be important for integrating evidence across disciplines?

A.6.2. Peer Review

The EPA's Peer Review Handbook dictates the process for scientific peer review of all EPA products (U.S. EPA, 2015b). Accordingly, a draft of the ISA is made available for review by the CASAC. Availability of the draft document to the public is also announced in the *Federal Register*, with instructions for submitting comments on the document to the public docket established for development of that ISA. The CASAC reviews the draft ISA at a public meeting that is announced in the *Federal Register*. The EPA considers comments, advice, and recommendations received from the CASAC and from the public in revising the draft ISA document. After appropriate revision based on comments received from the CASAC and the public, the final document is made available on the EPA website. A notice announcing the availability of the final ISA is published in the *Federal Register*.

A.7. REFERENCES

Cohen, AM; Hersh, WR; Peterson, K; Yen, PY. (2006). Reducing workload in systematic review preparation using automated citation classification. J Am Med Inform Assoc 13: 206-219. http://dx.doi.org/10.1197/jamia.M1929

Howard, BE; Phillips, J; Miller, K; Tandon, A; Mav, D; Shah, MR; Holmgren, S; Pelch, KE; Walker, V; Rooney, AA; Macleod, M; Shah, RR; Thayer, K. (2016). SWIFT-Review: a text-mining workbench for systematic review. Syst Rev 5: 87. http://dx.doi.org/10.1186/s13643-016-0263-z

U.S. EPA. (2020) Integrated Science Assessment (ISA) for Oxides of Nitrogen, Oxides of Sulfur and Particulate Matter Ecological Criteria (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-20/278.

U.S. EPA. (2019) Integrated Science Assessment (ISA) for Particulate Matter (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-19/188.

U.S. EPA (2015a). Preamble to the integrated science assessments [EPA Report]. (EPA/600/R-15/067). Research Triangle Park, NC: U.S. Environmental Protection Agency, Office of

Research and Development, National Center for Environmental Assessment, RTP Division. https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244

U.S. EPA (2015b). Peer Review Handbook. 4th edition. Science and Technology Policy Council, U.S. Environmental Protection Agency, Washington, D.C. EPA/100/B-15/001.

APPENDIX B AMBIENT AIR MONITORING AND DATA HANDLING

The EPA and state and local agencies have been measuring Pb in the atmosphere since the 1970s. Ambient air Pb concentrations are measured by five national monitoring networks. The networks include the State and Local Air Monitoring Sites (SLAMS network) intended for Pb NAAQS surveillance, the $PM_{2.5}$ Chemical Speciation Network (CSN), the Interagency Monitoring of Protected Visual Environments (IMPROVE) network, the National Air Toxics Trends Stations (NATTS) network, and the Urban Air Toxics Monitoring program. All of the data from these networks are accessible via EPA's Air Quality System (AQS): http://www.epa.gov/ttn/airs/airsaqs/ . In addition to these networks, various environmental organizations have operated other sampling sites yielding data (which may or may not be accessible via AQS) on ambient air concentrations of Pb, often for limited periods or for primary purposes other than quantification of Pb itself. Federal regulations specify requirements for the data collection and calculations performed to assess whether the Pb NAAQS are met. This appendix describes the ambient Pb measurement methods, the sites and networks where these measurements are made, and the data handling conventions and computations.

B.1. STATE AND LOCAL AIR MONITORING SITES NETWORK

This section describes the Pb monitoring requirements for the SLAMS network, the main purpose of which is surveillance for the Pb NAAQS. The EPA regulates how this monitoring is conducted to ensure accurate and comparable data for determining compliance with the NAAQS. The code of federal regulations (CFR) at parts 50, 53 and 58 specifies required aspects of the ambient monitoring program for NAAQS pollutants.[23]

B.1.1. Sampling and Analysis Methods

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

[23] The FRMs for sample collection and analysis are specified in 40 CFR part 50, the procedures for approval of FRMs and federal equivalent methods 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.

The current FRM for the measurement of Pb-TSP 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 inductively coupled plasma mass spectrometry (ICP-MS) as specified in 40 CFR part 50 Appendix G. In addition, there are 28 FEM currently approved for Pb-TSP.[24] All 28 Pb-TSP FEM are based on the use of high-volume TSP samplers and a variety of approved equivalent analysis methods.[25]

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

B.1.2. Network Requirements

Source-oriented monitoring sites are required near sources of air Pb emissions which are expected to or have been shown to contribute to ambient air Pb concentrations in excess of the NAAQS. At a minimum, there must be one source-oriented site located to measure the maximum Pb concentration in ambient air resulting from each non-airport Pb source estimated to emit 0.50 or more tons of Pb per year and from each airport estimated to emit 1.0 or more tons of Pb per year.[26] The EPA Regional Administrators may require additional monitoring beyond the minimum requirements where the likelihood of Pb air quality violations is significant. Such locations may include those near additional industrial Pb sources, recently closed industrial sources and other sources of resuspended Pb dust, as well as airports where piston-engine aircraft emit Pb (40 CFR, part 58, Appendix D, section 4.5(c)). As of July 2021, there were 125 active SLAMS sites reporting data to AQS with 101 reporting based on local temperature and pressure

[24] A complete list of FRM/FEMs can be found at the following webpage - https://www.epa.gov/sites/production/files/2019-08/documents/designated_reference_and-equivalent_methods.pdf

[25] A recent evaluation of the high-volume TSP sampler FRM performance, conducted in response to prior CASAC recommendations, documented good performance (Krug et al, 2017).

[26] 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 three-month average Pb concentration in ambient air in excess of 50 percent of the NAAQS level based on historical monitoring data, modeling, or other means (40 CFR, part 58, Appendix D, section 4.5(a)(ii)).

(LC), and 24 sites reporting based on standard temperature and pressure (STD) (Figure B-1Figure B-1). More information on the Pb SLAMS network can be found on EPA's website (https://www.epa.gov/amtic/lead-pb-monitoring-network).

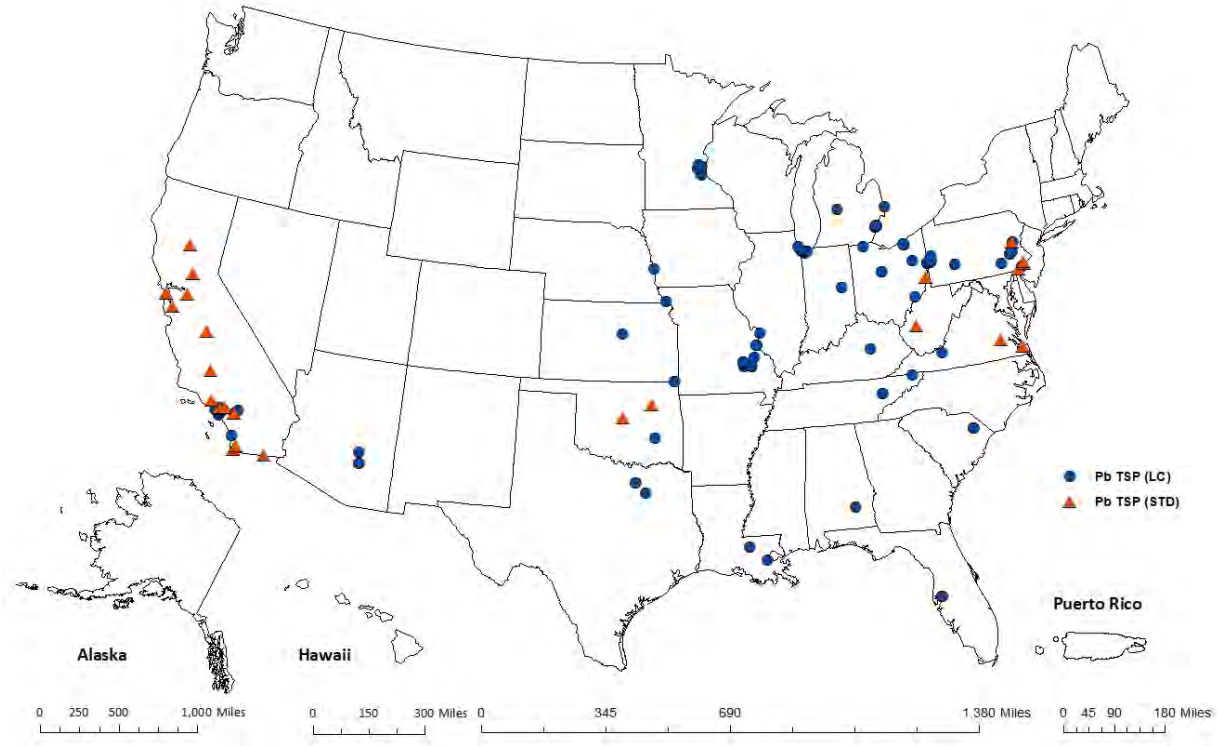

Figure B-1. Locations of SLAMS for lead.

In 2016 EPA removed the requirement to measure Pb at urban NCore sites (81 FR 17247). The requirement was removed because all NCore sites were measuring very low Pb concentrations (81 FR 17247). The requirement for non-source-oriented monitoring was originally finalized as part of the reconsideration of Pb monitoring requirements that occurred in 2010 (75 FR 81126); however, it was later removed because in all cases ambient Pb readings were very low compared to the level of the NAAQS. Since the requirement was removed, nearly all NCore sites have discontinued Pb monitoring. It should be noted however, that all NCore sites continue to measure Pb in $PM_{2.5}$ as part of the CSN, as discussed below.

B.2. OTHER NETWORKS MONITORING LEAD

In addition to being monitored for regulatory purposes in the SLAMS network, Pb is also monitored in three other sampling networks in different PM size fractions. These data are generally not usable for NAAQS surveillance because they do not use FRM/FEM methods.

However, the data can be useful for understanding geospatial variability in ambient Pb concentrations.

Pb-PM_{10} is monitored in the National Air Toxics Trends Station (NATTS) network. PM_{10} is collected either by high volume sampling with a quartz fiber filter or low volume sampling with a PTFE filter following EPA Compendium Method IO-3.5 (U.S. EPA, 1999b). Pb is one of seven core metals collected on Teflon filters and analyzed by ICP-MS. The NATTS network was developed to fulfill the need for long-term air toxics, also known as hazardous air pollutant (HAP), monitoring data of consistent quality. Among the principle objectives of the NATTS network are assessing trends and emission reduction program effectiveness, assessing and verifying air quality models (e.g., exposure assessments, emission control strategy development, etc.), and providing data for direct input to source-receptor models. The network was initiated in 2003, and the current network configuration includes 26 sites (21 urban, 5 rural) across the United States. There are typically over 100 pollutants monitored at each NATTS site, although only 19 of those are formally required including Pb. Figure B-2 shows the geographic distribution of the NATTS network. More information on the NATTS network can be found on EPA's website (https://www.epa.gov/amtic/air-toxics-ambient-monitoring).

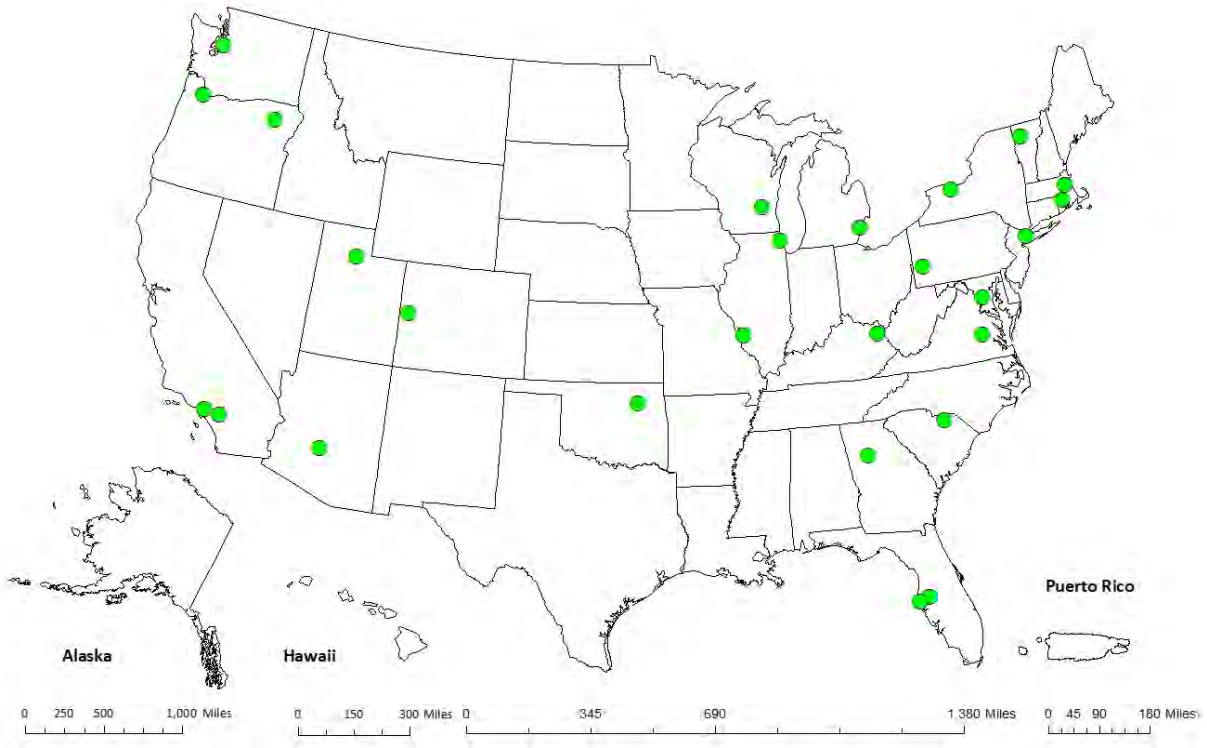

Figure B-2. Locations of Pb monitors in the NATTS network.

Pb-$PM_{2.5}$ is monitored at 139 monitoring sites as a part of the Chemical Speciation Network (CSN). The CSN currently use two samplers at each site to collect $PM_{2.5}$ on three

different filter types. The Met One SASS (or SuperSASS) is used to collect ambient air samples on Teflon and nylon filters, and the URG-3000N is used to collect ambient air samples on quartz filters. Pb is one of 33 elements that are analyzed by energy dispersive X-ray fluorescence spectrometry on the Teflon filters. CSN sites collect samples on either a 1-in-3 day or a 1-in-6 day sampling schedule, depending on the purpose of the site. Pb results from CSN are reported to EPA's Air Quality System (AQS), using AQS parameter 88128, approximately 6 months after filters are sampled. Figure B-3 shows the geographic distribution of the CSN. More information on the CSN can be found at EPA's website (https://www.epa.gov/amtic/chemical-speciation-network-csn).

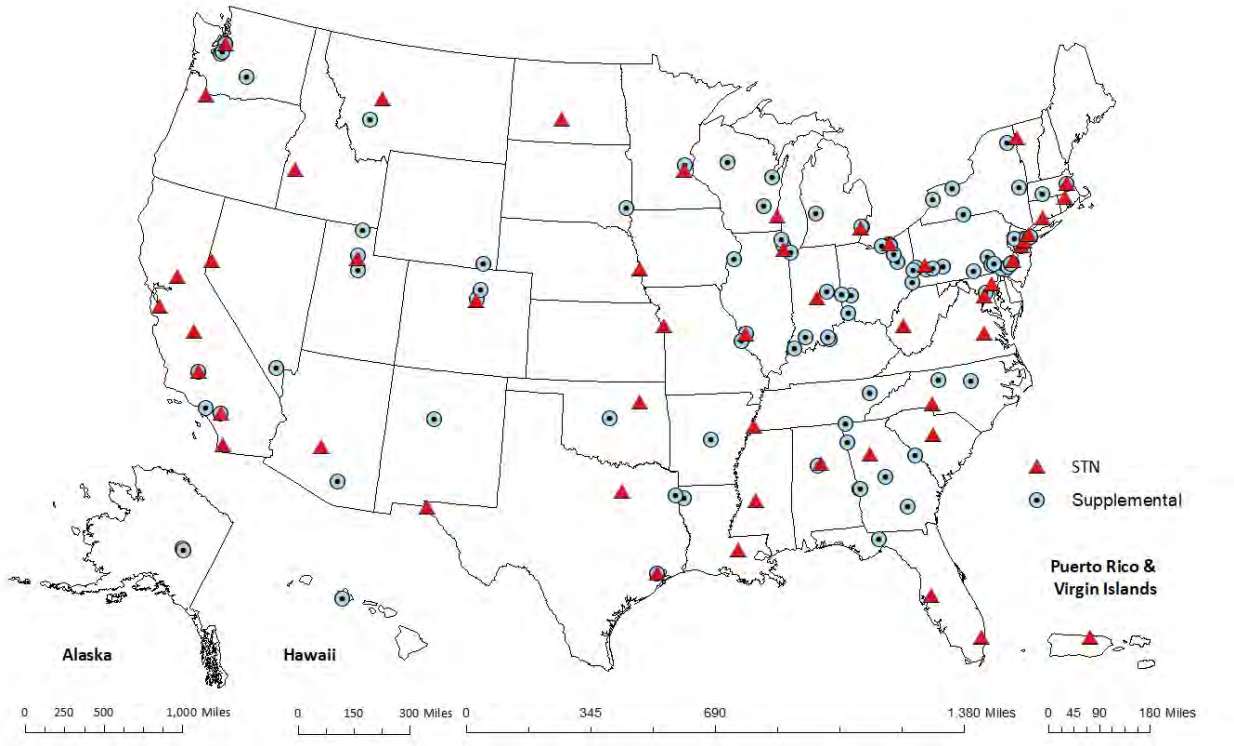

Figure B-3. Locations of chemical speciation network sites.

Pb-$PM_{2.5}$ is also monitored at 110 aerosol visibility-monitoring sites as a part of the Interagency Monitoring of Protected Visual Environments (IMPROVE) program. An additional 37 aerosol samplers are operated by state, local, or tribal monitoring organizations following IMPROVE protocols. IMPROVE is a cooperative effort by federal and state organizations to protect visibility in 156 national parks and wilderness areas as described in the 1977 amendments to the Clean Air Act. Objectives are (1) to establish current visibility and aerosol conditions in high priority (class I) areas for visibility protection; (2) to identify chemical species and emission sources responsible for existing man-made visibility impairment; (3) to document long-term trends for assessing progress towards visibility goals; and (4) to provide regional haze

monitoring representing protected federal areas in accordance with the regional haze rule. The IMPROVE sampler operates with four sampling modules, three for $PM_{2.5}$ and one for PM_{10}. Pb is not measured in PM_{10}, but one of the three $PM_{2.5}$ modules contains a Teflon filter used for determination of gravimetric mass, absorbance, and elemental analysis by XRF. A total of 24 elements are determined by energy dispersive XRF, including Pb. Pb results from IMPROVE and IMPROVE protocol sites are reported to EPA's AQS using parameter 88128 approximately 12 months after filters are sampled. Figure B-4 shows the geographic distribution of the IMPROVE network. More information on the IMPROVE network can be found on the IMPROVE website - http://vista.cira.colostate.edu/Improve/.

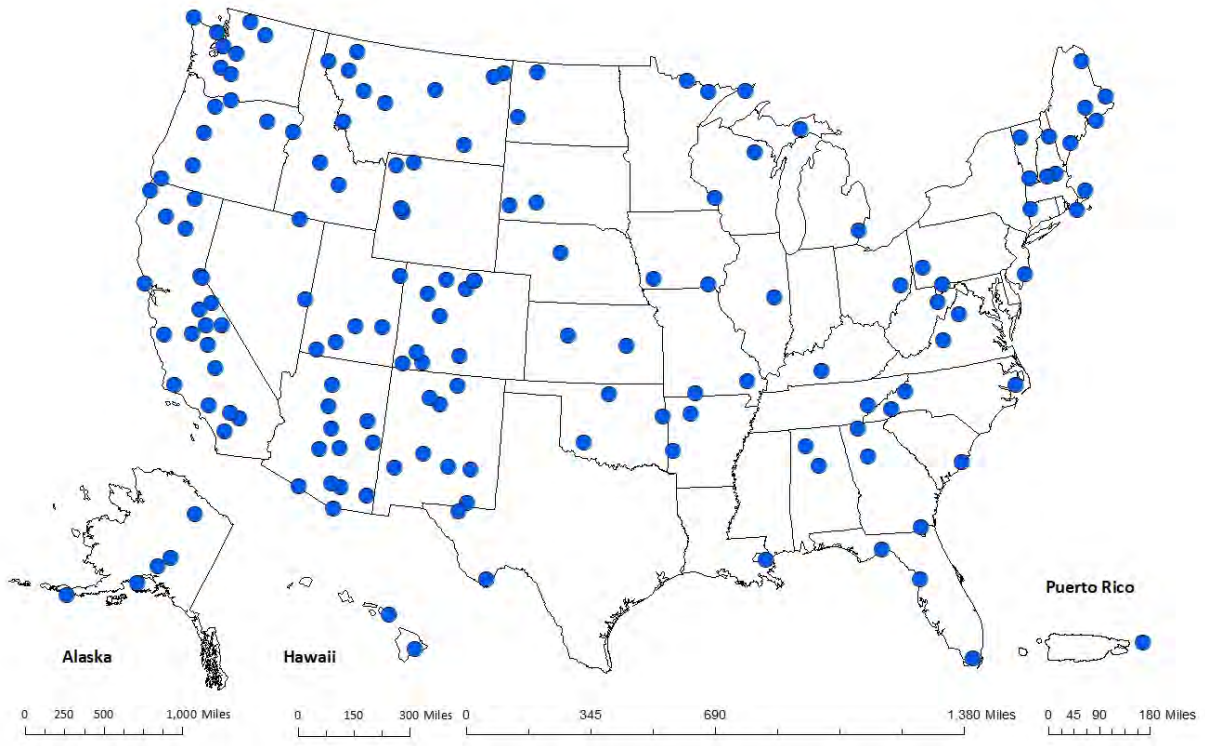

Figure B-4. Locations of IMPROVE sites.

B.3. DATA HANDLING CONVENTIONS AND COMPUTATIONS FOR DETERMINING WHETHER STANDARDS ARE MET

As summarized in section B.1 above, and specified in CFR, Title 40, 50.16, ambient air concentrations used in assessing whether the Pb NAAQS is met in an area must be measured by a FRM or FEM. Further, although Pb-TSP is the lead NAAQS indicator, Pb-PM_{10}, sampled and analyzed by an FRM or by an FEM, may be used for NAAQS comparisons as surrogate for Pb-TSP in some circumstances. Specifically, Pb-PM_{10} data can only be used to show that Pb NAAQS are violated (i.e., not met); they cannot be used to demonstrate that Pb NAAQS are met.

In this context, Pb-PM_{10} data used as surrogate Pb-TSP data must be processed at face value; that is, without any transformation or scaling.

To assess whether a location meets or exceeds the NAAQS, the monitoring data are analyzed consistent with the established regulatory requirements, as specified in CFR Title 40, part 50, Appendix R. Using these data, the Pb NAAQS are met when the maximum arithmetic 3-month mean concentration for a 3-year period, as determined in accordance with CFR Title 40, part 50, Appendix R, (i.e., the design value) is less than or equal to 0.15 micrograms per cubic meter. The design value for the Pb NAAQS is selected according to the procedures in Appendix R from among the valid three-month Pb-TSP and surrogate Pb-TSP (Pb-PM_{10}) arithmetic mean concentrations for the 38-month period consisting of the most recent 3-year calendar period plus two previous months (i.e., 36 3-month periods) using the last month of each 3-month period as the period of report.

Monthly means are computed by averaging the daily values for a calendar month at each monitoring site separately for Pb-TSP and Pb-PM_{10} (i.e., by site-parameter-year-month). These calendar month means are then used to calculate 3-month means (separately for each parameter: Pb-TSP, Pb-PM_{10}), which are the arithmetic averages of three consecutive monthly means on a rolling, overlapping basis, and are finally used in the NAAQS design value computations. Each distinct monthly mean will be included in three different 3-month means; for example, in a given year, a November mean would be included in (1) the September-October-November 3-month mean, (2) the October-November-December 3-month mean, and (3) the November-December-January (of the following year) 3-month mean.

The Pb NAAQS is violated at a monitoring site when the identified design value is valid and is greater than 0.15 $\mu g/m^3$, no matter whether determined from Pb-TSP or Pb-PM_{10} data. A Pb design value greater than 0.15 $\mu g/m^3$ is valid no matter how many valid 3-month means in the 3-year period it encompasses; that is, a violating design value is valid even if it (i.e., the highest 3-month mean) is the only valid 3-month mean in the 3-year timeframe. In judging a 3-month mean valid, data completeness requirements are considered. A 3-month parameter mean is considered valid (i.e., meets data completeness requirements) if the average of the data capture rate of the three constituent monthly means (i.e., the 3-month data capture rate rounded to the nearest integer) is greater than or equal to 75 percent.[27]

[27] A 3-month parameter mean that does not have at least 75 percent data capture and thus is not considered valid shall be considered valid (and complete) if it passes either of the two following "data substitution" tests, one such test for validating an above NAAQS-level (*i.e.*, violating) 3-month Pb-TSP or Pb-PM_{10} mean (using actual "low" reported values from the same site at about the same time of the year (*i.e.*, in the same month) looking across three or four years), and the second test for validating a below-NAAQS level 3-month Pb-TSP mean (using actual "high" values reported for the same site at about the same time of the year (*i.e.*, in the same month) looking across three or four years). Note that both tests are merely diagnostic in nature intending to confirm that there is a very high likelihood if not certainty that the original mean (the one with less than 75% data capture) reflects the true

Lastly, Appendix R also specifies rounding conventions in the derivation of design values. Monthly means and monthly data capture rates are not rounded. Three-month means are be rounded to the nearest hundredth $\mu g/m^3$, such that decimals for which thousandth value is 5 or greater are rounded up, and where that value is lower than 5, it is rounded down.

B.4. REFERENCES

Krug, JD; Dart, A; Witherspoon, CL; Gilberry, J; Malloy, Q; Kaushik, S; Vanderpool, RW. (2017). Revisiting the size selective performance of EPA's high-volume total suspended particulate matter (Hi-Vol TSP) sampler. Aerosol Sci Technol 51(7): 868-878. https://doi.org/10.1080/02786826.2017.1316358

over/under NAAQS-level status for that 3-month period; the result of one of these data substitution tests (*i.e.*, a "test mean", as defined in section 4(c)(ii)(A) or 4(c)(ii)(B)) is not considered the actual 3-month parameter mean and shall not be used in the determination of design values. For both types of data substitution, substitution is permitted only if there are available data points from which to identify the high or low 3-year month-specific values, specifically if there are at least 10 data points total from at least two of the three (or four for November and December) possible year-months. Data substitution may only use data of the same parameter type.

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