Responses to Significant Comments on the 2008 Proposed Rule on the National Ambient Air Quality Standards for Lead
(May 20, 2008; 73 FR 29184)

Docket Number OAR-2006-0735

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Frequently Cited Documents

The following documents are frequently cited throughout EPA's response to comments, often by means of the short names listed below:

Criteria Document (CD):
> Environmental Protection Agency (2006) Air Quality Criteria for Lead. Volumes I and II. Washington, DC, EPA/600/R–5/144aF and EPA/600/R–5/144bF. Available online at: http://www.epa.gov/ncea/

Preamble to the final rule:
> Preamble to the Final Rule on the Review of the National Ambient Air Quality Standards for Lead; to be published in the *Federal Register* in September or October 2008.

Proposal notice:
> National Ambient Air Quality Standards for Lead: Proposed Rule. 73 FR 29184, May 20, 2008.

Advance Notice of Proposed Rulemaking (ANPR):
> National Ambient Air Quality Standards for Lead: Advance Notice of Proposed Rulemaking. 72 FR 71488, December 17, 2007.

Staff Paper:
> Environmental Protection Agency (2007a) Review of the national ambient air quality standards for lead: assessment of scientific and technical information. OAQPS staff paper. (Final) November 2007. Research Triangle Park, NC: Office of Air Quality Planning and Standards; EPA report no. EPA– 452/R–07–013. Available online at: http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_sp.html

Final Risk Assessment Report:
> U.S. Environmental Protection Agency. (2007b) Lead: Human Exposure and Health Risk Assessments for Selected Case Studies, Volume I. Human Exposure and Health Risk Assessments—Full-Scale and Volume II. Appendices. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA–452/R–07–014a and EPA–452/R– 07–014b. Available online at: http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html

Pilot-phase Risk Assessment Report:
> ICF International (2006) Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas. Pilot Phase. Draft Technical Report (with appendices). Prepared for the U.S. EPA's Office of Air Quality Planning and Standards, Research Triangle Park, NC. December. Available online at: http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html

Responses to Significant Comments on the 2008 Proposed Rule on the National Ambient Air Quality Standards for Lead

I. INTRODUCTION

This document, together with the preamble to the final rule on the review of the national ambient air quality standards (NAAQS) for lead (Pb), presents the responses of the Environmental Protection Agency (EPA) to the thousands of public comments received on the 2008 Pb NAAQS proposal notice (72 FR 37818). All significant issues raised in timely public comments have been addressed. Where comments were submitted after the close of the public comment period, EPA responded to the extent practicable.

Comments were received from EPA's Children's Health Protection Advisory Committee, the American Academy of Pediatrics, the American Medical Association, the American Thoracic Society, two organizations of state and local air agencies (National Association of Clean Air Agencies [NACAA]and Northeast States for Coordinated Air Use Management [NESCAUM]), approximately 40 State, Tribal and local government agencies, approximately 20 environmental or public health organizations or coalitions, approximately 20 industry organizations or companies, and approximately 6200 private citizens (roughly 150 of whom were not part of one of several mass comment campaigns). Due to the large number of comments that addressed similar issues, this response-to-comments document does not generally cross-reference each response to the commenter(s) who raised the particular issue involved, although commenters are identified in some cases where they provided particularly detailed comments that were used to frame the overall response on an issue.

The responses presented in this document are intended to augment the responses to comments that appear in the preamble to the final rule or to address comments not discussed in the preamble to the final rule. Although portions of the preamble to the final rule are paraphrased in this document where useful to add clarity to responses, to the extent any ambiguity is introduced by this paraphrasing, the preamble itself remains the definitive statement of the rationale for the revisions to the standards adopted in the final rule.

In many instances, particular responses presented in this document include cross references to responses on related issues that are located either in the preamble to the Pb NAAQS final rule, or in this Response to Comments document. In other instances the comment is appropriately addressed by the Agency's discussion in other parts of the record. All issues on which the Administrator is taking final action in the Pb NAAQS final rule are addressed in the Pb NAAQS rulemaking record.

Accordingly, this Response to Comments document, together with the preamble to the Pb NAAQS final rule and the information contained in the Criteria Document (EPA, 2006a), the Staff Paper (EPA, 2007a), the Advance Notice of Proposed Rulemaking, and the Notice of Proposed Rulemaking should be considered collectively as EPA's response to all of the significant comments submitted on EPA's 2008 Pb NAAQS proposed rule. This document

incorporates directly or by reference the significant public comments addressed in the preamble to the Pb NAAQS final rule as well as other significant public comments that were submitted on the proposed rule.

Consistent with the final decisions presented in the notice of final rulemaking, comments on the following topics are addressed in section II: the primary Pb standard (section II.A), the secondary Pb standard (section II.B), data handling procedures (section II.C), and monitoring-related issues (section II.D). Comments on implementation-related issues are addressed in section III. Comments on issues related to the exceptional events rule are addressed in section IV. Section V includes responses to legal, administrative, procedural, or misplaced comments.

II.   RESPONSES TO SIGNIFICANT COMMENTS ON PROPOSED Pb STANDARDS

A.   Primary Pb Standard

1.   General Comments on Need for Revision

General comments based on relevant factors that either support or oppose any change to the current Pb primary standard are addressed in section II.B of the preamble to the final rule and/or in section II.A.1 below. Specific comments on the proposed primary standard, including comments on the indicator, averaging time and form, and level are addressed in sections II.C.1, II.C.2, or II.C.3, respectively, in the preamble to the final rule and/or in section II.A.2 below. Additional comments about the health effects evidence and the results of the human exposure and health risk assessments are addressed in sections II.A.3 or II.A.4 below.

a.   Support for Revising the Current Standard

The vast majority of public comments received on the proposal asserted that, based on the available scientific information, the current Pb standard is insufficient to protect public health with an adequate margin of safety and revisions to the standard are appropriate. Among those calling for revisions to the current standards are medical groups, including the American Academy of Pediatrics (AAP), the American Thoracic Society, and the American Medical Association (AMA), as well as medical doctors and academic researchers. Similar conclusions were also submitted in comments from local public health organizations, including Coalition to End Childhood Lead Poisoning, St. Louis Lead Prevention Coalition, and Physicians for Social Responsibility, as well as in letters to the Administrator from EPA's Children's Health Protection Advisory Committee (CHPAC) (Marty, 2008a, 2008b). Environmental groups also commented in support of revising the standard, including the Sierra Club, and the Natural Resources Defense Council (NRDC). All of these medical, public health and environmental commenters stated that the current Pb standard needs to be revised and that an even more protective standard than proposed by EPA is needed to protect the health of sensitive population groups. Some 6000 individual commenters also expressed such views.

The vast majority of State and local air pollution control authorities, as well as tribal governments and tribal air agencies who commented on the Pb standard supported revision of the current Pb standard. State organizations, including the National Association of Clean Air

Agencies (NACAA), and the Northeast States for Coordinated Air Use Management (NESCAUM) urged that EPA revise the Pb standard.

In supporting adoption of a more stringent NAAQS for Pb, these commenters variously stated that:
- the current evidence indicates Pb effects at much lower exposure levels than when the current standard was set;
- the current evidence indicates Pb effects in multiple systems (e.g., neurological effects in children, cardiovascular and renal effects in adults);
- there is now evidence of a greater air-to-blood ratio than that understood when the standard was set; and
- EPA's risk assessment indicates risks under current NAAQS of a magnitude clearly harmful to public health.

Comments received in support of revising the current standard are addressed in section II.B.2 of the preamble to the final rule.

b.   Support for Retaining the Current Standard

Three industry commenters (National Association of Manufacturers, Non-Ferrous Founders' Society, and the Wisconsin Manufacturers and Commerce) indicated support for retaining the current standard. In supporting this view, these commenters variously stated that:
- a revised NAAQS would require action by Pb air sources while other nonair or historic Pb sources of exposure contribute much greater risks to children's health;
- a revised NAAQS will "obstruct innovation" and have an "adverse impact on achieving environmental goals";
- reduction of the Pb standard will not provide meaningful benefits to public health; and
- risks associated with current NAAQS are due to non-complying sources.

These comments received in support of retaining the current standard are generally addressed in Section II.B.2 of the preamble to the final rule. We additionally note here that EPA disagrees with commenters regarding the significance of health risk associated with air-related Pb exposures allowed by the current standard, and that, under the Clean Air Act, EPA may not consider the costs of compliance in determining what standard is requisite to protect public health with an adequate margin of safety.

2.   Comments on Elements of Proposed Primary Pb Standard

a.   Indicator

The majority of public comments recommended retaining the indicator as Pb-TSP, with some commenters qualifying their recommendation that Pb-TSP should be retained only if the level for the standard is set at or above 0.10 or 0.20 $\mu g/m^3$. A few commenters recommended revision of the indicator to Pb-PM$_{10}$ (or Pb-PM$_{2.5}$) regardless of the level of the standard. These comments on indicator are described and addressed in section II.C.1.b of the preamble to the

final rule. Specific indicator-related comments not addressed in the preamble are described below.

(1) *Comment:* One commenter, in indicating support for retaining the current indicator of Pb-TSP, referenced two papers (Donguk and Namwon, 2004; Park and Paik, 2002) which they described as reporting that 35 to 70% and 11 to 49%, respectively, of airborne Pb associated with particular industries was in particle sizes greater than 10 micrometers in diameter.

Response: As discussed in section II.C.1.2 of the preamble to the final rule, EPA agrees with this commenter that Pb occurs in some areas in the U.S. in particle sizes that would not be captured by PM_{10} samplers, and accordingly EPA has decided to retain Pb-TSP as the indicator. EPA notes, however, that the studies cited by this commenter provide occupational exposure measurements for industries in Korea, rather than ambient air measurements for locations in the U.S.

b.   Averaging Time and Form

Comments received from public health and environmental organizations on the issue of averaging time for the Pb primary standard recommended revision of the averaging time to monthly, as did most comments from state and local air pollution control authorities and from private citizens. Among these commenters who also commented on form, most recommended a form of maximum monthly average, with a few recommending the form of 2nd maximum monthly average. Some of these commenters additionally recommended that the averaging time be derived as a rolling 30-day average. Another group of commenters comprised of industry associations and businesses and some state and local air pollution control authorities opposed a revision from quarterly to monthly averaging time. Some of these commenters additionally recommended that the averaging time be derived as a rolling 3-month average. These comments are summarized and addressed in section II.C.2.b of the preamble for the proposed rule. Specific aspects to some of these comments with regard to interpretation of the evidence are discussed below.

(1) *Comment:* A few industry commenters, most particularly, the International Lead and Zinc Research Organization (ILZRO), state that the evidence with regard to toxicodynamics and toxicokinetics of Pb in the body indicates that "longer averaging times are appropriate". The rationale provided included statements (without scientific citation) regarding the time period pertinent to neurological effects such as neurocognitive and neurobehavioral effects. For example, one industry group (ILZRO) generally states that effects associated with a time frame of weeks are limited to frank effects such as encephalopathy, and implies that neurological effects of interest in this review occur "over extended periods of cognitive development." Additionally, this commenter asserts that from a toxicokinetic standpoint, longer averaging times are appropriate (citing Leggett, 1993). For example, this commenter stated that the uptake rate of lead by the brain is "extremely low." They further stated that "at least 6 months is required for lead in the central nervous system to equilibrate with environmental exposures" and that from

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a "dose to target tissue" perspective a longer averaging time is appropriate as they state the "removal half-time" of Pb is "approximately two years."

Response: EPA disagrees with several aspects of these comments and the commenters' interpretation of the evidence. As discussed in the preamble section II.C.2, the response of blood Pb to environmental exposures to Pb is quite rapid and the evidence concerning neurocognitive effects indicates the importance of relatively short exposures. With regard the comments, particularly those from ILZRO, regarding short as compared to longer exposures, EPA first notes that in considering the appropriate averaging time, we are not, as implied by the framing of the comments, identifying the maximum allowable duration for a single exposure at the level of the standard. Rather, we are considering the shortest time period during which the level of the standard may not be exceeded, in the context of an ongoing, yet varying, ambient exposure to a persistent pollutant. Neurological effects in children, such as neurocognitive and neurobehavioral effects, and not encephalopathy have been identified as key effects in this review. As discussed in the preamble section II.C.2 (and in the proposal, ANPR, and Staff Paper and Criteria Document), the evidence for these effects indicates the importance of exposures on the order of 1 to 3 months. In several epidemiologic studies examining the relationship between neurocognitive effects and blood Pb levels, the strongest associations were observed with concurrent blood Pb levels (e.g., Chen et al., 2005; Lanphear et al., 2005). With regard to toxicokinetics of Pb in the body, EPA disagrees with the commenter's characterization of brain uptake of Pb as "extremely low." EPA notes that while the cited publication by Leggett (1993) reports that the author's model predicts 6 months to reach a peak level in the brain compartment after bolus administration, the author reports that within two months approximately 80% of steady state brain levels of lead are reached (Leggett, 1993). The uptake half-time varies by age in the Leggett (1993) paper from only 0.9 to 3.7 days. Further, contrary to the commenter's statement, the cited study (Leggett, 1993) does not indicate a compartment for the full CNS, only the brain. Thus, EPA concludes that given the rapid accumulation of lead from the plasma into the brain and subsequent slow removal from the brain, from a toxicokinetic standpoint, and the considerations described in the preamble section II.C.2.b, an averaging time longer than a few months (e.g., a 3-month period) is not appropriate.

(2) *Comment:* One industry commenter (American Smelting and Refining Company [ASARCO]) recommended that unless a provision was included to prevent counting a single month more than once, EPA should not use a rolling average form in order to avoid "double counting of exceedances".

Response: EPA disagrees with the commenter that for an averaging time longer than a month, air Pb concentrations during any one month should only contribute to a single statistic that is compared to the level of the standard. The use of a rolling average has neither the purpose nor effect of "double counting ... exceedances." The purpose of the rolling 3-month average, as discussed in the preamble, is to provide an average that is more representative of air quality over the 3-month period. An exceedance of the standard is only determined by reference to the 3-month mean, and each month, whether a "high" or "low" month, contributes to three 3-month means. Moreover, EPA notes that

the form of the standard is a not-be-exceeded (maximum) form measured over a 3-year span, so only a single exceedance of the standard is sufficient to violate the standard, regardless of whether there are additional contemporaneous violations.

c.   Level for Pb-TSP-based Standard

A large number of comments were received on the proposed range of levels for the primary Pb standard. The vast majority expressed support for a revision to a more health protective standard at or below the range of levels proposed by EPA; a small number expressed support for more modest adjustment or revision to a level ranging above the proposed range up to 0.50 μg/m^3; and a few commenters expressed opposition to any appreciable modification of the current Pb standard. These comments are summarized and addressed in section II.C.3.b of the preamble to the proposed rule. In addition to the discussion contained in that section, EPA provides the following responses to specific issues related to the level for the primary Pb standard in sections II.A.2.c.i through II.A.2.c.iv below. The subsequent sections (sections II.A.2.c.v and II.A.2.c.vi) respectively address additional specific comments on health evidence considerations and exposure and risk considerations related to consideration of the level for the primary standard. Additional specific comments on interpretation of the scientific evidence and the health risk assessment are included in sections II.A.3 and II.A.4 below.

i.   *General Comments on Level*

Specific aspects of general comments on level for the primary Pb standard not addressed in the preamble are addressed here.

(1) *Comment:* Several commenters (e.g., NRDC, Missouri Coalition for the Environment [MO Coalition]) stated that EPA's proposed range did not include a level protective of vulnerable and susceptible subgroups. In particular, these commenters identify minority and low-income children as a sensitive subpopulation for Pb exposures. In discussing these subgroups, some commenters note factors such as nutritional deficiencies as a factor contributing to susceptibility and cite the evidence of higher blood Pb levels in these populations as evidence that minority and low-income children are more likely to be exposed to high levels of lead. One commenter stated that, "Setting the NAAQS without reference to the nutritional deficiencies … of minority and low-income … fails to fulfill EPA EJ CAA obligations" (MO Coalition, p. 22). Another commenter stated that EPA must set the NAAQS in the lower part or below the proposed range "to protect the many, poor, minority, and urban individuals whose blood Pb already contains dangerously high levels of lead" (NRDC, p.22), referring to various EPA documents from this review as providing information pertinent to this point.

Response: EPA notes, as discussed in the proposal and this preamble, that due to additional scientific information about Pb since the 1978 standard was established (particularly the lack of an accepted safe level for Pb exposure), EPA is not using the 1978 approach of setting the NAAQS based on total Pb exposure, but rather is basing the NAAQS upon air-related Pb exposure. EPA considers the sensitive subpopulation for air-related Pb to be those children more highly exposed to air-related Pb (e.g., due to

proximity to sources) as compared to children on average. As discussed in the preamble, the Administrator selected the level, form, indicator, and averaging time with full consideration of the need to provide sufficient protection for sensitive groups with an adequate margin of safety.

EPA agrees with commenters that on average in the U.S., minority and low-income children have higher blood Pb levels than the general population, as shown by the NHANES information referenced in section II.A.2.b of the preamble and described in section II.B.1.a of the proposal (e.g., http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm). EPA also agrees that these higher average blood Pb levels are indicative of these subpopulations being sensitive with regard to total Pb exposures. However, EPA notes that this evidence does not provide information regarding a potential for increased sensitivity to air-related Pb exposure. Due to the nonlinear dose-response relationship between IQ loss and blood Pb, EPA concludes that the population with *lower* blood Pb levels from both air and nonair sources would be expected to have a greater incremental sensitivity to Pb impacts on IQ (i.e., greater risk of IQ loss per incremental unit of blood Pb). Thus, a standard that is selected to provide protection from the incremental amount of blood Pb associated with air-related Pb to populations with lower total blood Pb levels will also necessarily provide protection from the air-related Pb associated with exposures at the level of the standard to populations with higher total blood Pb levels. As explained in section II.C.3.b of the preamble, the air-related IQ loss framework focuses on children exposed at the level of the standard, children living near air sources of Pb who are likely to be most highly exposed. In concentrating on this highly exposed group of children, EPA has focused on providing sufficient protection for the appropriate subpopulation for this review.

(2) *Comment:* Some industry commenters (American Petroleum Institute [API], Association of Battery Recyclers [ABR], Doe Run Resources Corp.[1]) stated that any level for the NAAQS derived using the air-related IQ loss evidence-based framework should be viewed as pertaining to an averaging time, for the standard, of one year. In support of this premise, commenters generally reference the risk assessment, with one commenter stating that the levels in the table presenting air-related IQ loss estimates in the proposal table "can only be interpreted as annual average air lead levels in order to be consistent with the Risk Assessment" (API). Another commenter additionally states that the risk assessment "was used to support the proposed range of Lead NAAQS standards" (ABR). Based on the commenters' premise of levels for an annual average-based standard, these commenters state that the levels should be converted to ones more appropriate to the selected averaging time/form (e.g., maximum quarterly average or second maximum monthly), and they recommend the use of air quality data statistics for that purpose.

Response: EPA disagrees with the commenters' premise and finds no basis to interpret the levels for the evidence-based framework as pertaining to an annual averaging time for the standard. Rather, EPA concludes they are appropriately interpreted with an averaging time no longer than quarterly. To interpret them as the commenters have as longer than

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[1] Variously referred to throughout this document as "Doe Run" or "Doe Run Resources Corp.".

quarterly averages, ignores the body of evidence on the response of blood Pb and associated effects to Pb exposure described in detail in the Criteria Document, and summarized in the Staff Paper, ANPR, proposal and preamble to the final rulemaking. As discussed in section II.C.2 of the preamble, while the evidence is not precise as to the duration of exposures that trigger neurocognitive effects, for which IQ loss is the indicator used in the framework, these studies do not indicate that a duration as prolonged as a year is required; rather, they indicate the importance of durations of approximately one to three months. For example, as described in the Criteria Document and summarized in the Staff Paper, ANPR, proposal and preamble to the final rule, among the blood Pb metrics analyzed in these studies, concurrent blood Pb (i.e., blood Pb measured at the time of IQ test) has the strongest association with effects (Chen et al., 2005 and Lanphear et al., 2005)[2] and, the concurrent blood Pb metric is most strongly related to a child's exposure episodes within the past few (e.g., one to three) months, rather than exposures as long as a year in the past (e.g., CD p. 4-25).

Further, the evidence regarding transfer of air Pb along the multiple exposure pathways to the blood, while also imprecise, indicates the significance of durations appreciably shorter than a year's length. The studies for air-to-blood ratios, described in sections II.A.2.a.iii and II.C.3, generally do not specify air concentration durations, and consequently could not support a presumption that levels derived from the framework reflect a full year exposure at a particular level (with air-to-blood ratios as one of the inputs). While we are uncertain as to the precise duration for any one air-to-blood ratio and the ways in which an air-to-blood ratio may vary with the duration of the air Pb concentration, we cannot find a basis in the evidence regarding transfers of air Pb to blood Pb for the commenter's statement that the Table 7 levels pertain to an annual average form for the standard. Rather, EPA finds clear evidence to support the importance of time periods on the order of 1-3 months affecting air-related blood Pb levels and exposure pathways.

- For example, evidence from the time of leaded gasoline shows children's blood Pb levels responded to leaded gasoline sales with a time lag of one month. (Schwartz and Pitcher, 1989)
- Additionally, various studies have observed blood Pb levels to exhibit seasonal patterns, perhaps related to seasonality in exposure variables. (e.g., Rabinowitz et al 1985)
- One of the studies cited in the proposal, and published since 1986 CD, reported on air blood Pb levels near a smelter and reported a reduction in blood Pb levels in response to significantly reduced air Pb levels of 3-month duration. (Hilts, 2003)
- A dustfall study described in CD reported a relatively rapid response of indoor dust Pb loading to ambient airborne Pb, on the order of weeks.[3] (Caravanos et al., 2006)

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[2] The young ages at which effects have been observed further indicate the significance of exposures shorter than a year (e.g., Tellez-Rojo et al 2006; Canfield et al 2003). Additional health evidence demonstrates the sensitivity of the early years of life and increased vulnerability to specific types of effect during some developmental periods (e.g., prenatal), the length of which indicates an importance of exposures much shorter than annual.

[3] Similarly, one of the commenters (Doe Run Resources Corp.), in comments submitted on the ANPR, stated that "… due to the short residence time of dust in a house (on the order of months rather than years), it is unlikely that

- Dust Pb modeling analyses performed as part of the quantitative risk assessment provide an estimate of approximately four months as the time over which an increase in air Pb will reach 90% of the final steady state change in indoor dust Pb. (USEPA, 2007b)
- A study of changes in air, dust and blood Pb levels associated with smelter Pb emissions reports dust Pb levels, in terms of quarterly averages which show temporal variability by as much as a factor of 3 from quarter to quarter. (Hilts, 2003)

EPA further notes that the commenters' conclusion that the IQ loss estimates from the risk assessment pertain to annual average standard levels is not accurate. The risk assessment provided IQ loss estimates associated with just meeting the current and alternative standards with maximum quarterly or maximum monthly averaging times/forms. It did not include any assessment of just meeting alternative standards with an annual averaging time.

EPA did use relationships from air quality monitoring data between annual average Pb concentrations and maximum quarterly or maximum monthly average Pb concentrations in conducting these risk assessments because the blood Pb model used in the assessment does not accept air quality inputs of a temporal scale shorter than a year. Such air quality factors were used as a method for obtaining an annual average air Pb concentration (for input to the blood Pb model) that might be expected to be associated with just meeting the quarterly or monthly standards being assessed, to reflect the variability in air Pb concentrations that occur over time scales less than a year as a result of temporal changes in meteorology and source and emission characteristics. Commenters misinterpreted EPA's use of such factors as implying that the risk assessment results pertained to annual average standards at the alternate levels assessed. Based on that misinterpretation, the commenters stated that EPA needed to use such air quality factors to "adjust" the level of the standard to reflect a quarterly or monthly averaging time. However, for the reasons stated above, no such adjustment would be appropriate. EPA further notes that the use of such factors in the exposure simulation in the risk assessment is completely distinct from and unrelated to the evidence with regard to the duration over which air Pb concentrations contribute to health effects, which is the consideration pertinent to selecting the averaging time for the standard.

(3) *Comment:* Several commenters stated that the record does not support setting a NAAQS for Pb of zero in this review. Some of these commenters further stated that they agree with EPA's interpretation that the CAA does not require EPA to establish a "risk-free" standard, and stated that this interpretation is consistent with Congress' intent in enacting these provisions of the CAA and with case law interpreting the CAA.

Response: EPA agrees that the current record does not support setting a NAAQS for Pb of zero in this review, and for the reasons discussed in the preamble the final standard is

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yearly average air lead levels are the best predictor of observed dust lead levels." In fact, the Doe Run Resources Corp. comment went on to recommend that a monthly average air Pb is a more appropriate predictor of dust Pb than an annual average air Pb.

not set at a level of zero. EPA appreciates the views of commenters on whether a zero, or risk-free, standard would ever be justified.

(4) *Comment:* Two commenters (Teck Cominco Alaska and Alaska Department of Environmental Conservation) indicated we should consider issues related to bioavailability in setting the NAAQS for Pb. More specifically, comments from Teck Cominco state that the chemical form of lead in the ore and concentrate from their Red Dog Mine, lead sulfide, has low bioavailability, that was considered in a risk assessment conducted by Teck Cominco through the use of a lower value for the absolute bioavailability input to the IEUBK model than the EPA default. Teck Cominco stated that EPA should develop a NAAQS for lead sulfide compounds that reflects a lower bioavailability of these compounds, however, they did not provide specific suggestions for such standards. The Alaska Department of Environmental Conservation (ADEC) suggested EPA study toxicity and bioavailability of Pb to see if some forms of Pb should be addressed more urgently than others, noting concern with ore dust that "might be considered of low bioavailability but over time … becomes more bioavailable" and noting that there are many old mine sites in Alaska around which Pb may have relatively high bioavailability.

Response: EPA recognizes the points made by both commenters. As discussed in the Criteria Document (e.g., CD, section 4.2.1), the form of lead in soil can affect Pb solubility in the gastrointestinal (GI) tract and potentially absorption from the GI tract. The potential for absorption (or bioavailability) of ambient Pb can vary among Pb from different sources and the bioavailability of ambient Pb (e.g., from the same source), once released to the environment, can vary over time. For example, the bioavailability of galena, the term for commonly mined Pb ore which contains Pb sulfide, may be somewhat low upon initial release into the environment (CD, section 4.2.1), but there is information indicating a much higher bioavailability after some time in soil (USEPA, 2006b ; Casteel 2005). EPA notes that, particularly in light of evidence indicating changes in Pb sulfide bioavailability over time, the current air quality criteria do not provide a basis for setting a separate NAAQS for Pb sulfides based on bioavailability. EPA also notes that the NAAQS are set with applicability to all ambient air in the U.S., such that the primary Pb standard provides protection in areas across the U.S., regardless of site-specific Pb aspects. In considering the evidence on air-related Pb and associated health effects, EPA recognizes variability in the oral absorption of air-related ambient Pb that stems from multiple factors, including but not limited to bioavailability of different forms of Pb in different matrices. Other factors include those related to behavioral, physiological and dietary characteristics of the exposed public. EPA considered the variability contributed by all of these factors in setting the primary Pb standard that is requisite to protect public health with an adequate margin of safety.

(5) *Comment:* One industry commenter (Teck Cominco Alaska) stated that "the proposed NAAQS for lead assumes that all ambient lead is the result of anthropogenic activity" and that EPA should consider levels of naturally occurring Pb when setting the NAAQS. In support of their statement, the commenter states that naturally occurring lead in soil,

resulting from "surface exposure of mineralized rock" "can be released into the atmosphere … during higher wind conditions".

Response: Consistent with EPA's past practice, EPA considered as part of the risk assessment those risks associated with naturally occurring levels of Pb in ambient air. Accordingly, information regarding airborne Pb resulting from natural sources, including windborne soil particles from areas free of anthropogenic activity, is discussed in the Staff Paper (section 2.5) and the proposal (section II.A.3), and is briefly summarized in section II.A.1 of the preamble for the final rule. This information has lead EPA to conclude that such nonanthropogenic Pb in air (i.e., on the order of 0.00005 $\mu g/m^3$) is insignificant, particularly in comparison to the contributions from exposures to nonair sources. In support of their view on this issue, the commenter did not provide any estimates (e.g., of air Pb concentrations in areas where naturally exposed, naturally occurring Pb in the earth may contribute to atmospheric air Pb) in contradiction to EPA's characterization. EPA notes that issues of nonanthropogenic contributions to ambient concentrations may be relevant to implementation (e.g., exceptional events), but are not part of the evidence-based approach used as the primary focus in setting the standard.

ii.   *Comments on Public Health Policy Goal*

Comments were received on various aspects of the public health policy goal proposed for use with the air-related IQ loss evidence-based framework. These comments are described and addressed in section II.C.3.b of the preamble to the final rule.

(1) *Comment:* One industry commenter (ILZRO) disagrees with EPA's focus on IQ loss. They state that the argument that blood Pb in a population "will decrease the number of gifted children and increase the number of children with low intelligence", is misleading and incorrect, stating that "IQ scores merely assign ordinal rankings to individuals within society. There is no 'unit of cognitive function' attached to an IQ point - it is merely an indication of an individual's performance on the IQ test relative to expected societal norms…". The commenter goes on to note that "This is not to say that there may be no adverse impact of lead exposure from a societal perspective, but it is difficult to evaluate or define in a quantitative fashion." They also state that they offer no alternatives to the use of IQ.

Response: While EPA recognizes that IQ represents a relative ranking of individuals compared to a mean performance of the study population on one or more of several standardized tests of intelligence, EPA disagrees with the commenter that shifts in the intelligence of a population do not have significant implications on the number of gifted and handicapped children. In this case EPA recognizes IQ response to blood Pb as a useful, well studied, quantitative metric reflecting impact on neurocognitive function and neurodevelopment. Further, EPA considers it an appropriate metric for consideration of a public health policy goal for the NAAQS. For example, in discussing the public health significance of Pb-related IQ impacts, the Criteria Document stated the following:
> *In regard to neurodevelopment, although a two- or three-point decline in*
> *IQ might not be consequential for an individual, it is important to*

recognize that this figure represents the central tendency of the distribution of declines among individuals. Thus, some individuals might manifest declines that are much greater in magnitude, while others manifest no decline at all, reflecting interindividual differences in vulnerability. Moreover, the import of a decline for an individual's well-being is likely to vary depending on the portion of the IQ distribution. For an individual functioning in the low range due to the influence of developmental risk factors other than Pb, a Pb-associated decline of several points might be sufficient to drop that individual into the range associated with increase risk of educational, vocational, and social failure.

(2) *Comment:* In objecting to EPA's focus for the air-related IQ loss framework on population mean, one commenter stated that EPA did have the means to focus on a higher percentile of the population. In support of this view, the commenter stated that the findings of the performance evaluation performed by EPA on the blood Pb estimates indicated that upper percentile blood Pb estimates in the risk assessment compared well with NHANES estimates, thus indicating that EPA has methods (e.g., use of GSD as was done in the risk assessment) that might be used to derive upper percentile estimates of air-related IQ loss using the evidence-based framework. Additionally, this commenter suggested that EPA consider using the upper bounds of the confidence intervals for the concentration-response slopes.

Response: EPA agrees with the commenter that the total blood Pb estimates for the 95th percentile in the general urban case study were found to compare well to the NHANES IV data, providing some confidence in our ability to estimate total blood Pb (as described in section 3.5.2.3 of the Risk Assessment Report). EPA notes, however, that it is estimates of air-related blood Pb (and air-related IQ loss) with which we are concerned in the context of the air-related IQ loss evidence-based framework. As noted in the proposal (sections II.C.2.h, II.C.3.a and II.C.3.b), EPA recognizes limitations in the data and methods on which to base estimates for the air-related component of total blood Pb and associated IQ loss at the upper percentiles, and, accordingly, greater uncertainty in such estimates. EPA disagrees with the commenter's suggestion to use confidence intervals (CIs) associated with the concentration-response functions or slope for the models reported in the epidemiological studies to provide some sense of the magnitude of air lead-related IQ loss for upper percentiles of the subpopulation exposed at a level of the standard. EPA notes that the 95% confidence interval of the slope parameter specifies the range of estimates for the slope within which the true value for the study population is projected to lie with 95% confidence, based on use of a two-sided t-test of no effect at the 5% significance level given the model assumptions are true. We note that the 95% confidence interval represents a characterization of uncertainty associated with the best estimate of the slope for the study population, not the uncertainty for the 95th percentile of the population. The upper range of the 95% confidence interval for the concentration-response coefficients does not reflect the effect estimate for air-related blood Pb levels on IQ loss for the subpopulation that is more greatly affected (i.e., upper percentile estimates), as the commenter has implied. Rather, the size of the confidence

intervals in the epidemiological studies represent factors specific to those studies, including study population size, blood lead measurement error, collinearity of covariates, as well as the variability of the association between total blood Pb levels and IQ loss. Thus, the 95% confidence intervals reflect several other variables specific to the study design which are unrelated to the upper percentile estimates of air lead-related IQ loss.

(3) *Comment:* Some commenters stated that EPA should take into account the effects of total Pb exposure on children when setting the public health goal for a revised NAAQS (MO Coalition, p15). They note that, "Because a child may already experience significant IQ loss and other neurocognitive effects due to non-air lead exposures, the effects due to air-related lead exposures are of even greater significance."

Response: EPA acknowledges that a segment of the exposed population may experience blood Pb levels that are significantly higher than typical levels in the U.S. due to exposure to non-air related sources of Pb and that these children may experience degrees of IQ loss greater than the average U.S. child due to this exposure. However, EPA disagrees with the commenter that the impacts of air-related exposure will be even greater for children with significant non-air related Pb exposure. In the case of the child who experiences significant exposure to Pb due to non-air sources in addition to ambient air-related Pb exposure (producing a relatively larger total Pb exposure), the IQ loss for each increment of air-related Pb exposure will likely be less than it is for a child with lower total Pb exposure. This phenomenon reflects non-linearity in the relationship between IQ loss and blood Pb (with greater incremental IQ loss occurring at lower blood Pb levels). For this reason, given a focus on ambient air Pb exposure and risk, it is appropriate for the evidence-based framework to focus on children with total Pb exposure closer to the current U.S. average, since these children will have greater response to each increment of air-related Pb exposure than would children with higher overall blood Pb levels.

iii.   Comments on Air-to-blood Ratio

Several commenters (e.g., NACAA, NRDC, CHPAC) recommend greater weight be given to CASAC's advice supporting use of a ratio above the proposal range (e.g., closer to 1:9 to 1:10), some commenters (e.g., NESCAUM, New York Department of Health [NY DOH]) recommend use of a ratio at the upper end of the proposal range (i.e., 1:7), and three industry commenters indicate support for the proposal range (1:3 to 1:7), with one commenter identifying 1:5 as supported by the "weight of the scientific evidence" (Doe Run Resources Corp.). These comments are described and addressed in section II.C.3.b of the preamble to the final rule.

(1) *Comment*: A number of commenters (e.g., CHPAC, NACAA, NY DOH, Physicians for Social Responsibility, NRDC) recommended that EPA consider estimates of air-to-blood ratios higher than the range in the proposal (which was 1:3 to 1:7), citing evidence of estimates ranging up to 1:16 (NRDC). In support of higher ratios, one commenter (NY DOH) cites Schwartz and Pitcher (1989) as suggesting a ratio of approximately 1:9 reflecting all air Pb exposure pathways. This commenter also cites ratios up to 1:8.5 from the Brunekreef et al., (1984) meta-analysis of studies that included adequate quality

control measures and adjustment for co-variates. Several commenters also cite the exposure and risk assessment as providing support for air-to-blood Pb ratios up to 1:9 and higher (NY DOH, NRDC). Several commenters (e.g., NACAA, NRDC, CHPAC) also recommend that greater weight be given to CASAC's interpretation of evidence which supports use of ratios above the proposal range (e.g., closer to1:9 to 1:10), particularly noting today's lower air and blood Pb levels. Some (e.g., NESCAUM, NY DOH) recommend the upper end of the proposal range (1:7) as being well supported by the evidence or as representing the middle of a supportable range.

Response: EPA generally agrees with commenters regarding the evidence of air-to-blood ratios ranging up to approximately 1:10. Specifically, we recognize that a number of studies identified by the commenters including Schwartz and Pitcher (1989) and Brunekreef et al., (1984) support higher air-to-blood Pb ratios in the range of 1:7 to 1:10, while also reflecting key study design elements (i.e., quality control measures and adjustment for co-variates) that increase our confidence in the air-to-blood Pb ratios supported by these studies. Regarding the Hayes et al. (1994) study in particular, while EPA agrees that the study, also cited by CASAC, presents an air-to-blood ratio greater 1:10, we are not relying on this study in our decision as it has not been reviewed as part of the air quality criteria (as described in Section I.C of the preamble). We also agree that the risk assessment provides support for higher air-to-blood Pb ratios (in the range of 1:7 to 1:10). We also note, that these ratios from the risk assessment reflect blood Pb response to changes in a subset of air-related pathways (with all nonair and some air pathways held constant) and accordingly would not be affected by nonair blood Pb confounding and might have been higher if all air-related pathways were assessed.

(2) *Comment:* Three industry commenters indicate support for proposal range (1:3 to 1:7), with one identifying 1:5 as supported by "weight of the scientific evidence" (Doe Run Resources Corp.). One of the commenters also asserts that the upper end range for the air-to-blood ratios should be 1:6 to 1:8 and not 1:10 or higher.

- One commenter (ABR) asserts that the approach used by CASAC in deriving an air-to-blood ratio of 1:9 to 1:10 based on Schwartz & Pitcher (1989) utilizes a flawed method to relate gasoline usage to ambient air Pb levels. The commenter offers an alternate approach for deriving a ratio based on Schwartz and Pitcher (1989). The commenter's approach utilizes a regression relating gasoline usage to ambient air Pb levels that is derived from data presented in the 1986 AQCD for Pb and results in an air-to-blood ratio of 1:7.8.

- One of the commenters (ABR) asserts that Pb emissions from gasoline may behave differently in terms of the relationships between air Pb, Pb deposition and blood Pb, serving to overestimate air-to-blood Pb ratios, relative to what is found with other sources of Pb in air. In supporting this assertion, the commenter cites Hayes et al. (1994) and states that that study reports no significant relationship between air Pb and blood Pb when time is included as a variable. They also point to Brunekreef et al. (1983) and state that that study reports that deposition resulting from auto emissions was high when ambient air Pb levels remained low. The commenter concludes from this that there is a weak association between blood Pb and ambient air Pb resulting from leaded gasoline which

makes it inappropriate to use Schwartz and Pitcher (1989) to estimate an air-to-blood Pb ratio.

- Some industry commenters (ABR, ILZRO) disagreed with EPA's interpretation of the evidence of higher air-to-blood ratios. Specifically, they assert that the higher air-to-blood ratios reported in the literature (including those summarized in Brunekreef 1984) were derived without appropriate adjustment for nonair contributions to blood Pb and therefore may be biased high. One commenter (ILZRO) further stated that the higher ratios (e.g., at or near 1:10) are based on exposures scenarios "prone to exaggeration" due to confounding by changes in nonair exposures (e.g., Pb solder, Pb paint, and dietary Pb). Furthermore, one commenter (ABR) provided an analysis based on IEUBK blood Pb simulation intended to illustrate how a lack of adjustment for nonair contributions can produce higher air-to-blood ratios at lower blood Pb levels.

- Two commenters (Association of Battery Recyclers and Doe Run Resources Corp.) also suggested that the air-to-blood ratios presented in the risk assessment are over-stated due to underlying errors in the indoor dust models used to model both the urban case studies and the primary Pb smelter (subarea) case study. These comments are addressed in Section II.A.4 below.

Response: The alternate approach advanced by one commenter related to air-to-blood Pb ratio calculations combines the same factor relating blood Pb and gasoline usage (from Schwartz and Pitcher, 1989) used by CASAC (Henderson, 2007a) with a regression model relating gasoline usage and ambient air Pb levels (by quarter) to derive the air-to-blood Pb ratio. EPA considers both the CASAC approach and the alternate approach presented by the commenter to generally represent conceptually sound strategies for translating the relationship between gasoline usage and blood Pb (provided in the Schwartz and Pitcher, 1989 study) to air-to-blood Pb ratios. In addition, EPA notes that both approaches support air-to-blood ratios in the range of 1:7 to 1:10.

Regarding the assertion by the commenter that there is a weak association between blood Pb and ambient air Pb derived from gasoline Pb, which makes it inappropriate to rely on a ratio derived from Schwartz and Pitcher (1989), EPA disagrees with the commenter's view, noting that the body of evidence regarding this relationship is robust (e.g., USEPA, 1986, sections 11.3.6 and 11.6). As stated in the 1986 Criteria Document, "there is strong evidence that changes in gasoline lead produce large changes in blood lead" (USEPA, 1986, p. 11-187). We additionally recognize CASAC's acceptance of this study and note commenters' use of this study to independently derive a ratio of approximately 1:8.

Specifically regarding the commenter's assertion that the Hayes et al., (1994) study shows that a significant relationship does not exist between air Pb and blood Pb when time is included as a variable in regression modeling, EPA notes that Hayes et al. (1994) clearly states: "the overall decline in blood lead levels is associated with a corresponding decline in air lead levels, and average air lead levels by quarter are highly correlated with median blood lead levels by quarter…". While the addition of a sequentially ordered variable for each quarter did remove the statistically significant association between air Pb and blood Pb, the authors clearly note that they believed this provided additional

support for the role of Pb in dust, soil and food (contributed by gasoline Pb emissions) in determining overall blood Pb, as compared with direct inhalation alone (Hayes et al 1994). EPA notes, however, that it is not relying on this study for an estimate of air-to-blood ratio (as discussed in section II.C.3.b(iii) of the Preamble to the final rule) . In questioning the linkage between gasoline-related ambient air Pb and blood Pb, the commenter also points to Brunekreef et al. (1983) as showing that, while there are high levels of deposition associated with gasoline Pb emissions, ambient air Pb levels are low, pointing again (in their interpretation) to the unusual dynamics of gasoline Pb emissions. However, Brunekreef et al. (1983) describe a number of factors, which could account for the lower ambient air Pb levels seen in the suburban and urban study areas, including the ambient air Pb measurement methods, location of the study areas, wind conditions, and topography. These factors may make the air-to-blood ratios reported in this study more relevant to areas similar to those in the study. However, EPA does not believe that these factors call into question the well-established linkage between gasoline Pb and ambient air Pb, or argue for considering gasoline Pb to represent a fundamentally different type of ambient air Pb source, compared with other potential air Pb sources.

EPA disagrees with the comment that studies providing higher air-to-blood ratios (in the range of 1:7 to 1:10) do not include control for potential confounders to blood Pb. As noted in the proposal (section II.B.1.c) and in the 1986 Criteria Document, Brunekreef et al. (1983) provides an air-to-blood Pb ratio of 8.5 that has been adjusted for a variety of factors, including nationality, age, drinking water, milk consumption-calcium intake, house age, number of rooms (crowding), paint status in home, parental education, parental job attainment/income, mouthing behavior, pets, parent occupation/hobbies related to Pb exposure, and geographic area. Additionally, Schwartz and Pitcher (1989) addresses the issue of potential confounding, by providing evidence that reductions in children's blood Pb were directly associated with decreases in the use of leaded gasoline and not by simultaneous decreases in exposure to Pb paint, Pb in drinking water or dietary Pb. A more recent study described in the proposal (Hilts, 2003) includes an analysis that provides control for potential confounders, including alternate sources of Pb exposure, through study design (i.e., by following a similar group of children located within the same study area over a period of time). In addition, this study was conducted at a time (late 1990's through 2001) after the period when significant reductions in non-air Pb (e.g., solder used in cans) had taken place, thereby reducing the potential for temporal confounding by these non-air sources of Pb exposure. The study authors report a ratio of 1:6 from this study (Hilts, 2003) and additional analysis of the data by EPA for the initial time period of the study resulted in a ratio of 1:7.

Regarding the IEUBK-based analysis submitted by the commenter that they assert illustrates the potential for confounding by non-air related Pb sources in deriving air-to-blood Pb ratios. EPA agrees that this analysis illustrates the potential for confounding when air-to-blood ratios are derived based on total blood Pb without attempting to determine the fraction of total blood Pb that results from air-related Pb. It is specifically for this reason that, in selecting studies to inform the identification of an air-to-blood Pb ratio range, EPA focused on studies that address this issue of potential confounding by nonair Pb sources (see previous paragraph). In addition, in obtaining air-to-blood Pb

ratios from the risk assessment, EPA has also focused on identifying the fraction of total blood Pb that is specifically related to air Pb and excludes non-air related Pb to the extent feasible given the design of the analysis.

Lastly, EPA disagrees with the comments that air-to-blood ratios derived from the risk assessment may be overstated due to errors in the dust Pb models employed. As discussed more fully in section II.A.4 below, the dust Pb models used in the risk assessment for the different case studies were derived from available data for Pb in house dust for the different scenarios. While (as discussed in section II.A.4 below) EPA recognizes limitations in the models, EPA disagrees with the commenters conclusions that these limitations result in consistent bias in resultant dust Pb estimates.

In summary, EPA believes that the evidence supports consideration of ratios ranging up to approximately1:10 and that the results of the risk assessment add further support to this air-to-blood ratio range.

iv.   *Comments on Concentration-Response Function for IQ Loss*

The majority of commenters, which include public health organizations, national organizations of air pollution control agencies, environmental organizations, and state, tribal and local health and environmental agencies recommend the use of C-R function slopes from analyses of children with lower blood Pb levels, with some of these additionally suggesting alternate approaches to identifying the most relevant slopes. Industry commenters recommend use of the median value from the second set described in the proposal. These comments are described and addressed in section II.C.3.b of the preamble to the final rule. Specific aspects of these comments not discussed in the preamble are described and addressed below.

(1) *Comment:* A few industry commenters (ILZRO and ABR) state that EPA's conclusion of a nonlinear dose-response relationship between blood Pb concentrations and neurobehavioral or cognitive effects (e.g., IQ) is inappropriate because the supralinear behavior of the relationship between the lognormally distributed variable (blood Pb concentration) and the normally distributed variable (IQ) may simply reflect the expected statistical outcome of regression analyses between such distributions. One industry commenter (ILZRO) states that smaller number of observations at lower blood Pb levels exerts extra influence on shape of function. In support of their views, commenters variously cite Bowers and Beck (2006, 2007a, 2007b).

Response: This comment reflects the conclusions stated by Bowers and Beck (2006) in a theoretical analysis examining the relationship between blood Pb and IQ. This theoretical analysis inversely matched complementary percentiles of a lognormal distribution of blood Pb concentrations with a normal distribution of IQ (e.g., matched the 90th percentile blood Pb concentration with the 10th percentile IQ), which resulted in a perfectly supra-linear relationship between blood Pb levels and IQ as would be expected from their methodology. The authors concluded that "we expect to see the supra-linear IQ-blood lead slope in all such studies because it is a requirement of the shape of the blood lead concentration and IQ distributions" (Bowers and Beck, 2006).

Multiple comments on this analysis have been published. Critiques of this analysis addressed the appropriateness of matching complementary percentiles; the assumption of normality for the IQ data, IQ covariates, and the IQ effects of Pb; and Bower's and Beck's interpretation of their analysis (Hornung et al., 2006; Jusko et al., 2006; Bergdahl, 2006, 2007; Svendsgaard et al, 2007).

A discussion of the original Bowers and Beck paper and some of the published comments on that analysis was presented in the Criteria Document (section 8.5.1). This discussion notes that the analyses of Bowers and Beck (2006) are based on several assumptions, including that the blood Pb concentrations are log-normally distributed, the IQ values are normally distributed, and that the two distributions have an inverse relationship. The CD states that, while the conclusions drawn by Bowers and Beck may be true under these specified conditions, the authors' assumptions are not generally met in epidemiologic analyses, as is described using the example of the Lanphear et al. (2005) pooled analysis.

In their response to the comments noted above that were published after the Criteria Document was completed, Bowers and Beck (2007b) clarified that "our primary point remains that modeled (not true) supralinear dose-response relationships are an expected outcome of the type of analysis done in epidemiological studies, and are not, in themselves, evidence of non-linear dose-response biological mechanisms." Further, they stated that the main point of their original publication "was that there are instances where the statistical constraints imposed by the distributional properties of blood lead concentration data and IQ data do form the basis for the shape of the dose-response relationship and one should not automatically eliminate this possibility in the interpretation of non-linear dose-response relationships that are found" (Bowers and Beck, 2007a).

In conclusion, EPA finds that the analysis conducted by Bowers and Beck is too theoretical and narrow to contribute significantly to the interpretation of the epidemiological literature on the relationship between blood Pb concentrations and neurocognitive effects. EPA agrees with Bowers and Beck regarding the need to carefully interpret epidemiological findings, and has done so in the formulation of conclusions in the Criteria Document by considering all the available relevant literature on this matter.

(2) *Comment:* One commenter from an industry group implies that EPA's conclusion of supralinearity in the Pb-IQ loss C-R function is based on a linear slope reported by Lanphear et al. (2005) for the analysis of children with blood Pb levels that never exceeded 7.5 ug/dL (ILZRO). The commenter further states that EPA has not considered conclusions of others such as CDC with regard to the Lanphear et al. (2005) study findings.

Response: In considering these comments, EPA notes that the conclusion in this review with regard to the nonlinear relationship between IQ loss and blood Pb is not based on a single analysis. The Criteria Document contains an extensive discussion on the body of evidence indicating the occurrence of steeper C-R slopes for IQ loss with lower blood Pb

levels (CD, sections 6.2, 6.10 and 8.5.1). In several studies with cohorts of children with
varying population mean blood Pb levels, a trend of steeper C-R slopes for IQ loss with
lower blood Pb levels has been observed. In addition, in other studies which compared
C-R slopes below and above a blood Pb level cutoff point (generally 10, 7.5, or 5 µg/dL)
within the study cohort, steeper C-R slopes were observed below the cutoff point. EPA
also notes the strong evidence provided by the pooled international analysis of 1333
children by Lanphear and others (2005), supported by further analyses by Rothenberg
and Rothenberg (2006), which is discussed in the Criteria Document (CD, section
6.2.13). In this analysis, various models, including the linear model, cubic spline
function, the log-linear model, and the piece-wise linear model, were investigated. The
shape of the C-R relationship was determined to be nonlinear, with the log-linear model
providing a better fit for the data compared to the linear model. The additional analysis
of that data set which segregated data based on peak blood Pb levels above and below 7.5
µg/dL, also indicated significantly greater incremental Pb-associated intellectual
decrement for children with maximal blood Pb levels below 7.5 µg/dL compared to those
with maximal blood Pb levels at or above 7.5 µg/dL, providing further support for the
conclusion of nonlinearity. In considering the evidence with regard to nonlinearity, we
have explicitly considered the CDC review mentioned by the commenter (CD, pp. 6-64
to 6-65), noting the conclusion of the CDC review regarding the weight of evidence
support for "an inverse association between blood Pb levels <10 µg/dL and the cognitive
function of children" and the limitations recognized by the CDC review with regard to
the available studies that specifically examined the effect of blood Pb levels <10 µg/dL.
Further, as noted in the Criteria Document, there have been multiple studies published
since the CDC review that evaluate the effect of blood Pb levels <10 µg/dL, reducing
concern for the potential limitations cited by CDC.

(3) *Comment:* A few industry commenters (e.g., ILZRO) state that estimates of effects at blood
Pb levels less than 10 µg/dL are inherently unstable due to relatively limited size of study
populations. In stating this view, the commenter focuses on the pooled international
analysis by Lanphear et al (2005), noting the relatively smaller number of observations in
that dataset with concurrent blood Pb levels below 10 µg/dL as compared to above 10
µg/dL . They additionally note that most of the children in this less than 10 µg/dL group
are from the Rochester cohort and none are from the Port Pirie, Australia cohort, stating
that the differential contributions from the cohorts to the lower blood Pb component of
the full dataset weakens conclusions made with regard to lower blood Pb levels. Further,
they state that as most of the population in the full pooled dataset has much higher blood
Pb levels, that portion of the population somehow serves to inflate the correlation
coefficient (r^2) and reduce p-values and also reduce confidence intervals for the model
coefficients (beta estimates).

Response: As indicated in the previous response, EPA notes that the conclusion in this
review with regard to the nonlinear relationship between IQ loss and blood Pb is not
based on a single analysis, but rather based on the full body of evidence. The steeper C-
R slopes for IQ loss with lower blood Pb levels are observed both across different studies
with cohorts of children with varying population mean blood Pb levels and within studies
which compared slopes below and above a blood Pb level cutoff point. In response to the

specific comment that the C-R slope estimates from the low blood Pb level subset of the Lanphear et al. (2005) study is due to the varying contributions from the seven different cohorts, EPA notes that the Lanphear et al. (2005) study had conducted sensitivity analyses to examine the stability of their models. First, they evaluated the results of applying a random-effects model (with sites random) rather than a fixed-effects model. Lanphear et al. (2005) observed that results from the random-effects model compared to the fixed-effects model (only a 3.7% difference) suggested that there was little heterogeneity in effects across the different sites. Second, they examined the effect of any one site on the overall model by calculating the blood Pb coefficient after omitting each one of the seven cohorts at a time. Once again, there was little change in the blood Pb coefficient (ranging from a 2.6% decrease to an 8.9% increase), providing further evidence of the stability of the model and indicating that the results of the pooled analysis did not depend on the data from any single study. Therefore, EPA does not agree with the commenter that the data in the Lanphear et al. (2005) study were used inappropriately, resulting in inflated r^2 values and significance levels.

(4) *Comment:* A few commenters (e.g., ILZRO, ABR, BCI) cautioned against relying on Lanphear et al. (2005), particularly the slope estimate from the subgroup analysis which included children whose maximal blood Pb levels were below 7.5 µg/dL. They state that the slope from this analysis, which is the high end of first set of "steeper" slopes identified in the proposal, is an "outlier". That is, the commenter stated that the linear slope for the relationship of IQ with blood Pb levels from the Lanphear et al. (2005) analysis of children whose maximal blood Pb levels did not exceed 7.5 ug/dL should not be considered in identifying an estimate for the concentration-response relationship between blood Pb and IQ. The commenter notes that the sample size for this analysis included only 103 children, with majority representation (~67%) from the Rochester cohort and minority representation from the Boston and Yugoslavia studies.

Response: While EPA recognizes that the slope from the analysis of children with peak blood Pb levels below 7.5 ug/dL is notably higher than slopes from other analyses involving children with somewhat similar blood Pb levels, EPA disagrees with the commenters' view regarding the analysis supporting this slope (see response to previous comment). Further, in identifying a C-R slope for use with the air-related IQ loss evidence-based framework, EPA has relied on consideration of the four slopes from four different analyses from four different studies of children with blood Pb levels closest to those in the U.S. today, as described in section II.C.3.b of the preamble. The analysis from Lanphear et al. (2005) of children with peak blood Pb levels below 7.5 ug/dL is included among these four analyses. Given the general similarity of the blood Pb levels in these four analyses, EPA concludes that it is not appropriate to single one slope out, but rather has given equal weight to the full group. As described in section II.C.3.b of the preamble, the median from these slopes (1.75 IQ points loss per 1 µg/dL blood Pb) is used to avoid undue influence from any one study.

(5) *Comment:* A few industry commenters state that confounders can contribute to "the exaggeration of an observed non-linear slope to the concentration-response curve" (ABR, p. 13). They cite the CDC (2005) analysis in support of this point. One commenter

(ILZRO) additionally states that the handling of confounders in Lanphear et al. (2005) contributes to exaggeration of the slope in the nonlinear model reported by those authors.

Response: Some commenters have indicated that residual confounding may have contributed to the non-linear C-R relationship between blood Pb levels and IQ. The CDC work group provided a hypothetical example in which this may be the case. In their hypothetical example, children in a high exposure setting and children in a low exposure setting experienced the same absolute change in IQ associated with an unidentified factor. In the high exposure group, this change in IQ was observed across a change in blood Pb level from 10 to 20 ug/dL while in the low exposure group, this change in IQ was observed across a change in blood Pb level from 1 to 2 ug/dL. As the work group explains, the IQ loss-blood Pb slope derived in this hypothetical scenario is steeper in the lower blood Pb level setting than in the higher blood Pb level setting. One interpretation of how such an example might occur is that there is a change in IQ attributable to an unidentified factor that is the same regardless of the distribution of the blood Pb levels. This implies that the unidentified factor is not related to the exposure of interest (i.e., blood Pb levels) and therefore cannot be a confounder of the relationship between IQ and blood Pb levels.[4] Another interpretation of this example is that the impact of confounding is uneven along the distribution of the blood Pb levels. The only situation in which an unidentified factor would contribute to the log-linear C-R relationship observed between IQ and blood Pb levels is if this factor has a linear relationship with IQ but a non-linear relationship with blood Pb levels. Examples of such factors are unknown. Given that the non-linear relationship was observed in several different studies that adjusted for various different potentially confounding factors (e.g., home environment, parental IQ, parental education, indicators of SES, birth weight), it is unlikely that the non-linear relationship is solely driven by residual confounding. A related comment states that the handling of confounders in Lanphear et al. (2005) contributed to the exaggeration of the non-linear C-R function. The Lanphear et al.(2005) analysis initially examined ten factors individually and in combination with the other covariates to assess potential confounding of the relationship between IQ loss and blood Pb levels. Consideration was given to the stability of the parameter estimates as each additional term was added. For the final multiregression model, five covariates were chosen: site, HOME score, birth weight, maternal IQ, and maternal education. The addition of child's sex, tobacco exposure during pregnancy, alcohol using during pregnancy, maternal age at delivery, marital status, and birth order were not found to alter the effect estimate. Therefore, EPA does not agree that the non-linear C-R function in the Lanphear et al. (2005) study was due to the methodology used to select and adjust for potential confounders.

(6) *Comment:* Some industry commenters (e.g., ABR, ILZRO) disagree with EPA's interpretation of the evidence for nonlinearity, particularly for blood Pb levels below 10 µg/dL, stating that some studies (e.g., studies by Tellez-Rojo et al. [2006], Jusko et al. [2007] and Surkan et al. [2007]) do not provide statistical support for the existence of a

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[4] For something to be a confounder, it must be related to both the outcome of interest (IQ in this case) and the exposure of interest (blood Pb level), regardless of whether the exposure of interest is related to the outcome of interest. A confounder can either make it seem like there is a relationship between the outcome and exposure when there isn't at all, or make the relationship seem stronger or weaker than it actually is.

nonlinear C-R function. In making this comment, commenters additionally state that, contrary to the statement by CASAC in their July 2008 letter to EPA, Surkan et al. (2007), Jusko et al. (2007), and Solon et al. (2008) do not provide support for steep C-R function at low blood Pb levels or evidence of statistically significant nonlinearity at low blood Pb levels. They further state that the study by Solon et al. (2008) focused on children which are chronically malnourished making them more susceptible to neurodevelopmental effects and making this study inappropriate to this U.S. context. Further, with regard to Solon et al (2008), one commenter (ABR) states that the reported risk estimate must be the result of error.

Response: First, EPA notes that, as with all NAAQS reviews, we have considered the evidence in this review as a whole, and in assessing findings of individual studies, we consider them within the context of the larger body of evidence. Further, we note that three of the four studies cited by these commenters were published subsequent to the completion of the Criteria Document. We have provisionally reviewed these studies in conjunction with other relevant recent studies, published since 2006 and identified in routine review of journals, (e.g., Miranda et al., 2007 and Jusko et al., 2008)[5] in the context of the findings of the 2006 Criteria Document.

EPA disagrees with the comment that analyses by Tellez-Rojo et al. (2006), which are reviewed in the 2006 Criteria Document, do not support the general conclusion of nonlinearity in the relationship between IQ and blood Pb at low levels. This study observes a statistically significant loglinear relationship with blood Pb at 24 months in a group of children for whom the mean blood Pb is 4.28 µg/dL. Further, this study separately performed linear regression analyses on two subsets of the full dataset. From these analyses, the authors report a steeper slope for their study subgroup of young children with individual blood Pb levels below 5 µg/dL (n=193, for which the slope of -1.71 was statistically significant, p=0.01) than those with blood Pb levels between 5 and 10 µg/dL (n=101, for which the slope of -0.94 was not statistically significant, p=0.12). While these slopes were not found to be significantly different, EPA notes the consistency of the difference in slopes with the nonlinear relationship observed across the full data set. EPA also notes the similarity of the slope for children with blood Pb levels below 5 µg/dL, for which the mean blood Pb level is 2.9 µg/dL, and the slopes for other subgroups analyses for similarly low blood Pb levels. For example, the slope reported by Canfield et al. (2003) for children with peak blood Pb levels below 10 µg/dL (mean of 3.32 µg/dL) is -1.79 and that reported by Bellinger and Needleman (2003) for a similarly selected group of children (mean blood Pb level of 3.8 µg/dL) is -1.56. This is contrasted with the slope reported by Tellez-Rojo et al. (2006) for all children with blood Pb levels below 10 µg/dL (mean 4.28 µg/dL) of -1.04, and other analyses of subgroups with mean blood Pb levels between 7 and 10 µg/dL for which still lower slopes are reported (see CD, Table 8-7 and 6-1). Thus, EPA concludes that the findings of this study are consistent with and supportive of the conclusion of nonlinearity in the IQ loss-blood Pb relationship described in the Criteria Document, with this study providing particular

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[5] The complete list of studies on neurotoxic effects of Pb published subsequent to the Criteria Document that have been considered in light of these comments is provided in Appendix A.

support for this conclusion at low blood Pb levels (e.g., with analyses for mean and individual blood Pb levels below 5 µg/dL).

With regard to the study by Jusko et al. (2008; published after completion of the CD), EPA also disagrees with commenters. This study examined the relationship between blood lead levels and IQ loss in children followed from 6 months to 6 years of age. Their mean peak and concurrent blood Pb levels were 11.4 µg/dL and 5.0 µg/dL, respectively. They conducted categorical analyses that compared the difference in IQ scores for three categories of individual blood Pb levels, <5 µg/dL, 5.0-9.9 µg/dL, and ≥10 µg/dL. In the analyses of IQ loss with both peak and concurrent blood Pb, the authors observed a statistically significant decrease in full-scale IQ across the increasing blood Pb categories. Although mean blood Pb levels for the three categories are not reported, the mean concurrent blood Pb level across the complete data set was 5 µg/dL. We note that such categorical analyses, while supportive of the general conclusion regarding an inverse relationship of IQ with concurrent blood Pb, do not provide an assessment of the shape of the concentration-response relationship. The authors did examine the shape of the C-R function between IQ loss and peak blood Pb levels using individual-level data and observed a non-linear relationship. That is, they observed that the slope of the IQ loss-blood Pb relationship was steeper at lower than at higher peak blood Pb levels. Thus, while the shape of the C-R function for the relationship with concurrent blood Pb levels was not examined in this study, the nonlinear finding with regard to peak blood Pb levels is consistent with our conclusions of nonlinearity in the IQ loss blood Pb relationship.

With regard to the study by Surkan et al. (2007; published after completion of the CD), EPA notes that this paper does not include the type of analysis appropriate to draw conclusions regarding the slope or shape of the C-R function. Rather than an analysis of association across the full range of blood Pb levels studied, this study includes only a much less powerful categorical analysis in which the IQ scores are compared among three groups: children with blood Pb levels 1-2 µg/dL (n=286), 3-4 µg/dL (n=71) and 5-10 µg/dL (n=32). The paper reports a significant difference in full-scale IQ between children with blood Pb levels of 1-2 µg/dL and those with blood Pb levels of 5-10 µg/dL. Additionally, although a statistically significant difference in performance was reported between children with blood Pb levels 1-2 µg/dL and those with blood Pb levels 3-4 µg/dL on one of the IQ subtests (digit span) which has been shown previously to be affected by Pb, the authors did not find a significant difference in full-scale IQ between these two groups. This type of categorical analysis is highly sensitive to how subjects are grouped into categories. The small difference in the blood Pb levels in the two categories (only 1-2 µg/dL difference) likely contributed to this finding. In summary with regard to this study, however, EPA disagrees with commenters that it is contradictory to EPA conclusions of nonlinearity in the concentration-response relationship as it does not include analyses suitable to examine the issues regarding the shape of the concentration-response function.

The study by Solon et al. (2008; published after completion of the CD) focuses on children with somewhat higher blood Pb levels than those of the other two studies (mean of ~7) and examines the potential role of folate concentration in modifying the effect of

Pb on intelligence. The authors report a significant association of MDI scores with blood Pb levels, with a coefficient of -3.32 for this relationship for the theoretical case of a folate level of zero. Application of the mean folate level for the study (225 ug/ml) to this coefficient yields a coefficient for MDI of -1.07 IQ point loss per 1 μg/dL, a value comparable to coefficients reported for studies of similar blood Pb level children. Given this comparability, EPA disagrees with the commenter's view that the findings of this study are inconsistent with other studies within the body of evidence.

EPA also notes findings of other more recent studies not considered in the CD, which examined neurocognitive and neurobehavioral effects at low blood Pb levels. These include the study by Miranda et al. (2007), which observed a decline in reading and math scores at blood Pb levels down to 2 μg/dL. This study further found a non-linear relationship between blood Pb levels and these neurocognitive outcomes, i.e., steeper slope with lower blood Pb levels. Another recent study is that by Braun et al. (2006) which observed associations between individual blood Pb levels below 5 μg/dL and increased risk of attention deficit hyperactivity disorder. These two studies provide further evidence – among studies published subsequent to the Criteria Document - that other neurotoxic effects of lead are also observed at lower blood Pb levels, and also, in the case of Miranda et al. (2007) of a supralinear relationship between blood Pb and neurocognitive outcomes.

In summary, after consideration of the studies cited by commenters, EPA concludes that the more recent studies they cited provide only limited information with regard to the shape of the C-R curve and, in light of other recent studies and those reviewed in the Criteria Document, do not warrant reopening the air quality criteria for Pb to reconsider the evidence relied upon in this review of a nonlinear concentration-response relationship between blood Pb and IQ at blood Pb levels below 10 μg/dL. Having concluded that these more recent studies do not warrant reopening the air quality criteria review for Pb, EPA is not relying on them in this review for the reasons stated in the preamble (section I.C). Furthermore, EPA believes that the conclusion of nonlinearity is well founded in the evidence described in the Criteria Document.

(7) *Comment:* One industry commenter stated that the Lanphear et al. (2005) paper contains errors and cannot be relied upon (ABR pp. 10-11). For example, comments from ABR note an error regarding which EPA published a technical memo (Jan 26, 2007), describe a potential 2nd error in Table 4 of the paper that they note they cited in March 2008 comments to EPA, which they state has not been resolved, and also describe what they claim is a potential 3rd error regarding Figure 3 of the paper.

Response: EPA agrees with the commenter that two errors have been identified with regard to Table 4 in the Lanphear et al. (2005) publication. However, EPA notes the February 21, 2007 email from the R. Hornung, one of study authors, that is in the docket for this rulemaking, provides a corrected version of this table that addresses both of these issues. In addition, EPA identified typographical errors in two numbers associated with confidence intervals reported at the top of the 1st column on p. 897 of the publication, In reporting this information in the CD, EPA corrected these errors (CD, p. 6-70). Further,

none of the errors identified by EPA affect aspects of the study on which EPA has relied in this review.

EPA considers the commenters statements about Figure 3 to be without sound basis. Figure 3 illustrates the log-linear model for concurrent blood Pb level and IQ, along with the mean IQ and 95% confidence intervals on the mean for 5 subgroups of the full dataset. The commenters state that the confidence intervals shown in this figure are a function of sample size and they suggest that based on their interpretation of information in the paper for the sample size of the group with peak blood Pb levels below 10 µg/dL, the <5 µg/dL concurrent blood Pb level group is much smaller than the 5-10 µg/dL concurrent blood Pb, and accordingly the confidence interval bars should be much different in size. As the commenters state, the confidence intervals are a function of sample size, which is likely to differ notably among the study groups (although the authors do not report these sample sizes), however they are not simply a direct function of sample size. The standard deviation also affects the width of the confidence interval, and may vary in the different blood Pb categories. Thus, there is no basis to conclude that the confidence intervals displayed in Figure 3 are incorrect, although EPA's conclusions drawn regarding this study did not depend upon this figure. Additionally, in considering the Lanphear et al. (2005) publication, EPA notes the analysis by Rothenberg and Rothenberg (2005) of the same dataset. In the latter publication, the authors state that the data set "was analyzed with the original model specifications, including log-transformed BPb, using multiple regression analyses" and they obtained the same effect estimates for the loglinear model as those reported by Lanphear et al. (2005). These findings add to EPA's confidence in our consideration of the Lanphear et al. (2005) publication. Procedural concerns on this point raised by commenters and EPA's response are described in section V.A below.

(8) *Comment:* One commenter recommended use of a non-linear function to estimate IQ loss at different standard levels, stating that use of average linear slopes underestimate impact (NYDOH- pp. A-3 to A-4).

Response: When considering multiple changes in blood Pb level over a broad range of blood Pb levels, such as is done in the risk assessment, EPA notes that a non-linear function such as the log-linear model from Lanphear et al. (2005) may provide better estimates – across a broad range of blood Pb levels – than use of a single average linear slope.

However, for purposes of estimating IQ loss at the lower mean blood Pb levels that are of interest to EPA in considering estimated air-related IQ loss associated with the revised level for the standard, EPA has concluded that it is appropriate to utilize linear slopes derived directly from analyses with mean blood Pb levels near these levels. The median blood Pb level for the full Lanphear et al. (2005) pooled analysis is 9.7 µg/dL, which is substantially higher than the mean levels of interest. As the nonlinear model based on this data set is influenced by the full range of data points including those at the higher blood Pb levels, a linear slope derived from the low end of the log-linear model will necessarily not be as robust as a linear slope derived directly from data points in that

range. Accordingly, as described in section II.C.3.c of the preamble, in applying the evidence-based framework in consideration of a revised level for the standard, rather than relying on the Lanphear et al. (2005) log-linear C-R function, EPA has relied on the median of four analyses from four different studies for which the study group mean blood Pb levels were closest to the lower blood Pb levels of today's U.S. children.

v.   *Comments on Exposure and Risk Considerations*

With regard to considering how the quantitative exposure and health risk assessments should factor into a decision on the standard level, EPA notes that the comments generally fell into two groups, with one arguing that the risk assessment provided support for lower levels for the standard and the other arguing that the risk assessment indicated that substantial revision provided negligible public health benefit. These comments are described and addressed in section II.C.3.b of the preamble to the final rule and below.

(1) *Comment:* Some commenters (e.g., New York Department of Health, NRDC, MO Coalition for the Environment) state that more weight should be placed on the risk assessment in selecting a level for the standard and that the air-related risk estimates for both the median and 95th percentile of simulated populations support selection of a standard level at or below 0.2 μg/m^3. In support of this view, some commenters note CASAC support for the risk assessment. Additionally, one commenter asserted that EPA should not dismiss the results of the risk assessment for reasons of uncertainty, without stating why greater uncertainty is ascribed to the risk assessment than to the evidence-based framework (e.g., without a "transparent evaluation" of the relative uncertainties of the risk assessment vs. the evidence-based frameworks"). Several commenters (e.g., Physicians for Social Responsibility) also point to the IQ loss incidence results of the risk assessment as supporting a standard level at or below 0.02 μg/m3. In support of this view these commenters note results of the risk assessment with regard to the estimates for a standard of 0.02 μg/m^3, of reduction in number of children with IQ losses of 7 points or more and cite studies discussing research on the impact of Pb exposure-related cognitive impairment on earnings potential.

Response: EPA did consider the degree of uncertainty associated with both the risk assessment and the evidence-based considerations. Uncertainties associated with both approaches are thoroughly discussed in both the proposed rule and the preamble to the final rule. In the case of the risk assessment, specific sources of uncertainty are described, while in the case of the evidence based analysis, the basis for selection of individual analysis elements such as the air-to-blood Pb ratio is discussed in detail, including sources of uncertainty. The uncertainties associated with the evidence-based framework derive from uncertainties in the evidence itself, and what can be projected directly from the evidence. The uncertainties in the risk assessment include many of the same evidence-based uncertainties, as the risk assessment is largely premised on the same body of evidence (e.g., the development of a concentration-response function), as well as additional uncertainties such as those related to modeling of air dispersion, lead deposition, lead intake through ingestion and inhalation, and assignment of lead exposure to air-related and non-air related pathways. (see sections 2.4.6, 3.5, 4.3 and 5.3.3 of

Volume I of the Risk Assessment Report for details on characterization and discussion of uncertainty related to the risk assessment). Specifically with regard to the IQ loss incidence results referenced by the commenter and the potential public health benefit associated with reducing the number of children with total Pb-related IQ loss above seven points, EPA notes that we considered all of the risk metrics generated as part of the risk assessment in considering the alternate standard levels. We further note, however, that this particular category of IQ loss incidence results is subject to considerable uncertainty due to its focus on risk for upper percentiles of the population, as discussed in section 4.2.7 of the Staff Paper. Thus, as discussed further in sections II.B.3 and II.C.3.c of the preamble, the Administrator, in his decision-making for this review, gave primary consideration to the available evidence and the evidence-based framework, but also took the exposure and risk assessments into consideration in his decisions, noting that they provide some further perspective on the potential magnitude of air-related IQ loss.

2) Comment: Several industry commenters (ABR and the Doe Run Resources Corp.) recommended that more weight be placed on the risk assessment, which they state indicates little benefit to public health associated with levels in the lower part of the proposed range (e.g., "current conditions" in the risk assessment's urban case studies). One commenter (the Doe Run Resources Corp.) further noted that the reduction in incidence of children with greater than 1 IQ point lost due to Pb exposure under alternative standard levels (compared against current conditions) is relatively small and does not support setting the NAAQS at these alternative lower standard levels.

Response: Because the majority of the residential populations modeled in the location-specific urban case studies have current conditions that are well below a 0.2 $\mu g/m^3$ standard level, risk estimates for lower standard levels will show only modest risk reductions. However, this does not mean that a subset of an urban population would not experience more significant risk reductions at standard levels below current conditions. EPA has noted that the general urban case study can reasonably represent smaller subpopulations within urban areas that experience ambient air Pb concentrations at the standard level being evaluated. Therefore, risk results for this case study (for a particular standard) provide perspective on the degree of risk reduction that could be realized by urban populations or subpopulations experiencing ambient air Pb concentrations at the standard level of interest. As can be seen by reviewing risk results generated for the general urban case study (and comparing them to those generated for the location-specific case studies – proposal notice, Table 4), the degree of risk reduction seen for the general urban case study is larger across alternate standard levels. In addition, the more appropriate risk metric to consider in terms of the risk assessment is not the degree of risk reduction in moving between standard levels, but rather, the degree of air-related risk remaining at any particular standard level. That metric describes the risk faced by a population or subpopulation when a given standard is just met, which is the metric most relevant to selecting a standard that protects public health with an adequate margin of safety.

Regarding the comment concerning the population incidence results and particularly the small shift in the numbers of children with greater than 1 point total Pb-related IQ loss

under alternate standard levels (proposal notice, Table 5), it is important to note that the mean Pb-related IQ loss for the three location-specific urban case studies under all standard levels evaluated is above one IQ point. This means that we would expect to see little shift in the numbers of children with greater than one IQ point loss (since most children are above that level of IQ loss under all standard levels). Essentially, a focus on the shift in number of children with at least one IQ point loss emphasizes the extreme low-end of the risk distribution for all urban case studies. EPA notes that another risk metric related to evaluating population incidence in terms of magnitude of IQ loss is the number of children with greater than 7 points Pb-related IQ loss (proposal notice, Table 6). In contrast to the number of children with more than one IQ point loss, as shown in Table 5 of the proposal notice, Table 6 focuses on the upper-end of the risk distribution for urban children. By comparing the estimates in Tables 5 and 6 in the proposal notice, it can be seen that the various alternate standard levels result in a larger shift in the number of children with greater than 7 points Pb-related IQ loss than in the number of children with greater than 1 point Pb-related IQ loss.

d.   Comments on Adequate Margin of Safety

Some commenters indicated concern that EPA has not described how the proposed range of standards provides an adequate margin of safety, as required by the CAA. This comment is addressed in section II.C.3.c. An additional comment is responded to in this section.

(1) *Comment:* One commenter (Bayview Hunters Point Community Advocates) stated that in considering the level for the primary Pb standard, EPA failed to consider that EPA's socio-demographic analysis (Pekar et al., 2008) indicated that people living closer to monitors registering higher Pb levels tend to be poorer and more predominately African American than the county or national averages. The commenter stated that EPA could have estimated IQ loss in the risk assessment stratified by race and income. In the view of the commenter, such information about environmental inequities should be used in determining the adequate margin of safety for the standard.

Response: While as the commenter notes, EPA's socio-demographic analysis (Pekar et al., 2008) indicated that people living closer to monitors registering higher Pb levels tend to be poorer and more predominately African American than the county or national averages, EPA does not agree with the commenter that there were sufficient data available to stratify remaining air-related risk for each alternative standard level by race or income in the quantitative risk assessment, particularly in light of the use of a nonlinear C-R function. The data that would have been necessary to support more refined population-level modeling of ambient air-related Pb risk *for specific sensitive subpopulations*—such as demographic information about children (e.g., particular income or racial groups) at the appropriate geographic scale, as well as behavioral exposure factors specific to those groups —is not presently available. Thus, within the quantitative risk assessment, EPA did not characterize risk by these subgroups and for purposes of the socio-demographic analysis, EPA simply identified characteristics of populations living in proximity to Pb sources or monitors.

As explained in section II.C.3.b of the preamble, EPA's reliance on the air-related IQ loss framework in effect focuses on identifying a level for the Pb NAAQS that is requisite to protect the group of children who are living near air-related sources of lead who are likely to be most highly exposed.   Thus, to the extent that minority or low-income populations are in fact concentrated near stationary sources of air-related Pb emissions, they would be included in the subpopulation of children on which the Administrator has focused his attention through use of the air-related IQ loss framework. The revised Pb NAAQS are set at a level which, in the judgment of the Administrator, protects the health of the sensitive subgroup of more highly exposed children (along with other groups) with an adequate margin of safety. To the extent the commenter is suggesting the standard should be set more stringent than necessary to protect the health of sensitive groups with an adequate margin of safety, EPA disagrees.

3.   *Additional Comments on the Interpretation of Scientific Evidence*

Specific comments on the EPA's interpretation of the scientific evidence not discussed in the preamble to the final rule are described and addressed in this section.

(1) *Comment:* Several commenters stated that EPA's consideration of the health effects associated with low blood Pb levels should include more explicit recognition of neurological effects beyond IQ loss and effects beyond childhood. Such comments regarding health effects that were raised by commenters included reference to studies reviewed as part of the CD as well as a number of studies published subsequent to the 2006 Criteria Document. The effects noted from these more recent studies include the following:
- evidence of association of blood Pb levels with attention deficit hyperactivity disorder in children (with reference to Braun et al., 2006 and Nigg et al., 2008);
- evidence of association of childhood blood Pb levels with aggressive and criminal behavior in early adulthood (with reference to Wright et al., 2008);
- evidence of changes in brain volume at 19-24 years of age (with most affected areas including those responsible for executive functions, mood regulation and decision-making), associated with childhood Pb exposure (Cecil et al., 2008);
- evidence of association of blood Pb levels well below 10 μg/dL with cardiovascular mortality of adults (with reference to Menke et al., 2006); and
- irreversibility of Pb-related neurological effects (with reference to Miranda et al. 2007 and Jusko et al., 2008).

Response: As an initial matter, EPA has considered a range of health effects associated with low blood Pb levels beyond IQ loss and effects beyond childhood. These are described in detail in the CD and summarized in the Staff Paper, ANPR, proposal and final notice. While EPA has focused on IQ loss in selecting a level for the standard, the revised standard is judged to protect, with an adequate margin of safety, the health of children and other at-risk populations against an array of adverse health effects, with neurological effects in children among the most notable.

Discussion of the more recent studies cited by commenters was not included in the CD or in the Staff Paper, as they were published after the CD was finalized. EPA's provisional consideration of these studies in conjunction with consideration of other relevant recent studies[6], published since 2006 and identified in routine review of journals, in the context of the findings of the Criteria Document, concludes that the new information and findings do not materially change any of the broad scientific conclusions regarding the neurotoxic effects and cardiovascular effects of Pb exposure made in the 2006 Lead Criteria Document. Consistent with the conclusions reported in the CD, these studies, along with additional recent studies, have observed adverse effects of lead exposure on neurocognitive and neurobehavioral outcomes other than IQ, including academic achievement, behavioral problems, attention-deficit / hyperactivity disorder, conduct disorder, and criminal arrests. The study by Menke et al. (2006) observed an association between blood Pb levels and increased all-cause and cardiovascular mortality in adults, providing further supportive evidence for an association of Pb with cardiovascular morbidity and mortality, as reported in the CD. These studies add to the overall weight of evidence and focus on findings of neurocognitive and neurobehavioral effects beyond IQ, as well as findings of cardiovascular effects, in most cases involving study groups with lower blood Pb levels than were available for review in the CD. Having concluded that these studies do not warrant reopening the air quality criteria review for Pb, EPA is not relying on them in this review for the reasons stated in the preamble (section I.C). These studies will be fully considered in the next review of the Pb NAAQS.

(2) *Comment:* Several commenters stated that EPA was proposing to use 9 µg/dL as a baseline blood Pb level and provided recommendations for alternate views.

Response: EPA is not clear what the commenters are referring to. In the proposal, EPA has described the evidence of effects that extend to some of the lowest blood Pb levels assessed, including mean blood Pb levels below 2 ug/dL. EPA has not proposed to use 9 µg/dL as a baseline or acceptable level.

(3) *Comment:* Some industry commenters (ABR, p. 12, ASARCO) state that EPA, in considering the evidence for the impact of Pb (and particularly air-related Pb) on IQ has not adequately considered whether the past reduction in air Pb has resulted in a benefit to children's IQ. One commenter (ABR, p12) further cites an editorial by CDC scientists (Brown and Rhoads, 2008) as concluding that, while blood Pb levels have dropped since the late 1970s, there has been no observed increase in IQ by the amount that might be predicted by some concentration-response (C-R) curves under consideration in EPA proposed rule.

Response: EPA notes that there is evidence of increased IQ scores over the past several decades, this evidence is generally termed the "Flynn effect" (Flynn, 1994). This evidence indicates that IQ scores have increased by an average of 3 points per decade in the United States. Due to these observed increases in IQ scores, IQ tests are routinely re-standardized to ensure that subjects are not scored against inaccurate norms. For

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[6] The complete list of studies on neurotoxic effects of Pb published subsequent to the Criteria Document that have been considered in light of these comments is provided in appendix A.

example, the Wechsler Intelligence Scale for Children (WISC) has been renormalized three times, in 1974, 1991, and 2003, since it was originally developed in 1949. Hypothesized explanations for the observed Flynn effect include environmental changes, societal changes, and improvements in nutrition.

Additionally, as described in section II.A.2.c of the preamble to the final rule, the evidence indicates that the C-R function is nonlinear, such that to estimate IQ loss prevented by the drop in blood Pb levels from the late 1970s to today, a C-R function should be chosen from studies with blood Pb levels comparable to those of the late 1970s (e.g., mean of 15 µg/dL). Among those considered in the proposal, the Lanphear et al. (2005) study has the highest blood Pb levels, with a median of 9.7 µg/dL. Application of the average linear slope of -0.20 IQ points per µg/dL derived from this study (estimated for the range of data from from the 5th to the 95th percentile values of 2.5 to 33.2 µg/dL) would yield IQ gains on the order of 2-3 points for a decrease in the population mean blood Pb level from 15 to ~2 µg/dL over a 30 year period. This estimate is well within the increase in IQ scores observed by the Flynn effect (increase of 9 points over 30 years). EPA concludes, as have others (e.g., Nevin, 2000) that the decline in blood Pb levels likely contributed to the observed Flynn Effect. EPA additionally notes that other variables, including other environmental changes, societal changes, and improvements in nutrition also likely contribute to this effect.

(4) *Comment:* One commenter (American Farm Bureau) recommends that EPA clarify that agricultural related activities are not significant sources of Pb exposure.

Response: Based on the information currently available to EPA, we agree with the commenter that we do not have information indicating that agricultural sector activities are significant sources of Pb in human exposure pathways. While diet can be a significant source of Pb, particularly for adults, and Pb emitted into the air can make its way into dietary pathways, as described in the Criteria Document, Staff paper and Proposal (section II.A), agricultural activities have not been identified as a significant source of Pb to dietary pathways.

(5) *Comment:* One commenter (ILZRO) states that EPA incorrectly describes the IARC classification of Pb as a probable human carcinogen, noting that it is "inorganic lead compounds" which are classified by IARC as "probably carcinogenic to humans", while organo-lead compounds are assigned by IARC to Category 3 ("inadequate data to classify"), with metallic lead categorized as "possibly carcinogenic to humans" (Category 2B).

Response: EPA agrees with the commenter that different forms of lead have been given three different classifications by IARC, with the most prevalent form of ambient Pb, inorganic Pb compounds, being classified as "probably carcinogenic to humans" (class 2A). As the commenter notes, organic Pb compounds are classified by IARC as "not classifiable as to carcinogenicity to humans" (class 3) and metallic Pb is classified as "possibly carcinogenic to humans" (class 2B).

(6) *Comment:* One commenter (ILZRO) cited an assessment recently submitted to the European Union (EU) for their review in support of the commenter's statement that the effects of Pb on blood pressure and cardiovascular disease are overstated by EPA and should not be utilized as endpoints of concern for low-level human Pb exposure.

Response: EPA notes that the assessment cited by the commenter is not available to the public. It was submitted to the EU and is currently under review by that body. The Criteria Document identifies cardiovascular effects in adults as among the effects best substantiated as occurring at low blood Pb concentrations (e.g., as low as 5 to 10 μg/dL or possibly lower) and a category of effect that is "clearly of greatest public health concern" (CD, p. 8-60). EPA notes, however, that we have identified neurological and neurobehavioral effects in children as those of greatest concern in revising the primary Pb standard.

4. *Additional Comments on the Exposure and Health Risk Assessment*

Comments related to the exposure and risk assessment conducted for Pb that are not discussed in the preamble to the final rule (e.g., in sections II.B and II.C.3) are described and addressed in this section. EPA notes that the Admininstrator placed greater weight on the evidence-based framework in selecting the standard than on the risk assessment.

(1) *Comment:* Two commenters from industry (ABR and the ILZRO) asserted that the use of proportional roll-up and roll-down procedures for the location-specific urban case studies (to predict air quality conditions approaching the current standard and conditions under alternate lower standard levels, respectively) were not appropriate. Specifically, they argued that ambient monitoring trends in urban areas demonstrated that ambient air Pb levels tended to decrease disproportionately, with areas near existing industrial Pb sources (i.e., areas near source-oriented monitors) experiencing greater percentage reductions than areas more distant from sources. Furthermore, they noted that past experience with urban areas developing State Implementation Plans under the current Pb NAAQS suggested that areas in the vicinity of industrial Pb sources were the focus of emissions reduction actions, resulting in larger reductions in ambient air Pb near those locations compared with areas further from these sources. For these reasons, the commenters asserted that the use of proportional roll-up procedures to simulate conditions under the current NAAQS overstate likely associated Pb-related risk. Similarly, the use of a proportional roll-down approach to evaluate alternate standard levels likely over-states potential risk reduction.

Response: EPA acknowledges that there is significant uncertainty associated with the use of proportional roll-down and roll-up procedures for simulating ambient air Pb levels under alternate standard levels and the current NAAQS. Furthermore, EPA does not dispute the observation made by the commenters regarding the evidence from available monitoring data in some urban locations as well as experience with earlier efforts to attain the Pb NAAQS. However, given the limited monitoring data currently available in urban areas, EPA believes that application of a proportional roll-down or roll-up approach is reasonable and that efforts to develop regional-specific non-proportional

strategies could be subject to greater uncertainty than the approach used in the risk assessment.

Given the current uncertainty in simulating either roll-down or roll-up procedures to model alternate standard levels for larger urban areas, EPA believes that this supports placing greater emphasis on risk results from the general urban case study. This case study does not rely on a roll-down or roll up approach. This case study represents a smaller urban area expected to have ambient air Pb levels in-line with the standard level being evaluated, thereby avoiding the need to apply roll-down or roll-up procedures. There is uncertainty in this case study as well, but it derives from the modeling of representative gradients of air quality in a hypothetical urban area that meets a certain level of the standard, as compared to rolling ambient levels up or down for any one specific city.

2) *Comment:* One commenter (ABR) completed a sensitivity analysis looking at the potential impact on overall blood Pb levels from reductions in outdoor soil Pb levels associated with reductions in ambient air Pb. The sensitivity analysis utilized regression-derived relationships relating ambient air Pb to indoor dust Pb and outdoor soil Pb, with both relationships obtained from USEPA, 1989. The results of their analysis suggested that the change in outdoor soil Pb levels would result in a relatively small impact on total blood Pb levels for children. Therefore, they asserted that the uncertainty resulting from EPA not having considered the potential impact of air Pb deposition on outdoor soil, and any resulting bias toward underestimating risk estimates, is small and unlikely to be policy relevant.

Response: The sensitivity analysis completed by the commenter utilizes a regression-based relationship between ambient air and outdoor soil Pb that reflects an underlying dataset that may be significantly different from conditions encountered in present-day urban residential settings. The dataset underlying the regression model (see Tables A-3 and B-3 in USEPA, 1989) reflects primarily conditions near larger industrial point sources of Pb in the 1970's and 1980's and consequently (a) reflects ambient air Pb levels that are an order of magnitude or more higher than alternate standard levels evaluated in the commenter's sensitivity analysis and (b) includes residential areas with significant historical Pb impacts to soil, primarily from smelter facilities, which may in many instances not be representative of conditions in present day urban residential locations. Therefore, EPA believes that use of the regression model in the sensitivity analysis reflects an extrapolation of that model to conditions beyond the dataset used in its derivation and is therefore subject to significant uncertainty. There is the potential that urban areas under present or future conditions (i.e., lower ambient air Pb levels with a different particle size mix) could display different soil deposition and buildup dynamics from those reflected in the USEPA (1989) regression model.

3) *Comment:* Two commenters (Kentucky Division of Air Quality and ABR) asserted that the risk assessment overstates risk for urban case studies. The Kentucky DAQ noted that "the air quality scenario for the urban case studies assumes ambient air Pb concentrations higher than those currently occurring in nearly all urban areas nationally" (partial quote

from 73 FR 29210 cited in their comments), leading them to conclude that risk estimates generated for the urban case studies are overestimated. ABR asserted that risks for the urban case studies were overstated due to errors in the indoor dust model used by EPA for the urban case studies. Specifically, the commenter asserted that the indoor dust Pb model underestimates the contribution from nonair Pb sources due to a mathematical quirk associated with the nonlinearity of the model. They assert that the nonair contributions to Pb in housedust predicted by the model are significantly lower than levels seen in the literature and they argued that this underestimation results in residual indoor dust Pb being incorrectly assigned to air-related indoor dust Pb by the model, such that air-related indoor dust Pb estimates are biased high. Furthermore, the commenter suggested that a sensitivity analysis completed by EPA looking at two versions of the model, one as used in the risk assessment and an alternate model with fixed background dust Pb levels, shows that the model as used in the risk assessment overestimates risk reduction benefits associated with alternate standard levels.

Response: EPA disagrees with the commenter's assertion that air Pb concentrations in the urban case studies are higher than conditions in nearly all urban areas nationally. The statement from the proposal cited by the commenter pertains to the current NAAQS scenario in which ambient air Pb levels in the urban case studies are increased to just meet the current NAAQS. As stated in the NPR, this scenario is hypothetical and represents ambient air Pb levels which are significantly higher than current conditions in most urban areas, based on available monitoring data. In contrast, the "current conditions" air quality scenarios for the urban case studies are based on monitoring data specific to the urban case study areas. Additionally, alternative NAAQS scenarios simulated for the location-specific urban areas involved air Pb concentrations in those locations lower than those described as "current conditions" which represented recent air quality data.

Regarding the comment that risk for the urban case studies are overestimated due to errors in indoor dust Pb modeling, EPA acknowledges that the hybrid model has non-linearity in the underlying conversion of indoor dust Pb loading to concentration and that this results in an estimate of background non-air indoor dust Pb that varies and is dependent on the ambient air Pb level being modeled. However, the non-linear conversion of indoor dust Pb loading to concentration is based on an underlying HUD dataset that reflects a non-linear relationship between these two variables. Therefore, this aspect of non-linearity in the indoor dust Pb model is supported by the literature.

Regarding the assertion by the commenter that nonair contributions to Pb in housedust predicted by the indoor dust model are significantly lower than levels seen in the literature, EPA notes that the literature does not currently support the identification of a nonair indoor dust Pb level. Available datasets characterizing indoor dust Pb levels in the residential setting reflect housing subject to some degree of ambient air Pb impact and consequently indoor dust Pb concentrations presented in these studies reflect a combination of background and air-sourced Pb impacts. Furthermore, EPA notes that observations made by the commenter of houses in areas not adjacent to point sources having indoor dust Pb concentration values in the hundreds (ppm), likely reflect older

housing with increased potential for indoor dust Pb impacts from Pb paint. It was not the intent in developing the indoor dust Pb model to focus on older housing vintage, but rather to model a background (non-air) indoor dust Pb prediction that would represent broadly the U.S. housing stock, including both newer and older houses. It is likely that this non-air indoor dust Pb value would be lower than the value presented by the commenter (although as noted here, it is not possible to identify that value from the literature).

As the commenter noted, EPA conducted a sensitivity analysis to assess the influence of non-linearity in the indoor dust model on estimates of total and air-related exposure and risk (USEPA, 2007b). This sensitivity analysis included an alternate approach for estimating a fixed background (non-air) indoor dust Pb level. While this alternate approach did result in noticeably lower recent air-related exposure and risk estimates for each simulated standard level, total risk (for each standard level) was the same as that estimated using the original formulation of the indoor dust Pb model (i.e., the total change in exposure and risk between standard levels was the same for both model formulations). In addition, it is important to point out a key limitation in this alternate formulation of the indoor dust Pb model, which undermines the validity of this approach. By setting ambient air Pb levels to zero and then solving for indoor dust Pb, the alternate formulation used the steepest part of the loading-to-concentration curve to conduct the key step of translating indoor dust Pb loading to equivalent concentration. In reality, we would expect to always have a mixture of indoor dust Pb loadings from non-air and air sources, thereby resulting in a larger total loading value, which would in turn be translated into an indoor dust Pb concentration at a flatter portion of the curve (see Section 5.3.3.4 of Volume I of the Risk Assessment Report).

EPA does acknowledge the uncertainty in its modeling of indoor dust concentrations, and recognizes that this is one of the several sources of uncertainty in the risk assessment.

4) *Comment:* A few commenters representing industry (ABR and the Doe Run Resources Corp.) stated that EPA did not distinguish air-related Pb from nonair Pb in indoor dust for the primary Pb smelter subarea case study. One commenter states that this lack of separation of air from nonair sources to indoor dust Pb overstates the risk reduction associated with reductions in air Pb concentrations (as might be associated with alternative standard levels).

Response: EPA agrees that we did not develop separate estimates of air-related and nonair indoor dust Pb concentrations for this case study for reasons described in II.C.2.h of the proposal. However, this has no effect on the magnitude of differences in total Pb-related risk between alternative standards. The risk assessment first estimated total Pb-related risk and then partitioned those estimates of Pb-related risk to the pathways of interest in this review, with various limitations affecting how completely that partitioning could be done (as described in the proposal section II.C.2.e). Thus, not separating exposure pathways for air-related dust Pb from nonair-related dust Pb did not affect the derivation of total Pb-related risk estimates or the differences in magnitude of these estimates associated with different alternative standards.

5) *Comment:* One commenter (City of El Paso, Texas) stated that the risk assessment underestimated risk associated with the current NAAQS by underestimating the soil Pb concentrations that can result over time. Specifically, they assert that even the soil Pb levels reflected in modeling risk for the primary Pb smelter, for the remediation zone closest to the facility, do not fully reflect the contamination in residential areas that would be expected from this type of source. The commenter points out that the soil Pb levels used in the risk assessment for the subarea near the smelter, which reflect remediation activities, are significantly lower than levels in similar areas that have not undergone remediation. Furthermore, they argue that maternal blood Pb levels in areas with historically elevated ambient air Pb levels may be significantly higher than the central-tendency levels used in the risk assessment for that contribution to childhood blood Pb.

Response: EPA agrees there is uncertainty in the soil Pb concentration estimates, including those for the primary Pb smelter case study. As the commenter notes, the soil Pb estimates for areas near the smelter were based on post-remediation measurements of soil Pb contamination and EPA recognizes that this approach may produce an underestimate of Pb exposure (for the soil ingestion pathway) for the current NAAQS scenario. In response to the comment regarding higher maternal blood Pb levels, the application of a GSD reflecting national-scale variation in child blood Pb levels is likely to capture the relative contribution of these elevated maternal blood Pb levels to the broader distribution of blood Pb levels. However, EPA acknowledges that it has not specifically modeled the subpopulation of children whose mothers have blood Pb levels above the average national maternal level.

6) *Comment:* A number of commenters (Bayview Hunters Point Community Advocates, MO Coalition for the Environment, CARB, Sierra Club, NRDC) stated that EPA's risk assessment did not consider the fact that minority and low income groups are disproportionately exposed to Pb. In making this statement, one commenter (MO Coalition), cited the NHANES findings for these subpopulations. Further, one commenter (CARB) recommends using different maternal blood Pb levels specific to African American and Hispanic women as inputs necessary for adequately estimating childhood blood Pb levels for those subpopulations.

Response: EPA agrees with commenters that low-income subpopulations and some minority subpopulations have higher blood Pb levels, as evidenced by the NHANES data cited in the proposal. As noted in the proposal and in the risk assessment report, blood Pb levels are influenced by a range of exposure pathways (nonair-, as well as, air-related) and other factors related to human behavior, nutrition, and genetic factors. In planning the risk assessment and in considering at-risk populations in the Risk Assessment, Staff Paper, ANPR and proposal notice, EPA has recognized the disproportionately higher blood Pb levels of low income and African-American children. These portions of the U.S. population are considered to be represented in the risk assessment by the upper percentile estimates of total blood Pb and related IQ loss. Rather than developing separate blood Pb and IQ loss estimates for individual subpopulations of children such as those identified by the commenters, EPA characterized this variability in the risk

assessment by estimating blood Pb distributions using a geometric standard deviation based on the U.S. population, based on advice from CASAC on the analysis plan and draft assessments. While this precludes EPA from estimating blood Pb and IQ loss specific to those subpopulations, this method does provide estimates of blood Pb and IQ loss for the upper ends of the distribution for populations exposed to air concentrations meeting the level of the current standard and alternative standards, which may, as the commenters indicate, include notable representation by these subpopulations.

EPA additionally notes that the GSD approach employed in the risk assessment, consistent with CASAC advice, was adopted in recognition of the limited data and tools for developing subpopulation-specific estimates of blood Pb and IQ loss. While data are available for some key inputs, such as maternal blood Pb levels for the subpopulations noted by one of the commenters, data are quite limited to specify all needed exposure related factors specifically for special subpopulations, including those identified by the commenters.

Finally, EPA recognizes that the higher blood Pb levels identified in these subpopulations are indicative of these subpopulations being sensitive subpopulations with regard to Pb exposures overall. However, EPA notes this evidence does not indicate increased sensitivity to air-related Pb alone. For example, due to the nonlinear dose-response relationship of IQ loss with blood Pb, EPA concludes that it is that portion of this population with lower blood Pb and lower exposure to nonair sources that would be expected to be more sensitive to air-related Pb impacts on IQ per incremental unit increase in blood Pb.

7) *Comment:* One industry commenter (ABR) asserted that air-to-blood ratios derived in the risk assessment for the urban case study are over-stated due to underlying errors in the indoor dust model used. Specifically, they contend that the higher air-to-blood ratios generated at lower ambient air Pb levels for this case study result from non-linearities in the hybrid indoor dust model (i.e., higher indoor dust Pb concentrations being estimated per unit ambient air Pb at lower ambient air Pb levels) which they asserted are not supported by science.

Response: The non-linearities reflected in the hybrid indoor dust Pb model, which contribute to the higher air-to-blood Pb ratios at lower ambient air Pb levels, are based on empirical data (as detailed below) and therefore are scientifically supported. Non-linearity in the hybrid indoor dust model generates higher indoor dust concentrations per unit ambient air Pb at lower air Pb levels, primarily because of non-linearity in the conversion of indoor dust Pb loading to concentrations. EPA notes that the hybrid model generates initial dust predictions in terms of loading and these need to be converted to concentrations for use in blood Pb modeling. The procedure for converting estimated indoor dust Pb loading to indoor dust Pb concentrations within the hybrid model involves the use of regression equations derived from empirical data characterizing dust Pb levels in residential housing in the U.S. (see section G.3.4.1 and Attachment G-1 in Appendix G of Volume II of the Risk Assessment Report). The regression models used in completing the loading-to-concentration conversion are non-lineaer reflecting the underlying data

used in their derivation. Therefore, the non-linearity in the hybrid indoor dust Pb model is scientifically supportable since it reflects empirical data representative of residential dust Pb characteristics in the U.S., including the relationship between indoor dust Pb loading and concentration for different housing vintages.

8) *Comment:* Two commenters from industry (ABR and Doe Run Resources Corp.) asserted that air-to-blood ratios derived in the risk assessment for the primary Pb smelter case study subarea are overstated due to errors in characterizing indoor dust Pb exposure for this case study. Specifically, both commenters argued that EPA did not separate out nonair dust Pb from air-related indoor dust Pb. The commenters note that this precluded EPA from deriving air-to-blood ratios based on recent air. Furthermore, one of the commenters (the Doe Run Resources Corp.) suggested that a temporal mismatch in relating indoor dust Pb measurements and ambient air Pb levels for the regression-based model used in the primary Pb smelter case study also results in EPA overstating the air-to-blood Pb ratios. Furthermore, they suggested that a more appropriate approach would have been to match indoor dust Pb sampling data to ambient air Pb measurements from the nearest ambient air Pb monitor (with the indoor dust sampling data also being matched to the monitoring data in terms of the time period, or month). The commenter contends that this regression model would have predicted lower indoor dust Pb levels for a given ambient air Pb level (for the primary Pb smelter case study) than those estimated using EPA's approach.

Response: The comment asserts that failure to differentiate air-related and background sources of indoor dust Pb results in inflated air-to-blood ratios for the primary Pb smelter (subarea) case study. EPA acknowledges that due to modeling and data limitations, we were not able to parse out background sources of indoor dust Pb (e.g., indoor Pb paint) from ambient air-related Pb impacts. EPA was clear in stating the uncertainty and potential high-bias that this limitation meant for the policy-relevant risk results. However EPA does not agree that this limitation in the indoor dust model resulted in biased air-to-blood ratios. The category of air-to-blood Pb ratios given emphasis in the Staff Paper was generated by comparing total blood Pb levels estimated for adjacent standard levels, i.e., comparing the absolute change in blood Pb level to the associated difference in ambient air Pb levels between adjacent standard levels – see Section 5.2.5.2 of Volume I of the Risk Assessment Report. Because these air-to-blood ratios do not depend on the fraction of blood Pb that is considered air-related, but only on the difference in total predicted blood Pb between standard levels, these ratios are not affected by limitations in differentiating air-related indoor dust and associated exposure from background dust. The only factor that would be important in impacting these ratios would be the performance of the model in predicting levels of total indoor dust Pb under alternate standard levels.

Regarding the comment that there is a potential temporal mismatch in the ambient air Pb and indoor dust Pb datasets used in deriving the regression-based indoor dust Pb model for the primary Pb smelter case study, EPA acknowledges that some uncertainty is introduced into the model due to difference in the timing of the two datasets. However, the alternate strategy advanced by the commenter - regressing indoor dust Pb measurements directly on ambient monitor data for the same month - is likely to severely

under-represent any potential spatial relationship between indoor dust and ambient air Pb. The use of monitoring data without any form of spatial interpolation as the basis for characterizing the spatial gradient in ambient air Pb levels will result in a relatively undifferentiated spatial surface, compared to the use of an air concentration surface based on air dispersion modeling, as was done with the EPA's model. While EPA's regression model may have uncertainty related to a temporal mismatch in the indoor dust and ambient air Pb datasets, which EPA recognizes could introduce bias into the model, the alternate approach of using monitoring data is subject to considerably greater uncertainty and downward bias in the relationship between ambient air Pb and indoor dust Pb and therefore, can not be considered as a preferred approach for developing a site-specific indoor dust model for the primary Pb smelter case study.

9) *Comment:* One commenter (Kentucky Division of Air Quality), asserted that children's Pb exposures from toys and jewelry containing Pb is significant and was not considered in the risk assessment. Further, they state that EPA's limitations in separating blood and risk estimates between air-related and non-air sources have contributed to EPA deriving "risk attributed to ambient air Pb levels [that] is overly conservative and is not able to be used in determine [sic] the appropriate NAAQS for Pb".

Response: EPA recognizes that in certain instances Pb associated with toys and jewelry may contribute to significant Pb exposure. While the risk assessment did not explicitly model risks associated with ambient air Pb for the subset of children experiencing coincident exposure to high levels of Pb contained in toys and related items, the risk assessment did provide general representation for these children to the extent that they are represented in the set of children surveyed by NHANES IV. Specifically, the GSD used in modeling the distribution of blood Pb levels, and hence IQ loss, within the study populations included in the risk assessment was developed from the NHANES IV dataset. Children with elevated blood Pb due to a variety of sources, including contaminated toys, would be reflected in the GSD, therefore these children would also be reflected broadly in the population exposure and risk distributions developed in the risk assessment. However, EPA did not explicitly model the distribution of risk separately for these subpopulations, due primarily to limitations in the exposure input data required to support this level of refined modeling. EPA does acknowledge that in those instances where a child has been exposed to elevated Pb levels through contaminated toys or jewelry, such exposure may dominate overall Pb exposure and associated risk of IQ loss. However, the frequency of this type of higher Pb exposure related to toys and jewelry within the general child population is not currently known.

10) *Comment:* One commenter (California Air Resources Board) stated that the risk assessment should have considered prenatal exposures and associated risk in modeling IQ loss for the case studies.

Response: In modeling risk for child populations in the risk assessment, EPA included consideration for prenatal exposure (i.e., maternal Pb contribution) as a component of overall Pb uptake in determining lifetime average and concurrent blood Pb levels for the 7 year old child. Specifically, prenatal exposure is simulated within IEUBK as an initial

contribution to child blood Pb. Additionally, while EPA recognizes the potential for adverse health effects resulting from prenatal exposure to Pb, the health endpoint on which we focused in the quantitative health risk assessment for this review is developmental neurotoxicity in children, with IQ decrement as the risk metric. This reflects EPA's consideration of CASAC advice on the priority endpoint for the risk assessment (as stated in Staff Paper section 4.1.2).

B.   Secondary Pb Standard

The public comments received on the proposed secondary standard for Pb were very general in nature basically expressing support for revising the current secondary to be identical to the revised primary standard. Public comments on issues related to the secondary Pb standard are described and addressed in section III.B.2 of the preamble to the final rule.

C.   Comments Related to Data Handling (Appendix R)

1.   Use of "standard conditions" Pb-TSP data collected prior to January 1, 2009 without adjustment to represent "local conditions"

(1)   *Comment:* Several commenter addressed EPA's proposal that in the future lead concentration data be reported in terms of local temperature and pressure conditions, and that data collected before January 1, 2009 and already reported on the basis of standard temperature and pressure be comparable to the NAAQS without adjustment to local conditions, with the state having the option to withdraw the data and make those adjustments if it wishes. One commenter argued that Pb concentrations should continue, as in the past, to be reported in terms of standard temperature and pressure conditions and that only those values should be compared to the level of the NAAQS. In support of this view, this commenter claimed generally that ambient air Pb concentrations used in deriving relationships between air Pb concentrations and blood Pb levels were in terms of standard temperature and pressure. Another commenter expressed a similar but less specific concern about consistency between the conditions for reporting concentrations and the logic used by the Administrator to set the level of the NAAQS. A commenter gave the example of monitoring conducted at 0 degrees C (32 degrees F), for which the concentration reported on the basis of local conditions would be 9 percent higher than if reported on the basis of standard conditions.

Response: As stated in the proposal, EPA believes that a concentration expressed in terms of local conditions of temperature and pressure is more closely related to the rate of and total deposition of lead to the ground and other surfaces, because that concentration is directly proportional to the amount of lead in the air within a fixed distance of the surface onto which deposition occurs. Thus, concentrations expressed in terms of local conditions are the better indicator of the risks which the NAAQS seeks to limit, and thus comparing these concentrations to the NAAQS allows the NAAQS to protect public health more effectively and more consistently across areas in the U.S., given differences in local temperature and pressure. EPA believes that the disparity, if any, attributable to the use of historical data that may have been based on standard conditions in air-to-blood

relationships when selecting the level of the NAAQS is less than the 9 percent anecdote cited by the commenter, because most data used to relate air concentrations and blood lead levels were collected at temperature and pressures much closer to standard conditions, so the adjustment factor would be less. EPA notes that the disparity, if any, is small, particularly compared to the magnitude of the reduction in the level of the standard and to other uncertainties which the Administrator has considered in selecting the elements of the revised NAAQS. Although it is not possible for all the historical data to be re-adjusted due to the lack of information on temperature and pressure conditions for each measurement day in each study, EPA considered the potential for a disparity between historical monitoring data reported at STP and the requirement to report data for the revised NAAQS at local conditions in setting the standard.

2. *Data Completeness Tests*

(1) *Comment:* One commenter stated that the imputation procedures in the proposed Appendix R are similar to those that states have been required to use for $PM_{2.5}$. This commenter believes that there is little to be concerned about, except in the highly unusual cases where virtually every scheduled sample in a single calendar quarter is missing. This commenter was concerned that the proposed imputation procedures may not satisfactorily resolve a situation in which a large portion of the scheduled sampling fails to yield valid data, because the proposed diagnostic tests for use in the case of missing data are quite conservative. One test substitutes high estimates for the missing data to see if nevertheless the mean concentration is below the NAAQS, and the other test substitutes low estimates for the missing data to see if nevertheless the mean concentration is above the NAAQS. The commenter is concerned that these tests may leave some situations unresolved, and recommends that that there be room for an alternative treatment in such cases.

Response:The final rule addresses this concern by including the proposed provision which allows data from periods that do not meet the completeness criteria to be considered valid (and complete) with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(2) *Comment:* In the proposed rule, EPA invited comment on also incorporating into the final rule two other possible tests that could allow a NAAQS exceedance determination to be made on the basis of monthly data that is not at least 75% complete. The first test would compare the monthly (or quarterly) mean to a fraction of the NAAQS level, for example 50 percent, and consider the month to be exceedance-free if the (incomplete) monthly mean were less than that fraction of the NAAQS. The other test would use a statistically based confidence interval for the monthly (or quarterly) mean to test for a high probability of either an exceedance or non-exceedance with the NAAQS for that month. The commenter noted that the preamble to the proposed rule stated that EPA was planning to analyze data sets using hypothetical data to explore these two possible

approaches, and reserved comment on this issue until this analysis became available for review.

Response: This issue is addressed in section IV.C of the preamble to the final rule.

(3)   *Comment* A state environmental agency proposed, in the context of a second maximum monthly mean concentration form for the NAAQS, that when in spite of everyone's best efforts completeness requirements are not met for two months in a 3-year period, the next highest monthly average of the remaining 33 months in the 3-year period should be used as a valid design value.

Response: While the comment was made in the context of a different averaging time/form than was selected in the final rule, the general sense of the recommendation can also be taken to apply to the selected averaging time/form (a rolling 3-month mean concentration) as a recommendation that the completeness criteria overlook a small number of incomplete 3-month means and allow a finding of compliance with the NAAQS if the highest valid 3-month mean is below the NAAQS. EPA recognizes that a failure to meet completeness requirements can occur despite everyone's best efforts to collect samples on the scheduled days or on allowed make up days. As a practical matter, the inability to make a finding of attainment due to data incompleteness in the most recent 3-year period could affect states and sources only where a site has recorded a NAAQS violation in a previous 3-year period. If there has been no previous violation, there is no practical effect from the lack of a compliance finding for the 3-year period that does not meet completeness requirements. In a situation in which there has been a prior violation, EPA believes it would be inappropriate to overlook incompleteness in order to make a finding of attainment. Instead, no new finding should be made until complete data for a 3-year period does show attainment.

3.   *Criteria and Formula for site-specific scaling factors*

(1)   *Comment:* Comments on the subject of scaling factors to relate Pb-PM$_{10}$ measurements to Pb-TSP concentrations were generally negative towards EPA's proposed requirement for the development of site-specific scaling factors. Also relevant to this issue are the comments regarding whether Pb-TSP or Pb-PM$_{10}$ should be the indicator for the NAAQS. Many commenters argued that Pb-PM$_{10}$ should be selected as the indicator for the NAAQS only if the level of the NAAQS were set at or below the low end of the range proposed by EPA, i.e., at or below 0.10 $\mu g/m^3$.

Response: These comments are summarized in more detail and responded to in section IV.D of the preamble to the final rule.

(2)   *Comment:* A monitoring agency submitted an analysis of data from a monitoring site near Detroit at which two Pb-TSP monitors and two high-volume Pb-PM$_{10}$ monitors operate simultaneously. The data analysis concluded that the precision levels of these monitoring methods were not greatly different, and that the ratio of concentrations of Pb-TSP and Pb-PM$_{10}$ was highly variable.

Response: These data were part of the data examined by EPA in preparing the proposed and final rules. The findings stated by the commenter are consistent with EPA's findings based on data from this and other collocation sites.

(3)   *Comment:* A monitoring agency submitted a brief analysis of collocated Pb-TSP and Pb-PM_{10} data from a monitoring site near a secondary Pb smelter in Tampa, FL, for the period of January through June 2008. This data set included two Pb-TSP samplers and one Pb-PM_{10} sampler. The analysis indicated a mean Pb-TSP concentration during this period of 0.4 micrograms per cubic meter and a mean Pb-PM_{10} of 0.2 micrograms per cubic meter. This factor of two difference was consistent with the slope of a regression between daily measurements of the two parameters. The analysis also showed close agreement between the duplicate measurements of Pb-TSP.

Response: These data appear not to have been submitted to AQS at the time these comments were reviewed for this document. The close agreement between duplicate measurements of Pb-TSP is consistent with EPA's stated opinion at the time of the proposal that the Pb-TSP sampler is reasonably precise and is suitable, but not ideal, for purposes of implementing the NAAQS. The factor of two difference between the two sizes of Pb is about the same as the highest factor in the data examined by EPA when developing the proposal, and confirms EPA's conclusion that monitoring for Pb-PM_{10} near industrial sources of Pb may result in measurements that do not indicate the actual concentration of Pb-TSP, the indicator selected in the final rule. EPA notes that the graph submitted by the commenter appears to be mislabeled as a comparison of Pb-PM_{10} and Pb-TSP concentrations, when it actually is a comparison between the two Pb-TSP measurements.

4.   *Criteria for exclusion of data from comparison to the NAAQS based on the influence of an exceptional event*

(1)   *Comment*: One commenter addressed the topic of excluding Pb concentration data that has been affected by an exceptional event. In the commenter's view, the proposal did not address what an exceptional event would be for lead, in particular for resuspension of lead from lead-contaminated soils. The commenter argued that local construction activities or agitation of barren lead-contaminated soils by vigorous winds could lead to significant re-suspension of lead particles that in turn could adversely impact local monitors. A state air quality agency would have little control over these activities, and for local construction, no notice, yet these conditions could significantly contribute to a violation. The commenters said that the final rule should set forth criteria for exceptional events unique to lead.

Response: 40 CFR 50.14, Treatment of air quality monitoring data influenced by exceptional events, contains general criteria for determining whether an event is exceptional and whether data may be excluded when making comparisons to the NAAQS. EPA believes that the provisions of 50 CFR 50.14, and the illustrative examples in the preamble to the final rule explaining that section, are suitable for

application to lead and that no special critiera or further explication are needed or appropriate. EPA notes that local construction activities or agitation of barren soils by vigorous winds can also lead to re-suspension of PM2.5 and PM10 and cause exceedances of those NAAQS, so these possibilities do not make the lead NAAQS uniquely different.

D.   Comments Related to Monitoring

1. Existing Sampling and Analysis Methods

(1) *Comment*: We received a number of comments on our proposal to continue the use of high-volume TSP samplers as the sampling method for Pb.   In their comments on the proposed rule, CASAC reiterated their concerns over the measurement uncertainty due to effects of wind speed and wind direction on sampling efficiency. These concerns were discussed in detail in our proposed rule, and as such are not reiterated here. However, CASAC stated that if the final level of the NAAQS were to be set at 0.10 $\mu g/m^3$ or above, then the high-volume Pb-TSP sampler should be used. Some public commenters also stated similar concerns with the performance of the Pb-TSP sampler. A large number of other commenters stated that the high-volume TSP sampler should continue to be the sampler for determining compliance with the Pb NAAQS. They expressed concerns that PM_{10} samplers would not capture ultra-coarse particles (i.e., particulate matter with an aerodynamic diameter greater than 10 µm), and could greatly underestimate Pb concentrations in the ambient air, especially near Pb sources.

Response: This issue is addressed in V.A.1 the preamble to the final rule.

(2) *Comment:* We received several comments supporting the need for the development of a low-volume Pb-TSP sampler. However, in our consultation with CASAC's AAMM Subcommittee, we were cautioned against finalizing a new low-volume Pb-TSP FRM without an adequate characterization of the sampler's performance over a wide range of particle sizes.

Response: We agree with the interest for a low-volume Pb-TSP sampler and the desire for such a sampler to be adequately characterized prior to being promulgated as a new FRM. Accordingly, we plan to further investigate the possibility of developing a low-volume FRM in the future.

(3) *Comment:* One commenter suggested allowing the use of low-volume Pb-TSP samplers at special purpose monitoring sites (SPM). The data could be used to determine the need for an official SLAMS site and would provide data for the possible approval of new FRM/FEM methods.

Response: We agree with the commenter, and point out that monitoring agencies may use non-FRM/FEM methods at non-required sites. However, we note that these data from these non-FRM/FEM monitors can not be compared to the NAAQS.

2. *Proposed Pb-PM$_{10}$ Federal Reference Method*

(1) *Comment*: The CASAC AAMM Subcommittee agreed with our proposed use of the PM$_{10}$c sampler. Other comments on our proposed use of the low-volume PM$_{10}$c sampler for the Pb-PM$_{10}$ FRM were in support of the PM$_{10}$c as an appropriate sampler for the FRM.

Response: As discussed in the preamble in section V.A.2, Pb-PM10 monitoring is permitted in some limited situations that meet certain specified conditions. For those situations, we are promulgating the Pb-PM$_{10}$ FRM based on the use of the low-volume PM$_{10c}$ sampler.

(2) *Comment:* We received comments on our proposed use of XRF as the analysis method for the Pb-PM$_{10}$ FRM, including comments from CASAC's AAMM Subcommittee during the peer review of the proposed FRM. Several commenters agreed with our proposed use of XRF as the analysis method, citing several of the advantages we identified in the preamble to the proposed rule. However, several other commenters suggested that Inductively-Coupled Plasma-Mass Spectrometry (ICP-MS) would be a more appropriate analysis method for the FRM.

The AAMM Subcommittee and other commenters raised concerns with the potential for measurement bias due to non-uniform filter loadings. They noted that the analysis beam of the XRF analyzer does not cover the entire filter collection area; therefore, it is possible for the measurement to be biased if the Pb particles deposit more (or less) on the edge of the filter as compared to the center of the filter.

Response: This issue is addressed in the preamble to the final rule.

(3) *Comment:* Several commenters suggested that Inductively-Coupled Plasma-Mass Spectrometry (ICP-MS) would be a more appropriate analysis method for the FRM. Advantages identified with ICP-MS included the analysis of the entire filter deposit and a higher sensitivity (i.e., lower MDL.) In addition, a number monitoring agencies noted that their laboratories were already equipped for ICP-MS making ICP-MS less costly than XRF for them.

Response: This issue is addressed in section V.A.2 of the preamble to the final rule. We expect that other analysis methods, including ICP-MS are likely to be approved as FEM to compliment the PM$_{10}$-FRM. Following approval, monitoring agencies will have the option of choosing between XRF, or other approved FEMs.

(4) *Comment:* One commenter suggested that high-volume PM$_{10}$ samplers should be considered for the FRM or FEM because the method collects a larger sample which should result in a higher precision, allow for split analyses, and allows for options for repeat analysis.

Response: We do not plan to accept high-volume Pb-PM$_{10}$ samplers as either an FRM or FEM. While we agree that high-volume Pb-PM$_{10}$ samplers do collect a larger sample that would lead to lower detection limits, they have a less precise cut point which may be

affected by wind-speed. High-volume samplers also have less precise flow-control capabilities than low-volume samplers and most current high-volume samplers do not possess the ability to actively control flow to actual temperature and pressure conditions.

(5) *Comment:* One commenter suggested that XRF may not be an adequate analysis method due to poor detection capabilities. The commenter indicates that XRF is used as a "screening method" for analysis of metals in solids.

Response: We are aware of XRF instruments that are used for screening level analyses, however, these instruments would not meet the FRM analysis method description. The XRF analysis method defined in the FRM is for a research grade laboratory analysis method that is capable of precisely measuring Pb at levels well below the level of the final Pb NAAQS.

(6) *Comment:* One commenter suggested that detailed guidance was needed on how to perform XRF analysis.

Response: We believe the final FRM provides adequate details concerning the details of how the analysis is to be completed. Therefore, we believe that further detailed guidance is not required at this point.

3. FEM criteria

(1) *Comment*: One commenter suggested that the proposed MDL requirement, 1 percent of the NAAQS, was overly stringent, and that an MDL of 5 percent would be sufficient. Another commenter suggested that an MDL at 10 percent would be more achievable.

Response: This issue is addressed in the preamble to the final rule. See section V.A.3.

(2) *Comment:* We received two comments supporting the development and consideration of the use of continuous Pb monitors.

Response: We agree that the FEM criteria should allow for the development of continuous Pb monitors as FEM. As such, we have revised the FEM criteria to accommodate the potential of continuous Pb FEM.

4. Quality Assurance

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

Response: This issue is addressed in the preamble to the final rule. See section V.A.4.

5. *Adequacy of Existing Network Design Requirements*

(1)   *Comment*: We received numerous comments that the existing monitoring network and network design requirements were not adequate for a lowered NAAQS. We did not receive any comments stating that the existing network was adequate.

Response: We agree with the comments that the existing network design requirements need to be updated. We are finalizing new network design requirements as described in the preamble to the final rule, see section V.B.

6. *Source-oriented Monitoring Requirement*

(1)   *Comment*: We received several comments supporting the need for monitoring near Pb sources. Alternatively, one commenter suggested that near source monitoring is not necessary because "the EPA and the State already know where and what the problems are" and "EPA should … develop control standards to deal with the problem …"

Response: We note that under CAA sections 107 and 110 states must submit State Implementation Plans (SIPs) that include measures to attain the NAAQS as expeditiously as possible. These measures can require control of emissions at sources contributing to an exceedence of the NAAQS. Thus, monitoring near Pb sources is needed to ensure controls of Pb sources contributing to violations of the NAAQS.

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

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

commenters suggested that EPA was in the best position to determine which sources had the potential to exceed the NAAQS.

Response: This issue is addressed in the preamble to the final rule, see section V.B.3.

(3)   *Comment*: We received several comments supporting the need for monitoring waivers, and one comment that did not support waivers. Those in favor of the waivers pointed out that, as discussed above, many Pb sources will result in much lower Pb impacts than the "worst case" Pb source. They argued that the states need flexibility in meeting the source-oriented monitoring requirements, and agreed that it is appropriate to focus on sites near those Pb sources with the greater potential to result in Pb concentrations that exceed the Pb NAAQS. The commenter who cautioned against the allowance of monitoring waivers expressed concerns that modeling techniques have uncertainty that could result in waivers being granted when actual Pb concentrations could exceed the NAAQS.

Response: We agree that it is appropriate to allow for monitoring waivers as proposed, see section V.B.3. We took the uncertainty of modeled data into account when proposing to limit waivers to situations where the modeled data indicated maximum impacts would be 50 percent of the NAAQS, rather than at 100 percent of the NAAQS, and we believe this provides an appropriate margin of safety.

(4)   *Comment*: We received comments questioning the need to restrict the provision of waivers to sites near sources emitting less than 1000 kg/yr when it is possible for sources impact to be well below the level of the Pb NAAQS.

Response: We agree it is possible for sources greater than 1000 kg/yr to have an impact less than 50 percent of the NAAQS under certain conditions. We also acknowledge the need for flexibility in implementing the Pb NAAQS monitoring network. As such, we have reconsidered our proposed restriction limiting waivers to those for sources emitting less than 1000 kg/yr, and we are not finalizing a restriction on the size of sources near sites eligible for a waiver from the source-oriented monitoring requirement.

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

Response: This issue is addressed in the preamble to the final rule, see section V.B.3.

(6)   *Comment*: We received comments that the proposed source-oriented monitoring requirements did not address situations where multiple sources contribute to Pb concentrations at one location.

Response: This issue is addressed in the preamble to the final rule, see section V.B.3.

(7)   *Comment*: We received two comments that source-oriented monitors should be located at the maximum estimated Pb concentration without consideration for the potential for population exposure, and six comments that source-oriented monitors should be located in an area where population exposure occurs. In their comments on the proposed rule, one commenter argued that monitors "should be located in or around only those Pb point sources with a nearby population base" because "air Pb concentrations have regulatory importance largely in those areas where significant groups of children are exposed for considerable time periods." They argue that as an example "a rural road going by a lead mining facility is an unlikely place that children will spend considerable amounts of time" and as such "placing a monitoring site on such a road would have de minimis, if any, value." Another commented that "monitors should be located near playgrounds, sports fields, long-established highways, and the like."

Response: This issue is addressed in the preamble to the final rule, see section V.B.3.

(8)   *Comment*: We received a comment that in our calculation of the emission threshold we should have used the maximum of the four methods rather than the average of the four methods in determining the emission threshold.

Response: The threshold used in the final regulation is not derived directly from the emissions calculations, for further discussion see the preamble.

(9)   *Comment*: We received a number of comments that the emission threshold was not realistic and was based on worst case assumptions. One commenter suggested the threshold should be reconsidered based on modeling performed for the risk assessment.

Response: The emission threshold is intended to represent a reasonable worst case impact from an emission source. States are allowed, and encouraged, to request a waiver of the monitoring requirement based on more refined modeling which includes site specific characteristics such as stack heights, temperatures, etc.

(10)   *Comment*: We received a comment that we should not require monitoring of Pb impacts due to combustion sources for several reasons including inadequate inventories, an inability of States to control such sources through the SIP process, and because this issue would be similar across many areas of the country. The commenter suggested that EPA conduct Pb monitoring at selected sites to determine if it was likely that these sources would result in violations of the NAAQS.

Response: While combustion of traditional fuels was identified as a potentially significant source of Pb emissions nationwide, we expect that states generally would be able to meet the requirements to receive a waiver for most of the combustion sources because these types of facilities typically have tall stacks, high exhaust velocities, and hot exhausts, which would result in significant dispersion and reduced ambient impacts.

(11)   *Comment*: A number of commenters suggested that the emphasis on source-oriented monitoring was a departure from network designs for other NAAQS pollutants such as ozone and $PM_{2.5}$.

Response: One of the primary objectives for all NAAQS monitoring networks is to identify locations of maximum concentrations as well other objectives as described in the proposal. As such the EPA is finalizing both source and nonsource-oriented monitoring requirements as preamble.

(12)   *Comment*: One commenter suggested that EPA develop different emission thresholds for a number of different source categories (e.g., airports and combustion sources).

Response: We do not have sufficient data to develop different emission thresholds for different source categories at this time.   However, we plan to work with monitoring agencies to develop information on a number of different source categories such as airports that will be useful in estimating the impact on Pb concentrations from these sources.

(13)   *Comment*: One commenter suggested that the EPA needs to develop a "regulatory off ramp" for when source-oriented monitors can be shut down.

Response: Once a monitor has collected 3-years worth of data, the data can be used to request a waiver of the source-oriented monitoring requirement if the data shows that concentrations were less than 50% of the NAAQS.

(14)   *Comment*: One commenter suggested that if a facility increased its operations, that only the increased emissions should be modeled, and the highest concentration from the existing monitoring data could be used to predict the impact on Pb concentrations.

Response: We believe that the most recent emissions data available for a facility should be used in a scientifically justifiable means (e.g., dispersion modeling) to determine if Pb monitoring is required. If a facility increased its operations resulting in increased emissions above emissions data contained in the NEI, for example, the highest level of emissions should be evaluated as part of the monitoring demonstration.

(15)   *Comment*: One commenter suggested that certain types of Pb sources (including smelters, battery manufacturers, and mines with tailings piles) should not be allowed to receive a monitoring waiver.

Response: We agree that these source types should be given additional scrutiny by monitoring agencies, but believe that under certain circumstances it is possible that these source types may ~~also~~ have minimal impact on Pb concentrations. As such, we do not believe it is appropriate to categorically disqualify these source types from being capable of receiving a monitoring waiver.

(16)   *Comment*: One commenter suggested that the EPA should consider presumptively not requiring monitoring for facilities in source categories that already have extensive lead controls in place.

      Response: The presence or lack of controls does not necessarily affect the impact of Pb emissions on ambient Pb concentrations. That is to say, emissions of 1.0 tons per year from a well-controlled facility would likely have a similar impact on Pb concentrations as 1.0 tons per year of emissions from an uncontrolled facility.

(17)   *Comment*: One commenter suggested it can be very difficult, and in some places impossible, to find suitable locations for monitoring stations and to gain access to the areas.

      Response: Our final monitoring requirements allow for the consideration of logistics when siting a required Pb monitor.

(18)   *Comment*: One commenter suggested that EPA needs to provide guidance on probe heights.

      Response: Probe height requirements are clearly defined in the existing 40 CFR part 58, Appendix E requirements.

7. *Nonsource-oriented Monitoring Requirement*

(1)   *Comment*: One state and several tribes commented that the proposed population limit would result in no required non-source oriented monitors in low population states and tribal lands. One commenter expressed concerns that the population limit was too high, and would result in environmental justice concerns since many poor communities would not be monitored.

      Response: This issue is addressed in the preamble to the final rule, see section V.B.3.

(2)   *Comment*: One commenter suggested that NCore multi-pollutant sites would be an appropriate location for nonsource-oriented sites.

      Response: We agree that a few of the planned NCore sites that are located in CBSAs of 500,000 people or more could be appropriate locations for nonsource-oriented sites especially when such sites represent areas near schools, parks, or other areas where children may live and play. However, the final Pb network design states that non-source

Pb monitors should be located to estimate neighborhood scale Pb concentrations in urban areas impacted by re-entrained dust from roadways, closed industrial sources which previously were significant sources of Pb, hazardous waste sites, construction and demolition projects, and other fugitive dust sources of Pb. The NCore network design discourages placement of stations near sources that are not representative of relative wide areas, so relatively few of the NCore stations are likely to be ideal non-source Pb monitoring locations.

(3)   *Comment*: One commenter suggested that the nonsource-oriented threshold of 1,000,000 was too high and would result in areas where 60% of children live in poverty with no monitors.

Response: As discussed in the staff paper, based on the analysis of the existing monitoring network, we do not expect areas away from Pb sources to show Pb concentrations in excess of the NAAQS. However, we have decreased the population threshold for requiring non-source Pb monitors from CBSAs of 1,000,000 people to CBSAs of 500,000 people, bringing in approximately 50 more CBSAs into the requirement. Furthermore, we are requiring Pb monitors near Pb sources regardless of the size of the community, or its economic status.

8. Monitoring Near Roadways

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

Response: This issue is addressed in the preamble to the final rule, see section V.B.3.

9. Use of Pb-PM_{10} Monitors in lieu of Pb-TSP Monitors

(1)   *Comment*: Several commenters suggested an approach for the use of Pb-PM_{10} monitors as an alternative to the proposed use of scaling factors. As suggested by the commenters, Pb-PM_{10} monitoring would be allowed in certain instances. Specifically, Pb-PM_{10} monitoring would be allowed where estimated Pb concentrations were predicted to be less than 50 percent of the NAAQS and where Pb in ultra-coarse particulate was expected to be low. Again as suggested by the commenter, if at some point in the future the monitor were to show that Pb-PM_{10} concentrations exceeded 50 percent of the NAAQS, the monitoring agency would be required to replace the Pb-PM_{10} monitor with a Pb-TSP monitor.

Response: This issue is addressed in the preamble to the final rule, see section V.B.2.d.

(2)   *Comment*: One commenter raised concerns that a PM_{10} sampler may collect PM greater than 10 microns in diameter and may result in an over estimate of PM_{10}.

Response: We have chosen Pb-TSP as the indicator for the Pb NAAQS. As such, this concern does not apply to this rule making. While Pb-PM_{10} is being allowed as a surrogate for Pb-TSP in certain circumstances, any potential over sampling of ultra-coarse particulate would just move the estimated concentration closer to the actual Pb-TSP level that would have been measured by a Pb-TSP sampler had one already in operation.

10. Required Timeline for Monitor Installation and Operation

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

Response: In response to these comments, EPA is permitting a tiered network deployment process over two years. This issue is addressed in the preamble to the final rule, see section V.B.3. We believe that two years is sufficient to site and deploy the approximately 235 new monitors that will be required by this rule.

(2)   *Comment*: We received comments from a number of states expressing concerns that the number of required monitors would fluctuate year to year due to changes in the actual Pb emissions inventory.

Response: We have tied the monitoring requirement to the Pb emissions estimates in the "most recent" NEI. Since the NEI is updated once every 3 years, this would mean that States would need to reassess the Pb monitoring requirement once every 3 years. We also expect States to perform network assessments every 5-years as required by 58.10(d). Such assessments should include an evaluation of Pb network changes that may be required due to changes in the NEI or the availability of other information that supports re-evaluation of potential source impacts on ambient Pb concentrations.

11. Sampling Frequency

(1)   *Comment*: We did not receive any comments on our proposed sampling frequency for a NAAQS based on a quarterly average. We did receive 4 comments supporting a move to a 1 in 3 day sampling frequency if the final Pb NAAQS was based on a monthly averaging time, 3 that supported maintaining the 1 in 6 day sampling frequency despite a move to a monthly averaging time, and 2 comments that supported daily sampling if the final Pb NAAQS was based on a monthly averaging time.

Response: The final NAAQS is based on a rolling 3-month average. The statistical and practical monitoring considerations are the same for a 3-month average as with a calendar quarterly average. As such, we are maintaining the current 1-in-6 day minimum sampling frequency as proposed.

(2)   *Comment*: Two commenters supported allowing for less frequent sampling if the measured Pb concentrations were less than 50% of the standard.

Response: We are maintaining the current 1-in-6 day sampling frequency. Since we are not moving to a 1 in 3 day sampling frequency we do not believe it is necessary, or appropriate to allow for a reduction from the 1 in 6 day sampling schedule.

12. Monitoring for the Secondary Standard

(1)   *Comment*: We received one comment supporting our proposed reliance on the IMPROVE network Pb-PM$_{2.5}$ data for tracking trends in Pb concentrations in rural areas. We did not receive any other comments on additional monitoring needs to support the secondary Pb NAAQS.

Response: We are not finalizing any additional requirements for Pb monitoring specifically for the secondary Pb NAAQS.

13. Cost of Monitoring Network and Funding Issues

(1)   *Comment*: We received numerous comments that raised concerns with the cost of the proposed Pb monitoring network, and need for flexibility in implementing the monitoring network. Several monitoring agencies questioned where the money for the new Pb requirements would come from, and suggested that EPA fund the monitoring network either partially or fully through 103 monitoring grants.

Response: While the CAA prohibits us from considering costs when setting the Pb NAAQS, we may consider costs when establishing implementing requirements such as monitoring requirements. As such, we have attempted to provide substantial flexibility to monitoring agencies responsible for implementing the monitoring requirements, while still ensuring that the monitoring network will be sufficient to determine compliance with the final Pb NAAQS. Nonetheless, the final monitoring requirements will result in an increase in monitoring expenses to some monitoring agencies. We will work with the state, local, and tribal monitoring agencies to appropriately address these issues.

III. RESPONSES TO COMMENTS RELATED TO IMPLEMENTATION

Many comments on implementation issues are addressed in section VI of the preamble. Significant comments on specific issues not addressed in the preamble are addressed in this section.

A. Nonattainment Area Boundaries

(1) *Comment*: Several commenters state that they support the use of the county, or smaller, boundaries for nonattainment areas dominated by single large emitting sources. These commenters state that they support this position on the assumption that EPA will have sufficient monitoring and modeling data to determine with confidence that areas outside of the nonattainment boundary do not, in fact, have ambient lead concentrations exceeding the revised lead NAAQS. The commenter recommends that EPA adopts the alternative boundary presumption, the Metropolitan Statistical Area (MSA), for urban areas. Such areas likely have a combination of factors contributing to their nonattainment status, and the larger area should allow for a more holistic SIP.

Response: The EPA agrees with the commenter that lead emissions do not generally transport over long distances (as compared, e.g., to fine particulate matter). In the proposed rule, EPA proposed to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard. In the proposed rule, EPA also stated that, at the revised level of the standard, EPA expects stationary sources to be the primary contributor to violations of the NAAQS, although we also believe that nearby area sources may also contribute to concentrations of lead emissions that may affect a violating monitor. In light of the possibility that a number of smaller sources may collectively contribute to concentrations in excess of the NAAQS, EPA believes that adopting the county boundary as the presumptive boundaries for lead nonattainment areas is appropriate. However, as stated in the proposed rule, a state, Tribe, or EPA may conduct additional area-specific analyses that could lead to the boundary for an area either being increased or decreased from the presumptive county boundary. In situations where a single source, rather than multiple sources, is causing a NAAQS violation, the EPA believes that a state may well be able to use area-specific analyses to identify whether a nonattainment area that is smaller than the county boundary is appropriate.

(2) Comment: The commenter states that they have serious concerns over EPA's use of "presumptive boundaries" for nonattainment purposes. The preamble to the lead NAAQS proposal notes that the EPA is proposing county boundaries as the presumptive boundaries for lead nonattainment areas and is taking comment on the use of the MSA boundaries. The commenter further states that they have asserted in the past and continues to insist that the OMB has defined the metropolitan areas for statistical purposes to include the collection, tabulation, and publication of data by federal agencies for geographic areas to facilitate the uniform use of comparability of data on a national scale. The commenter further states that for EPA to default to a presumptive boundary for "consistency" purposes stifles the creatively to improve air quality as expeditiously as possible to bring clean air to the public and rewards those who chose to wait. EPA's

broad brush approach discourages initiatives by local areas, counties, and states to be proactive.

Response: As stated previously, the EPA believes that lead emissions do not generally transport over long distances (as compared, e.g., to fine particulate matter). In the proposed rule, EPA proposed to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard. EPA solicited comment on the use of MSAs as presumptive boundaries, but is not adopting that approach in the final rule. In the proposed rule, EPA also stated that, at the revised level of the standard, EPA expects stationary sources to be the primary contributor to violations of the NAAQS, although we also believe that nearby area sources may also contribute to concentrations of lead emissions that may affect a violating monitor. In light of the possibility that a number of smaller sources may collectively contribute to concentrations in excess of the NAAQS, EPA believes that adopting the county boundary as the presumptive boundaries, and the starting point for setting the boundaries for an area, for lead nonattainment areas is appropriate. However, as stated in the proposed rule, a state, tribe, or EPA may conduct additional area-specific analyses that could lead to the boundary for an area either being increased or decreased from the presumptive county boundary. In situations where a single source, rather than multiple sources, is causing a NAAQS violation, the EPA believes that a state may well be able to use area-specific analyses to identify whether a nonattainment area that is smaller than the county boundary is appropriate. The commenter further states that for EPA to use a presumptive boundary for "consistency" purposes stifles the creatively to improve air quality as expeditiously as possible to bring clean air to the public and rewards those who chose to wait. To the contrary, EPA believes that by adopting a presumptive boundary, and by providing states with the opportunity to submit recommendations based upon qualitative information, which substantiates the deviation from the presumptive boundary provides flexibility in terms of setting the correct boundaries for the areas and helps to target the appropriate sources to control.

(3*) Comment*: The commenter states that they oppose EPA's suggestion that it can use the MSA as the presumptive boundary for the designation of lead nonattainment areas. The commenter states that the use of the MSA would mean that a single violating monitor results in the entire MSA being designated as being nonattainment unless a regulated entity or other party establishes that an exception is warranted. Because lead concentrations, unlike ozone or PM-2.5, are effectively the result of direct emissions, the long range transport concerns of ozone and PM-2.5 are not present. Thus, rather than "presuming" that contribution to the lead problem is regional in nature, the EPA should restrict the area to no larger than the county boundary or defer to the recommendations made by the state or Tribal government.

Response: The EPA agrees with the commenter that using the MSA as the presumptive boundary for designating areas for the Pb NAAQS would be inappropriate due to the fact that lead emissions are usually deposited within short ranges of the initiating sources. Therefore, EPA is finalizing the proposed option of using the county as the presumptive

boundary for designating areas, and provides for the use of several factors to make determinations where deviating from the presumptive boundary is necessary.

(4) *Comment:* Several commenters stated that they believe that nonattainment boundaries will need to be developed using specific data. As the preamble discusses, lead will be associated with stationary emission sources, and thus where nonattainment area boundaries need to be established, they will be inherently associated with these sources, not political boundaries or consensus based boundaries. The commenters agree with this premise, stating that in their experience with lead nonattainment, the issue was source oriented in nature. The commenters narrowed down the nonattainment boundary to the city blocks that were affected through use of modeling and monitoring. The commenter states that based upon their experience with the two options provided in the proposed rule, they support using the county boundary as the presumptive boundary for designating areas, with the use of the 8 factors to support the changing of the boundaries. The commenter further states that they do not support the use of MSA as the presumptive boundaries for designation.

Response: As stated previously, at the revised level of the standard, EPA expects stationary sources to be the primary contributor to violations of the Pb NAAQS, although we also expect that in some areas a number of smaller sources may collectively contribute to concentrations in excess of the NAAQS. MSAs are frequently composed of a number of counties. Recognizing that lead emissions, particularly ultracoarse particles, deposit relatively short distances from the proximity of their initial source, EPA believes that adopting the county boundary as the presumptive boundary for lead nonattainment areas is more appropriate than using the much larger MSA boundary. Furthermore, as stated in the proposed rule (and the previous response), a state, Tribe, or EPA may conduct additional area-specific analyses that could lead to the boundary for an area either being increased or decreased from the presumptive boundary.

(5) *Comment:* The commenter states that in regard to designations, EPA believes that a key factor in establishing lead boundaries is "to include both the area judged to be violating the standard as well as the source areas that are determined to be contributing to these violations." The commenter states that EPA must, however, define "how" it will establish which sources are contributing to monitored lead nonattainment. While modeling is often used for this assessment, EPA has not yet established a modeling significance level for lead. Absent lead significance levels, use of modeling to determine lead nonattainment areas is not a viable option.

Response: As stated in the preamble to the final rule, EPA believes that the county boundary should be used as the presumptive boundary for designating areas for the Pb NAAQS. In cases where there is a determination that areas should be either increased or decreased from the presumptive boundary, the EPA is finalizing factors that should be used to substantiate any deviation from the presumptive boundary. EPA will, as appropriate, review and revise guidance, regulation, or policy related to modeling and designations following the promulgation of the NAAQS.

(6) *Comment:* The commenter states that EPA should refrain from employing the same methodologies used to establish ozone and PM-2.5 nonattainment area boundaries when designating lead nonattainment areas. This methodology is inappropriate in determining the health threat from lead to the local population. Unlike ozone and PM-2.5, lead concentrations are not driven by complexed chemistry or long range transport issues. The proposed methodologies will encompass large nonattainment areas. In contrast, existing monitoring data shows sharp lead gradients surrounding known lead emissions sources. Bounding a nonattainment area using MSA should only be considered if there is irrefutable evidence that area source emissions within the entire MSA are contributing to a violation of the lead NAAQS.

Response: As stated previously, the EPA believes that lead emissions do not generally transport over long distances (as compared, e.g., to fine particulate matter or 8-hour ozone). In the proposed rule, EPA proposed to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard. In the proposed rule, EPA also stated that, at the revised level of the standard, EPA expects stationary sources to be the primary contributor to violations of the NAAQS, although we also believe that nearby area sources may also contribute to concentrations of lead emissions that may affect a violating monitor. In light of the possibility that a number of smaller sources may collectively contribute to concentrations in excess of the NAAQS, EPA believes that adopting the county boundary as the presumptive boundaries, and the starting point for setting the boundaries for an area, for lead nonattainment areas is appropriate. However, as stated in the proposed rule, a state, tribe, or EPA may conduct additional area-specific analyses that could lead to the boundary for an area either being increased or decreased from the presumptive county boundary. The EPA is finalizing the factors relevant to such an analysis as described in the proposed rule because we believe that they will allow for both the State as well as EPA in some cases to more accurately define the appropriate boundaries for an area. Also as stated previously, the state may in addition to the factor analysis also choose to submit information to recommend lead nonattainment boundaries using any one, or a combination of the following techniques, the results of which EPA would consider when making a decision as to whether and how to modify the Governors' recommendations: (1) qualitative analysis, (2) spatial interpolation of air quality monitoring data, or (3) air quality simulation by dispersion modeling. In situations where a single source, rather than multiple sources, is causing a NAAQS violation, the EPA believes that a state may well be able to use area-specific analyses to identify whether a nonattainment area that is smaller than the county boundary is appropriate. On the other hand, where it appears that emissions from one or more sources are contributing to nonattainment throughout an MSA, the site-specific analysis may result in the boundaries of the nonattainment area overlapping with those of the MSA.

(7) *Comment:* The commenter states that in the proposed rule EPA states that states may conduct additional area specific analysis using factors that "closely resemble the factors identified in recent EPA guidance for the 1997 8-hour ozone and PM-2.5 NAAQS, and the 2006 PM-2.5 NAAQS nonattainment area boundaries that could lead EPA to depart from the presumptive boundary. These factors, as listed in the proposal are: (1) emissions, (2) air

quality, (3) population density and the degree of urbanization, (4) expected growth, (5) meteorology, (6) geography/topography, (7) jurisdictional boundaries, and (8) level of control of emission sources. The commenter states that 4 of these factors may be inappropriate for nonattainment areas that are based on source oriented monitors. (1) Population density and degree of urbanization, (2) expected growth, and (3) jurisdictional boundaries have absolutely no relationship to current or expected lead emissions from the specific lead sources that may be causing high ambient lead levels. Also, if lead emissions from specific source or sources that were the basis for locating the source oriented monitor are found to be causing or significantly contributing to NAAQS violations, then the level of control of these emissions should not be a factor in nonattainment boundaries. The commenter therefore states that the only appropriate factors that should be considered in determining the boundaries for lead nonattainment areas are: (1) emissions, (2) air quality, (3) meteorology, and geography/topography

Response: As stated in the preamble to the final rule, EPA is finalizing the use of the factors as proposed for making determinations related to the deviation from the presumptive boundary for designating areas for the Pb NAAQS. The EPA believes that all of the factors as proposed provide useful information in making a determination concerning whether the boundaries for a nonattainment area should be either increased or decreased. Depending on the circumstances in each case where a violation is observed, certain factors may be more or less important in determining an appropriate boundary. EPA believes that the commenter is incorrect in stating that the factors or "population density and degree of urbanization", "expected growth", and "jurisdictional boundaries" are not important in terms of making decisions related to the appropriate boundaries for designating lead areas. As stated in the preamble to the final rule, EPA generally expects contributions to violations of the lead standard to be the result of emissions from larger stationary point sources, however, smaller area sources may also contribute to these violations. In these cases, "population density and degree of urbanization" and "expected growth" may bear a direct relationship to actual and possible future lead source emissions, and emissions caused by re-entrainment of lead embedded in soil. Also, while not necessarily bearing a direct relationship to emissions, "jurisdictional boundaries" may be an important consideration for practically managing air quality, and therefore may be relevant to establishing a boundary where nonattainment area requirements can be managed. Therefore, EPA is finalizing the guidance identifying factors for deviating from the presumptive boundary as provided in the proposed rule. We note also that EPA does not view this list of factors as necessarily inclusive. Boundary determinations may also be influenced by additional relevant factors identified by states when making the boundary recommendations, or by the public in commenting on the state- or EPA-developed boundary recommendations.

(8) *Comment:* The commenter states that the maximum impact from the secondary lead smelter and the battery manufacturing plant in Tampa, Florida are close in proximity to their plants. Emissions from fugitive sources, short stacks and unenclosed activities seem to be the biggest contributors to off-site problems. Given their low release height, the affected air generally should only be in the immediate vicinity of the source. As such, it does not appear to be a good public policy to make nonattainment designations in all cases using

county boundaries or MSA. The key to making any designation would be the scale of the offending monitor.

Response: As discussed in the preamble and in response to other comments, EPA recognizes that nonattainment may be a result of a number of sources, or of a single large source. Therefore, EPA believes it is appropriate to begin with the county boundary, and then consider adjustments to that boundary as appropriate.

B.   Nonattainment Area SIP Submittals

(1) *Comment:* The commenter states that the proposed rule would allow States [and Tribes] the statutory maximum 18 months after designation, per the CAA section 191(a), to submit nonattainment SIPs. For reasons set forth elsewhere in the comment letter, existing nonattainment and maintenance areas likely have the greatest need for immediate action to bring ambient lead concentrations down to the revised NAAQS levels. Because of history of excessive exposure of young children in these areas, and the likely familiarity of affected States with at least some of the relevant concerns, the nonattainment SIP submittal deadline for current nonattainment and maintenance areas (assuming that they are also designated nonattainment under the revised lead NAAQS) should be nine months after their nonattainment designation.

Response: Section 191(a) states "Any State containing an area designated or redesignated under section 107(d) as nonattainment with respect to the national primary ambient air quality standards for … lead … shall submit to the Administrator, within 18 months of the designation, an applicable implementation plan meeting the requirements of this part." EPA does not interpret this language as granting authority to require states to submit SIPs sooner than 18 months following designation, although states are certainly allowed to do so. Furthermore, given the time needed for the state to adopt the appropriate control measures for the sources within the nonattainment area in order for the area to demonstrate attainment, EPA believes that the time period provided under section 191(a) is appropriate. We also believe that requiring the submittal of the SIP within the 18 months provided under section 191(a) allows sufficient time for the adoption of control measures and provides sufficient time for emissions reductions to be obtained in order for the area to demonstrate attainment within the 5 year period allowed under subpart 5 of the CAA for the areas to attain the standard.

C.   Emissions Inventory Requirements

(1) *Comment:* One commenter stated that the existing reporting requirements contained in the CERR are sufficient to develop lead SIPs for most areas. Problematic areas that are substantially influenced by local sources may require additional inventory information, but should be evaluated on a case-by-case basis. Any additional inventory reporting requirements should be identified during the SIP development process, in cooperation with the EPA regional office, and should be addressed through the CERR/AERR.

Response: The EPA acknowledges that problematic areas may require information in addition to that required by the CERR. EPA agrees that the need for additional data may vary by nonattainment area, and thus it may be important for states to determine what additional data needs may exist for their lead nonattainment areas as part of the SIP development process in consultation with the EPA regional office. EPA notes we are updating the SIP emission inventory requirements set forth in 40 CFR § 51.117(e) in this rule. In addition, we note that the Air Emissions Reporting Requirements (AERR) rule, which will replace the CERR, has been proposed but not yet promulgated. The AERR is expected to be a means by which the Agency will implement additional data reporting requirements for the Pb NAAQS SIP emission inventories..

(2) *Comment:* One commenter stated that EPA should develop additional guidance on emission inventories related to the SIP submittal because the requirements under the CERR and the AERR may not be enough to adequately address the emissions inventory requirements related to the attainment demonstration for the SIP. Commenters also stated that EPA should provide guidance on what should be the base year for the emissions inventory for the nonattainment SIP submittal.

Response: As discussed earlier in this section, EPA acknowledges that requirements under the CERR may not be adequate to address the emission inventory requirements for lead SIPs. We are evaluating the need for additional guidance to states on lead SIP emission inventory development. Existing guidance is presented in a document titled "Emission Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards and Regional Haze Regulations" (EPA-454/R-05-001, updated November 2005). EPA anticipates that if we determine additional guidance on developing lead SIP emission inventories is warranted, it will be presented as an update to this document. The EPA will review, and as appropriate, revise or update regulations, policies, and guidance related to the implementation of the revised Pb NAAQS following the promulgation of the NAAQS.

(3) *Comment:* One commenter stated that states currently work with regional offices in developing nonattainment area inventories and that this approach should be encouraged. The commenter further indicated that states should be allowed to start with the National Emissions Inventory (NEI) and customize their nonattainment area inventories to analyze nonattainment problems.

Response: The EPA encourages the states to continue to work closely with the EPA Regional Offices in developing their nonattainment area emissions inventories as well as any enhancements that need to be made to the NEI. The EPA condones and encourages the use of the NEI as a tool to assist states in developing their nonattainment area SIP emissions inventory. States, however, should be reminded that the nonattainment area SIP emissions inventory is required pursuant to 40 CFR 51.117(e) and must be approved by EPA pursuant to the CAA and is subject to the public hearing requirements pursuant to section 110(a)(2).

(4) *Comment:* Several commenters stated that EPA should revise 40 CFR 51.117(e)(1), relating to the emissions reporting threshold level for lead nonattainment area SIPs. The current threshold level as stated in 51.117(e)(1), requires that the point source inventory on which the summary of the baseline lead emissions inventory is based must contain all sources that emit 5 or more tpy of lead.

Response: The EPA agrees with the commenter that the requirement for the emissions inventory reporting threshold for lead nonattainment SIPs, as stated in 40 CFR 51.117(e)(1), should be revised to reflect the stringency of the revised Pb NAAQS. Accordingly, the EPA is setting the threshold level of the emissions inventory reporting requirement at 0.5 tpy consistent with the threshold for analysis of RACT/RACM control measures.

(5) *Comment:* In general, several commenters said better data should be used to quantify Pb emissions from sources for implementation purposes. Several commenters (Alaska Department of Environmental Conservation; Georgia Environmental Protection Division; New York State Department of Environmental Conservation; Pennsylvania Department of Environmental Protection; Tennessee Department of Environment and Conservation, Division of Air Pollution Control; and American Foundry Society) expressed concerns with the accuracy of the National Emission Inventory (NEI), and recommended allowing states to use "the best available information" on emissions from Pb sources. Some commenters pointed to differences in Pb emissions data reported in the Toxics Release Inventory and the NEI as evidence that the NEI was inaccurate. One industry commenter (American Foundry Society) said current practices to reduce toxic emissions are not reflected in the NEI and wanted the opportunity to update the information. Commenters said EPA should correct the errors in the NEI or allow states to submit revised local data that more accurately reflect Pb emissions before emissions inventory data are used to determine which sources exceed the threshold.

Response: The EPA agrees that the most accurate Pb emissions information, based on scientifically justifiable methods and data, should be used when making decisions about implementing the Pb NAAQS. This may include supplemental datasets that could include sources not contained in the NEI. We acknowledge that many of the NEI emission estimates likely would be improved with more site specific data (e.g., emissions test data). For this reason we specified that one option available to monitoring agencies seeking a monitoring waiver is to demonstrate that actual emissions are less than the emission threshold.

(6) *Comment:* One commenter said the lead and lead compound reporting requirements under the Consolidated Emissions Reporting Rule (CERR) were insufficient concerning both the threshold and timeline. The commenter said the reporting threshold for lead under the CERR is much higher than the proposed monitoring thresholds so the EPA should use some other inventory instead of the NEI to determine which sources exceed the threshold. The commenter also said sources above the RACT threshold should be required to report Pb emissions annually instead of every 3 years.

Response: The EPA recognizes the commenter's concerns that the emissions inventory reporting threshold is too high; however, the emission inventory reporting threshold for Pb and the timeline for reporting emission inventories to EPA for the National Emission Inventory are set under the CERR and are apart from the Pb NAAQS. .   EPA notes we are updating the SIP emission inventory requirements set forth in 40 CFR § 51.117(e) in this rule. In addition, we note that the Air Emissions Reporting Requirements (AERR) rule, which will replace the CERR, has been proposed but not yet promulgated. The AERR is expected to be a means by which the Agency will implement additional data reporting requirements for the Pb NAAQS SIP emission inventories..

(7) *Comment:* One commenter (Georgia Environmental Protection Division) said EPA emission factors should be improved for significant source categories of Pb emissions. The commenter said the absence of or below-C ratings on AP-42 emission factors for facilities such as Pb smelters and cement kilns showed that emissions estimates to be used for monitoring determinations may be insufficient.

Response: Response: The EPA agrees that the available lead emissions factor in AP-42 may be less than optimum for use in ambient air monitoring determinations and that improved emissions factors may help siting of monitoring stations. Nevertheless States should obtain the most current lead emissions information for those facilities that are expected to adversely impact the ambient air quality so that the lead monitoring sites are placed appropriately. At this time, the EPA has no specific plans to update the factors mentioned by the commenter. EPA is establishing a process to allow States and Industry to supply quality assured source test data for future improvements in the emissions factors. It is suggested that future emissions test information be fully documented electronically to facilitate improved emissions factors development.

(8) *Comment:* One commenter (Georgia Environmental Protection Division) said EPA should share the methodologies its technical experts used to adjust 2002 NEI data that EPA believed significantly overestimated Pb emissions from sources.

Response: EPA made adjustments to the industrial process emission estimates for those sources that appeared to be emitting very high levels of Pb after consultation with the EPA Regional Offices and State and local agencies. Boiler emissions were adjusted using the procedure described in the May 1, 2008 technical memo to the docket (Document ID EPA-HQ-OAR-2006-0735-5160). In addition, EPA refined its estimates for airport-specific lead emissions, as explained in another memo to the docket (Document ID EPA-HQ-OAR-2006-0735-5483).

(10) *Comment:* Two commenters said EPA needs to provide tribes with updated guidance on developing emission inventories for Pb.

Response: EPA is committed to working with tribes that want to develop emission inventories for tribal lands. EPA has training opportunities and programs such as the

Tribal Emissions Inventory Software Solution (TEISS) available for tribes that choose to develop an emission inventory.

D.   RACM and RACT for Lead Nonattainment Areas

(1) *Comment:* One commenter states that certain facility types, such as secondary lead smelters and lead-acid battery manufacturing plants should be required to implement RACT regardless of their claimed emissions. The commenter states that most emission estimates use once a year stack test, and assumptions about fugitive emissions and upsets, that are not necessarily accurate. The commenter states that if there is a monitored violation of the standard, and these types of facilities contribute, then at a minimum they should be required to implement RACT. This would close the door on operators who attempt to seek RACT exemptions using best case stack tests and not correctly quantifying fugitive emissions.

Response: EPA believes that the appropriate requirement is for States to do a RACM/RACT analysis for point sources within the nonattainment area that meet the threshold level as finalized in the Pb NAAQS rulemaking. As explained in the preamble, EPA believes that it is appropriate to set the recommended threshold for the RACT analysis at 0.5 tpy. As discussed in the preamble, while EPA is today setting the threshold level for sources that the state should include in its RACM/RACT analysis at 0.5 tpy, the state's control technology analysis should also include, as appropriate, sources which actually emit less than the threshold level of 0.5 tpy of lead, or lead compounds, in the area or other sources in the area that are reasonable to control, in light of the attainment needs and feasibility of controls for the affected area. In some cases this may mean that controls must be placed on sources such as those suggested the commenter (secondary lead smelters, lead-acid battery manufacturers, and those sources identified in 40 CFR 51.117(a)(1)). The state must provide appropriate analysis which demonstrates timely attainment in the area in light of the attainment needs for the affected area. As stated in the preamble, this may also mean doing an analysis on those sources that are at or below the threshold level being identified for RACM/RACT.

(2) *Comment:* Several commenters stated that the implementation proposals for the new Pb NAAQS level fail to consider the relative bioavailability (RBA) of different lead forms, even though the much lower RBA of lead sulfide (PbS or galena), which is a predominant form at lead mining sites, means that it has a much lower potential for adverse health effects. The commenter further states that despite the widespread recognition that lead sulfide (galena) has low bioavailability, the implementation plans do not differentiate between it and other lead forms with higher RBA, or make any other adjustment for varying degrees of RBA for different Pb forms, in determining whether a particular emissions source is in compliance with the NAAQS. The comments further state that rather, and apparently based on the erroneous premise that all Pb forms present equivalent health risks, any and all Pb emissions are counted for compliance purposes. The commenter further states that, this overestimates the amount of Pb that could possibly present a health risk by failing to recognize that galena in particular is not bioavailable through either ingestion or inhalation, and thus does not contribute to

possible health effects. The commenters further state that because the potential health effects related to Pb exposure vary with RBA of the Pb source, consideration of RBA in determining compliance would be appropriate.

Response: For the reasons discussed above (in section II.A.2.c.i), the current air quality criteria do not provide a basis for setting a separate NAAQS for Pb sulfides based on bioavailability, and therefore EPA did not set such a standard. In light of that conclusion, there is no basis on which to consider RBA in determining compliance with the NAAQS. EPA must determine compliance with the standard in accordance with the indicator, form, averaging time, and indicator selected by the Administration to protect public health with an adequate margin of safety, pursuant to CAA section 109(b).

(3) *Comment:* Those seeking to implement Reasonably Available Control Measures ("RACM") should be directed by EPA to start their consideration with far more than the 1993 Addendum to the General Preamble referenced at 73 Fed. Reg. 29271. That document (published at 58 Fed. Reg. 67748, 67750-52 (Dec. 22, 1993)) focused principally on stationary point sources emitting more than 5 tons per year. While it properly addressed concerns regarding fugitive dust from such sources and possible releases into the air from historic emissions, much more information has since been developed on control of the "area sources" that now are the focus of concern.

Furthermore, it is incorrect for the Agency to imply, as it does at 73 Fed. Reg. 29271, that consideration of "the impact and reasonableness of the measures" mandated as RACM is a concern only where municipal or other governmental entity resources are involved, or that the economic feasibility of RACT for area sources should be governed by what stationary sources have been able to achieve. Nor is it appropriate for EPA to judge the cost-effectiveness of all elements of revised SIPs submitted in response to a revised lead NAAQS on the basis of cost per ton of reduction. This measure is sensible for industrial point sources, but where major contributions to children's exposure are coming from previously deposited lead in soil or paint-related house dust, cost effectiveness needs to be measured by the reductions achieved in the immediate areas of those releases.

The Agency appears to properly recognize (at 73 Fed. Reg. 29272) that it would be incongruous to require RACT analyses only where sources release more than five tons of lead per year when the threshold of concern for monitoring is expected to be set between 200 kg/year and 600 kg/yr. In response to the request for comment as to what release level should trigger a RACT analysis, BCI provides this two-fold response: for stationary sources and fugitive sources associated with them, RACT analysis is only appropriate as to those facilities at which an exceedance of the NAAQS is measured or reasonably anticipated. As to "area sources," however – i.e., roadsides, public parks, etc. – the threshold for RACT analysis should be the soil contamination level EPA has projected to be likely to create an exceedance in that particular immediate area. Based on analyses discussed by CASAC in its submissions to EPA, these exceedances appear likely to occur even in the immediate areas of roadsides and parks.

Response: The EPA's historic definition of RACT is the lowest emissions limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility. RACT applies to the "existing sources" of lead in an area including stack emissions, industrial process fugitive emissions, and industrial fugitive dust emissions (e.g., on-site haul roads, unpaved staging areas at the facility, etc) (see section 172(c)(1)). The EPA's previous guidance for implementing the pre-existing Pb NAAQS recommends that stationary sources which emit a total of 5 tpy of lead or lead compounds, measured as elemental lead, be the minimum starting point for RACT analysis (see 58 FR 67750, December 22, 1993). As explained in the preamble, the EPA believes that it is appropriate to set the recommended threshold for the RACT analysis at 0.5 tpy. While EPA is today recommending a threshold of 0.5 tpy for sources that the state should include in its RACM/RACT analysis, EPA also agrees with commenters that the state's control technology analysis should also include sources which actually emit less than the threshold level of 0.5 tpy of lead or lead compounds in the area, or other sources in the area that are reasonable to control, in light of the attainment needs and feasibility of controls for the affected area. In addition, and as stated in the preamble to the final rule as it relates to RACM/RACT control analysis, EPA still believes that states should start should their consideration controls for the affected nonattainment area with the guidance provided in the 1993 Addendum to the General Preamble referenced at (published at 58 Fed. Reg. 67748, 67750-52 (Dec. 22, 1993)) taking into consideration EPA's guidance concerning the threshold 0.5 tpy for a RACM/RACT analysis as stated in the preamble to the final rule.

In addition, as stated in the proposed rule, EPA believes that the regulations, policies, and guidance currently in place for the implementation of the pre-existing Pb NAAQS are still appropriate to address the issues required to implement the revised Pb NAAQS. The EPA believes that these guidance, policies, and regulations should be used by states, local, and Tribal governments to implement the revised Pb NAAQS at this time. The EPA will, as appropriate, review, and revise or update policies, guidance, and regulations to provide for effective implementation of the Pb NAAQS.

The EPA also believes that in identifying the range of costs per ton that are reasonable, information on benefits per ton of emission reduction can be useful as one factor to consider. It should be noted that such benefits estimates are subject to significant uncertainty and that benefits per ton vary in different areas. Nonetheless this information could be used in a way that recognizes these uncertainties. If a per ton cost of implementing a measure is significantly less than the anticipated benefits per ton, this would be an indicator that the cost per ton is reasonable. If a source contends that a source-specific RACT level should be established because it cannot afford the technology that appears to be RACT for other sources in its source category, then the source should support its claim by providing detailed and verified information regarding the impact of imposing RACT on:
- fixed and variable production costs ($/unit),
- product supply and demand elasticity,
- product prices (cost absorption vs. cost pass-through),

- expected costs incurred by competitors,
- company profits, and
- employment costs.

(4) *Comment:* Given the current capabilities of dispersion models and whole atmosphere models (such as CMAQ and CAMx), the affect of various lead emission reduction strategies can be analyzed to determine their effectiveness at reducing ambient lead levels. The annualized cost of the control measure can be combined with the results of this modeling analysis to yield a cost effectiveness metric in dollars per microgram per cubic meter ($/µg/m3). This $/µg/m3 metric is a better indicator of the cost effectiveness of a control measure toward attaining the lead NAAQS than a simple $/ton metric which ignores the effectiveness of a measure in reducing ambient lead levels. Therefore, dollars per microgram per cubic meter ($/µg/m3) should be used in lieu of, or at least in addition to dollars per ton ($/ton) when evaluating the economic feasibility of a lead emission reduction technology.

Response: As stated in the preamble to the final rule, the EPA still believes that in determining appropriate emission control levels, the state should consider the collective public health benefits that can be realized in the area due to projected improvements in air quality. Because EPA believes that RACT requirements will be met where the state demonstrates timely attainment, and areas with more severe air quality problems typically will need to adopt more stringent controls, RACT level controls in such areas will require controls at higher cost effectiveness levels ($/ton) than areas with less severe air quality problems. In identifying the range of costs per ton that are reasonable, information on benefits per ton of emission reduction can be useful as one factor to consider. It should be noted that such benefits estimates are subject to significant uncertainty and that benefits per ton vary in different areas. Nonetheless this information could be used in a way that recognizes these uncertainties. If a per ton cost of implementing a measure is significantly less than the anticipated benefits per ton, this would be an indicator that the cost per ton is reasonable. The EPA, however, agrees with the commenter that the dollars per microgram per cubic meter ($/µg/m3) may be a reasonable approach to consider in lieu of, or at least in addition to dollars per ton ($/ton) when evaluating the economic feasibility of a lead emission reduction technology. The EPA believes that the decision to use of this metric should be left to the state, or tribal government to decide, taking into consideration the persistent nature of Pb. However, the appropriateness of the conclusion related to the results of dollar per ton or $/ug/m3 determination will be assessed by the EPA during the review of the nonattainment area SIP for the area during the EPA review of the SIP for approval.

(5) *Comment:* As with the monitoring issues discussed above, the Proposed Rule's discussion of RACM, RACT, RFP, and other attainment planning requirements (73 Fed. Reg. at 29270-73) gives inadequate attention to non-point sources of air lead emissions. Where the principal driver for reducing the NAAQS is the potential effect of lead exposure on children's intellectual development, and where it is undisputed that reentrainment of historic emissions is a significant contributor to current emissions, efforts to reach

attainment must give considerable attention to such "area sources" as playgrounds, parks, and similar areas.

Response: EPA expects that exceedances of the revised Pb NAAQS will be primarily attributable to industrial sources of Pb, and not to reentrainment of historic emissions in areas such as playgrounds and parks.   The EPA further believes that it is appropriate to set the recommended threshold for the RACT analysis at 0.5 tpy. While EPA is today recommending a threshold of 0.5 tpy for sources that the state should include in its RACM/RACT analysis, EPA also agrees with commenters that the state's control technology analysis should also include sources which actually emit less than the threshold level of 0.5 tpy of lead or lead compounds in the area, or other sources in the area that are reasonable to control, in light of the attainment needs and feasibility of controls for the affected area. The EPA also believes that the regulations, policies, and guidance currently in place for the implementation of the pre-existing Pb NAAQS are still appropriate to address the issues required to implement the revised Pb NAAQS. The EPA believes that these guidance, policies, and regulations should be used by states, local, and Tribal governments as a starting point to begin implementation of the revised Pb NAAQS. The EPA will, as appropriate, review, and revise or update policies, guidance, and regulations to provide for effective implementation of the Pb NAAQS.

E.   Attainment Demonstration and Modeling Requirements

(1) *Comment:* One commenter stated that the proposal cites 40 CFR 51.117 as requiring the use of dispersion modeling for the demonstration of attainment in vicinity to point sources. This is appropriate for source oriented lead nonattainment areas. However, the use of whole atmosphere models (such as CMAQ or CAMx), which can model emissions from a large number of point, area, and mobile sources should be acceptable for use in urban-oriented nonattainment areas.

Response: Since Pb is an inert pollutant, Gaussian models such AERMOD (or CALPUFF when long range transport is of concern) are used due to factors such as ease of use and costs. However, selection of the best air quality model for the individual application is encouraged in consultation with the EPA Regional Office.

F.   Transportation Conformity

(1) *Comment:* One commenter stated that they support EPA's finding that transportation conformity does not apply to the revised Pb NAAQS, since lead additives in gasoline have been eliminated.

Response: The EPA agrees with the commenter that transportation conformity does not apply to the revised Pb NAAQS. (See also the preamble for a discussion of this issue).

G.   Transition from the current NAAQS to a Revised Lead NAAQS

(1) *Comment:* The commenters states that EPA proposes that, for the current nonattainment areas, that current NAAQS would remain in effect until the approval of new SIPs. We suggest, instead that the revised NAAQS take effect upon designation under the revised NAAQS. We understand that the existing SIP will remain in effect, and enforcement, until a new SIP under the revised NAAQS is approved. Having the revised NAAQS in effect will focus the area as promptly and realistically as possible on the extent to which ambient air exceeds the revised lead NAAQS and spur the development of strong, effective SIP measures as promptly as possible.

Response: EPA notes that the revised Pb NAAQS will take effect 60 days after publication of the final rule in the *Federal Register*. Thus, during the transition both the old and the new NAAQS will be in effect, as reflected by the revisions to 40 CFR § 50.12 in addition to the promulgation of 40 CFR 50.16. EPA expects this approach will enable a smooth transition to the revised standard while also addressing the concerns identified by the commenters.

(2) *Comment:* One commenter states that in the proposed rule, EPA describes the rationale for transitioning from the current Pb NAAQS to a new or revised Pb NAAQS. EPA proposes to revoke the existing standard one year following the promulgation of nonattainment designations for the new standard. With final designations for a newly revised standard scheduled for September 2011, the existing standard would be revoked in September 2012. The commenter stated that they support this approach.

The commenter further states that, for areas in current non-attainment with the pre-existing Pb NAAQS, EPA proposes to apply the new Pb NAAQS and revoke the pre-existing Pb NAAQS only after "the affected area submits, and EPA approves, an attainment demonstration which addresses the attainment of the revised Pb NAAQS". Under this approach, areas in nonattainment with the pre-existing standard could be subject to two NAAQS-the old standard as well as the new standard- at the same time until EPA approves the SIP submittal demonstrating attainment of the revise Pb NAAAQS. The commenter states that the period of potential overlap could range from at least 3 years from the September 2011 designation to a much longer and possibly indeterminate period of time if a state is unable to submit a SIP that demonstrates attainment with the revised standard or EPA issues a FIP for the area. The commenter states that this raises a question that EPA should address, when a state is unable to submit a SIP to demonstrate attainment with the revised Pb NAAQS, what is the transition process.

Response: As stated in the preamble to the final rule, the EPA believes that Congress generally did not intend to permit states to relax levels of pollution control when EPA revises a standard until the new or revised standard is implemented. Therefore, we believe that controls that are required under the current Pb NAAQS, or that are currently in place under the current Pb NAAQS, should generally remain in place until new designations are established and, for current nonattainment areas, new attainment SIPs

are approved for any new or revised standard. As a result, EPA proposed that the current Pb NAAQS should stay in place for one year following the effective date of designations for any new or revised NAAQS before being revoked, except in current nonattainment areas, where the existing NAAQS will not be revoked until the affected area submits, and EPA approves, an attainment demonstration for the revised Pb NAAQS. Accordingly, the CAA mechanisms, including sanctions, that help ensure continued progress toward timely attainment would remain in effect for the existing Pb NAAQS, and would apply to existing Pb nonattainment areas. In cases where the state does not submit a SIP which demonstrates attainment of the revised Pb NAAQS, the pre-existing (1978) Pb NAAQS as well as the revised Pb NAAQS would remain in effect for the affected area until the state submits and EPA approves an attainment demonstration for the revised Pb NAAQS.

IV.   RESPONSES TO SIGNIFICANT COMMENTS RELATED TO EXCEPTIONAL EVENTS INFORMATION SUBMISSION SCHEDULE

One comment was received regarding the exceptional events information submission schedule. This comment is described and addressed in section VII of the preamble of the final rule.

V.   RESPONSES TO LEGAL, ADMINISTRATIVE, AND PROCEDURAL ISSUES AND NONGERMANE COMMENTS

A number of comments were received that addressed a wide range of issues including legal, administrative, and procedural issues, as well as issues that are not germane to the setting of the NAAQS. Many legal issues are addressed generally throughout the preamble to the final rule. Specific responses to other comments are presented below.

In addition, EPA also notes that in CASAC's July 2008 advice to the Agency on the proposal (Henderson, 2008b), CASAC expressed concern, with respect to the air-related IQ loss evidence-based framework, that "[a]ll other previous analyses, risk/exposure assessments, staff, CASAC and public recommendations appear to have been set aside, with this single new meta-analysis used as the exclusive basis for the proposed NAAQS level."

EPA fully agrees with CASAC that it would be inappropriate to set aside all of the other information, evidence, and input before the Agency and instead rely exclusively on this evidence-based framework. However, EPA did not do so in the proposal, and is not doing so in this final rule. Instead EPA's proposal carefully considered the entire body of evidence and information, in an integrated fashion, giving appropriate weight to each part of that body of evidence and information. (See proposal section II.E.3., discussed in preamble section III.C.3.a.) In the proposal EPA discussed at length its analysis of the evidence, including two different evidence-based frameworks. EPA also discussed at length its evaluation of the risk assessment, as well as the advice and recommendations received from CASAC and the public. While EPA placed primary weight in the proposal on the guidance derived from the air-related IQ loss evidence-based framework, EPA did not rely on it solely or exclude other information or

evidence. For example, while EPA did not give primary weight to the information from the risk assessment, EPA did determine that it was generally supportive of the estimates obtained from the evidence based framework. (73 FR 29184, 29243).

(1) *Comment*: A number of commenters, including states and tribes, expressed concerns about EPA's new NAAQS review process, variously citing CASAC's concern that the new process weakened the scientific foundations for the NAAQS review and the need for EPA to return to the practice of issuing Staff Papers. One commenter (API) supported the issuance of an ANPR, finding it helpful in reviewing the proposed rule.

Response: EPA appreciates receiving the views of commenters on the revised NAAQS process. The current NAAQS review process is consistent with the requirements of the CAA and was developed after consultation with CASAC and public comment to improve the efficiency of the process while ensuring that the Agency's decisions are informed by the best available science and timely advice from CASAC and the public. In addition, EPA notes that while this review included certain aspects of the new process, such as the issuance of an ANPR, a Staff Paper was also issued in this review.

(2) *Comment:* One commenter (ABR) stated, and another (BCI) agreed, that EPA cannot rely upon the Lanphear et al. (2005) study in promulgating the final NAAQS standard because the underlying data have not been reviewed by EPA or made publicly available.   In support of this argument, ABR cites a number of cases which stand for the proposition that under the APA an agency must disclose the technical studies and data on which the proposed rule relies.

Response: EPA notes that revisions to the NAAQS are promulgated under section 307(d) of the Act, and the APA rulemaking provisions generally do not apply to such rulemakings. See CAA section 307(d)(1). When this precise question was raised in a challenge to the 1997 PM NAAQS, the U.S. Court of Appeals for the D.C. Circuit looked to the specific language of CAA 307(d) and concluded that the "Clean Air Act imposes no … obligation [to obtain and publicize data underlying published studies on which the Agency relies]; it merely directs EPA to include in any notice of proposed rulemaking 'data, information, and documents … on which the proposed rule relies.'" *American Trucking Associations, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002).   The court found that since EPA was relying on the published studies, not the underlying data, it was unnecessary to docket the underlying data. The court explicitly endorsed EPA's view that imposing a requirement on EPA to obtain data for published studies would be impractical, unnecessary, and would make plainly relevant scientific information unavailable to EPA for use in standard-setting.

EPA continues to believe, for the reasons stated in the notice of the final rulemaking for the PM NAAQS in 1997 (62 FR 38652, 38689), that it would unnecessarily and improperly limit EPA's scientific review to interpret the CAA as requiring that data underlying studies be included in the docket, even where (as here) EPA has never been in possession of, or reviewed, the raw data underlying a study. As was the case for the PM NAAQS reviewed in *American Trucking*, EPA has placed in the docket all data,

information, and documents on which it relied in promulgating this rule. EPA placed in the docket the Lanphear et al (2005) publication, as well as documentation of correction of two errors with regard to Table 4 of that publication. These errors were identified as a result of EPA's examination of the published study in the course of the risk assessment, and were corrected by the study authors. EPA recognized at that time that the errors did not affect the results of the risk assessment (Pekar, 2007). In addition, EPA identified typographical errors in two numbers associated with confidence intervals reported at the top of the 1st column on p. 897 of the publication. In reporting this information in the CD, EPA corrected these errors (CD, p. 6-70). Further, as EPA notes in response to comment (7) in section II.A.2.c.iv above, none of the errors identified by EPA affect aspects of this study on which EPA has relied in this review. ABR has alleged in its comments that there are additional, uncorrected mathematical errors in Figure 3 of the Lanphear et al. (2005) study. As discussed elsewhere in this Response to Comments (section II.A.2.c.iv), EPA has no reason to believe that Figure 3 of this published, peer-reviewed study contains the errors suggested by the commenter, and further notes that conclusions drawn regarding this study did not depend on this figure. Furthermore, even assuming the items identified by ABR are errors, EPA does not believe they would rise to the level of fraud, abuse or scientific misconduct warranting review of the raw data. EPA notes that this study was generally consistent with a large body of other evidence demonstrating associations between exposure to Pb and neurocognitive decrement in children. EPA does not consider ABR's comments to provide a basis for doubting the overall, fundamental validity of the study's conclusions. The public had adequate opportunity to comment on the strengths and weaknesses of each study, including Lanphear et al. (2005). EPA does not consider its reliance on this study, its lack of review of the underlying data, and the lack of docketing of the underlying data, to be an error, either procedural or substantive.

(3) Comment: Some commenters stated that EPA has failed to meet the requirements of E.O. 12898 on Environmental Justice. One commenter reached this conclusion because the Agency did not "legitimately determine, acknowledge, assess, evaluate, analyze, or address the disproportionate adverse impacts of lead exposure on poor and minority populations" (Sierra Club, p. 2). In the commenter's view, the Agency disregarded available literature, failed to make a proper assessment of disproportionate exposure and sensitivity to lead among minority and low-income populations, and proposed no remedies for these disparate impacts. Another commenter agreed, stating that EPA had failed to meet its legal obligation to carry out an environmental justice assessment of proposed NAAQS alternatives (NRDC, p. 22). A third commenter stated that "the proposed rule … essentially ignores environmental justice" (Bayview Hunters Point Community Advocates p. 4) and suggests that, given that the standards under consideration by the Agency in the proposal were not risk free, EPA should have considered the distribution of the risks that would remain under alternative standard levels, and whether those risks would be disproportionately borne by communities that have traditionally been subject to discrimination.

Response: The NAAQS must afford requisite protection with an adequate margin of safety, including for sensitive subpopulations as well as to the general populace. See,

Section I.B. of the preamble. Minority and low-income populations are often such sensitive subpopulations. The Pb NAAQS established in today's final rule are nationally uniform standards which in the Administrator's judgment are requisite to protect public health with an adequate margin of safety. As discussed in section II of the preamble to the final rule and in other comment responses, the Administrator expressly considered the available information regarding air-related Pb exposure and health effects among sensitive populations, including low income and minority populations, in making these determinations.

In accordance with E.O. 12898, EPA has considered whether the decisions promulgated in the final rule may have disproportionate negative impacts on minority or low-income populations. This rule establishes national ambient air quality standards for lead that are significantly more protective than the current standard and is not expected to have disproportionate negative impacts on minority or low-income populations. EPA did conduct a quantitative analysis of the socio-demographics of populations living near ambient air Pb monitors and Pb sources emitting more than one ton of Pb per year. This analysis was necessarily limited by the lack of data on certain key parameters which prevented the Agency from assessing actual exposures and risks to these adjacent populations. However, EPA believes that the revised Pb standards will reduce health risks precisely in the areas subject to the highest ambient air concentrations of Pb, including areas immediately adjacent to Pb-emitting sources.

EPA notes that, as discussed elsewhere in the preamble and this response to comments, we concluded that the approach used in 1978 was no longer appropriate in light of scientific developments and the Administrator set the standard in this review based on protecting sensitive groups from air-related Pb risk. EPA further notes that populations with the greatest total exposure to Pb may not be the populations most sensitive to air-related Pb, but a standard set to protect sensitive populations (including populations with greater exposure and increased susceptibility) from air-related Pb risks with an adequate margin of safety would also provide sufficient protection for other populations as well. In the Administrator's judgment these national standards will protect public health, including the health of sensitive groups, with an adequate margin of safety. To the extent any of the commenters is suggesting E.O. 12898 requires additional quantitative analysis or assessment of environmental justice issues related to revising the Pb NAAQS, or that the standard should be set more stringent than necessary to protect the health of sensitive and other groups with an adequate margin of safety, EPA disagrees.

(4) *Comment*: Some commenters provided comments on the cost or economic impact of monitoring, implementation, or compliance associated with a revised Pb NAAQS. For example, one commenter, on behalf of Doe Run Resources Corp., submitted a lengthy comment on the domestic and international lead markets, and the possible effect of the revised Pb NAAQS on those markets (based on assumed shutdowns of Pb primary and secondary lead smelting facilities), and other commenters indicated that monitoring costs would be burdensome unless borne by EPA.

Response: As noted in section I.B of the preamble, the Clean Air Act bars consideration of costs in setting the NAAQS, and accordingly EPA has not considered costs, including the costs or economic impact of monitoring, implementation or compliance, in revising the Pb NAAQS.

(5) Comment: Some commenters stated that EPA is obligated to consider studies that EPA indicated it would not rely upon because the studies in question were not included in the Criteria Document and Staff Paper, which have undergone CASAC and public review. One commenter (MO Coalition) stated that a study by Hayes et al. (1994) is highly relevant, had been timely submitted to EPA as part of the review and cited by CASAC, and must be considered by EPA under CAA section 307(d)(6)(C). The commenter also questioned EPA's statement in the proposal (made in reference to Hayes et al. (1994) and a second study) that "EPA is not basing its proposed decisions on these two studies, but notes that these estimates are consistent with other studies that were included in the 1986 and 2006 Criteria Documents and accordingly considered by CASAC and the public" (MO Coalition, pp. 27-28).

Response: For the reasons stated in section I.C of the preamble, EPA is not relying upon studies that were not included in the Criteria Document and Staff Paper, which have undergone extensive critical review by EPA, CASAC and the public. EPA believes that even where a study has been identified in public comment on the drafts of the CD or Staff Paper, if the study is not cited in the CD or Staff Paper, EPA does not consider it to have undergone the expected intensive review by CASAC, EPA and the public, just because it was included in a public comment on a draft of the CD, and therefore should not be relied upon for this review. This approach is consistent with EPA's practice in prior NAAQS reviews and its interpretation of the requirements of section 109 of the CAA. EPA does not consider the language of section 307(d)(6)(C), which specifies the record for judicial review, to be inconsistent with its interpretation of section 109. Likewise, a citation by CASAC in a letter to the Administrator on the proposal is not an adequate substitute for the review associated with the development of the Criteria Document and Staff Paper. Accordingly, EPA considered the study by Hayes et al. (1994) and other "new" studies only provisionally, in conjunction with other "new" studies, and in the context of the air quality criteria to determine whether the "new" studies, considered in context, materially change any of the broad scientific conclusions regarding the health effects and exposure pathways of ambient air Pb made in the air quality criteria. The results of EPA's provisional consideration of these studies (including the study by Hayes et al.[1994]) was that they do not materially change those broad scientific conclusions and thus do not warrant reopening the air quality criteria review. As EPA notes in the preamble, there are strengths and limitations for the Hayes et al. (1994) study which may affect the specific magnitudes of the ratios reported in that study, but the study's findings and trends are generally consistent with the air quality criteria and analyses considered in this review.

(6) Comment: One commenter states that "there are several errors in the Agency's data base that relate to lead acid battery manufacturing facilities and the nation's sole remaining primary lead smelter" and that "[c]orrections should be made before EPA bases any conclusions on the erroneous data" (BCI p. 3).

Response: EPA appreciates receiving the information on Pb emissions inventories submitted by the commenter, and acknowledges that we have continued to refine our information about Pb emissions inventories during the course of this review based on additional information. EPA notes, however, that neither the revision of the NAAQS nor other decisions made in the final rule depend on the data identified for correction by the commenter.

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Appendix A. Studies on neurotoxic effects of Pb cited by public commenters that were published after closure of 2006 Air Quality Criteria Document and other relevant recent studies published since that time that were identified in routine review of journals. These studies were provisionally considered by EPA, as discussed in section I.C of the preamble and in this document, in responses to comment number 6 in section I.A.2.c.iv and comment number 1 in section II.A.3, respectively.

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