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EPA-CASAC-08-007

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee's (CASAC) Review of the Advance Notice of Proposed Rulemaking (ANPR) for the NAAQS for Lead

Dear Administrator Johnson:

The Clean Air Scientific Advisory Committee (CASAC or Committee), augmented by subject-matter-expert Panelists — collectively referred to as the CASAC Lead Review Panel (Lead Panel) — met on December 12–13, 2007, in Washington, DC, at the request of EPA's Office of Air and Radiation to review the Agency's Advance Notice of Proposed Rulemaking (ANPR) for the National Ambient Air Quality Standards (NAAQS) for Lead. The Panel also reviewed and provided comments on EPA's Final Lead Staff Paper and the *Human Exposure & Health Risk Assessment (Full-Scale) Document* (Final Lead Risk Assessment). The Lead Panel roster is attached as Appendix A, and Panelists' individual comments are found in Appendix B.

The CASAC is quite pleased with the content and conclusions of the Final Lead Risk Assessment and Final Lead Staff Paper. *The Committee unanimously and fully supports Agency staff's scientific analyses in recommending the need to substantially lower the level of the primary (public-health based) Lead NAAQS, to an upper bound of no higher than 0.2 µg/m^3 with a monthly averaging time. The CASAC is also unanimous in its recommendation that the secondary (public-welfare based) standard for lead needs to be substantially lowered to a level at least as low as the recommended primary NAAQS for Lead*. However, *the CASAC finds the ANPR for the Lead NAAQS to be both completely unsuitable and inadequate as a basis for rulemaking*, in that it does not provide the underlying scientific justification for the range of options for standard-setting that the Agency is currently considering.

In the Committee's last two letters to the Administrator on this topic (EPA-CASAC-07-003, dated March 27, 2007; and EPA-CASAC-07-007, dated September 27, 2007), the CASAC acknowledged that the Agency wished to move forward with the implementation of the revised NAAQS review process, and that this implementation would begin in the middle of EPA's cur-

rent review cycle of the lead standards — thus resulting in a "hybrid" process, blending elements of the old and the new NAAQS processes. Thus far, the Panel has reviewed two drafts of the air quality criteria document (AQCD) for Lead — a key component of the Agency's *former* review process that has been replaced by an Integrated Science Assessment (ISA) for subsequent criteria pollutant NAAQS reviews — and then received a stand-alone risk/exposure assessment document in keeping with the *new* process, which has also twice undergone CASAC review. As the final major step in the NAAQS review process, EPA asked the Committee to review the ANPR for the Lead NAAQS. As noted in the December 7, 2006 memorandum from EPA Deputy Administrator Marcus Peacock entitled, "Process for Reviewing National Ambient Air Quality Standards," the Staff Paper would be replaced by a *policy assessment* to be published as an ANPR. Nevertheless, the CASAC was particularly pleased to note that, pursuant to a Federal court order, EPA was required to produce a Final Lead Staff Paper for CASAC and public review in addition to an ANPR for the Lead NAAQS. On November 1, 2007, the Agency released the Final Lead Staff Paper and the Final Lead Risk Assessment report. On December 5, 2007, EPA released the ANPR for the Lead NAAQS, which was published in the *Federal Register* on December 17, 2007 (72 FR 71488).

Overall, the Lead Panel judged that the Agency's Final Lead Risk Assessment report is responsive to the CASAC's comments in the previous review and, with the incorporation of the few suggestions listed below, was considered adequate for use in rulemaking. Likewise, EPA's Final Lead Staff Paper, with some exceptions also noted in this letter, was considered to be an excellent document that clearly laid out the scientific evidence for options for the indicator, level, averaging time and statistical form of a new air-lead standard. EPA staff are to be commended for their careful, scholarly approach to the development of the Final Lead Staff Paper, which the Panel also considered to be adequate for use in rulemaking.

By sharp contrast, *the CASAC found the Advance Notice of Proposed Rulemaking for the Lead NAAQS* — the first such document of this type to be issued under EPA's revised NAAQS review process — *to be entirely unsuitable and inadequate for use in rulemaking*. The notable shortcomings of this ANPR are the timing in this review cycle for the Lead NAAQS and the absence of substantive information found in the ANPR document itself. The Agency chose to employ an ANPR as the regulatory vehicle for soliciting broad-based CASAC and public input on the full range of available policy options for the lead standards at this late stage in the process. To the CASAC's understanding, the EPA had not previously used an ANPR in its NAAQS rulemaking activities. Having now seen the structure and content of an Agency ANPR, the members of the Committee think that it is a regulatory tool more appropriately-suited to the *beginning* of the process for reviewing a NAAQS. Even more fundamental, the information contained in this ANPR fell far short of what the CASAC expected, per the EPA's own implementation guidance.

Specifically, as noted in the Deputy Administrator's December 2006 memo, a key element of the Agency's revised NAAQS review process was for EPA to develop a *policy assessment* in lieu of a staff paper, in order to properly reflect the views of Agency management, consistent with other EPA rulemakings, and publish this in the *Federal Register* as an ANPR. This policy assessment was described in the Deputy Administrator's memo as a document that would "identify conceptual evidence- and risk-based approaches for reaching policy judgments, discuss what the science and risk/exposure assessments say about the adequacy of the current standards,

and present any preliminary risk/exposure information associated with alternative standards." Importantly, this policy assessment would also "*describe a range of options for standard setting, in terms of indicators, averaging times, [statistical] form, and ranges of levels for any alternative standards, along with a description of the alternative underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making NAAQS decisions*" (emphasis added). In addition, we read in that memo that "such [a policy] assessment should help to 'bridge the gap' between the Agency's scientific assessment and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the standards" — a description that is virtually *identical* to what has heretofore been used in reference to EPA's staff papers for its NAAQS reviews (see, for example, the November 29, 2006 *Federal Register* notice announcing the Agency's release of the 1st Draft Staff Paper for Lead [71 FR 69117]). Therefore, the Committee had every reason to expect that this policy assessment to be released and published in the form of an ANPR would contain the breadth and depth of information and analyses that were previously contained in the Final Staff Paper for a given criteria air pollutant.

However, the ANPR for the Lead NAAQS did not *contain any such "policy assessment" as described above.* Rather, this ANPR simply laid out *all* policy options for the CASAC's and the public's consideration while omitting the underlying scientific rationale for many of them. Indeed, only EPA's Final Lead Staff Paper provides the scientific justification for each of the options that Agency staff presented for consideration in the rulemaking process. The Committee had anticipated that having both the ANPR and the Lead Staff Paper would provide an opportunity to compare the approach and content of the two documents — and also, not insignificantly, to assess the consequences of replacing the Staff Paper with the ANPR. As it turned out, *without the Lead Staff Paper, the CASAC would not have had the data and supporting analyses* necessary *to make scientifically-informed recommendations to the EPA Administrator concerning the adequacy and basis of the Lead NAAQS, as required by the Clean Air Act (CAA).*

The Agency's ANPR for the Lead NAAQS thus represented a remarkable weakening of the scientific foundation of the NAAQS review process. Far from improving the efficiency of the review, the ANPR essentially *reversed* the process. After describing the scientifically-based advice and recommendations of the CASAC — and the similar, scientifically-grounded choices of Agency staff (which agreed almost completely with the Committee's findings) — the ANPR opened up the discussion of options that had already been considered in open public advisory meetings and dismissed on scientific grounds by both the CASAC and EPA staff. For example, the ANPR solicited additional public comment on whether lead should be de-listed as a criteria pollutant. However, the Agency had already requested this evaluation in the 1st Draft Lead Staff Paper (December 2006), along with an accompanying assessment as to whether revocation of the Lead NAAQS is an option appropriate for the EPA Administrator to consider, in light of the currently-available scientific information. In its March 2007 letter to the Administrator from its review of that document (reiterated in the Committee's September 2007 letter), *the CASAC unambiguously concluded that the option of de-listing lead as a criteria air pollutant was scientifically indefensible*. As an example of the Committee's scientific rationale for this recommendation, the CASAC noted that, although over the past three decades, ambient air exposures and therefore blood lead (blood Pb or PbB) concentration levels in the U.S. population have drastically declined (primarily due to the elimination of lead from gasoline), much more is now known about

the adverse human health effects of even low levels of environmental lead exposure, and of corresponding PbB concentrations levels < 10 µg/dl, particularly in children. Yet in spite of this, EPA's ANPR effectively disregarded the CASAC's prior discussions and recommendations and reopened this issue. Numerous other examples of the inadequacy of this ANPR are furnished below in the Committee's responses to specific sections of the document, as are more detailed comments on the EPA's Final Lead Staff Paper and the Final Lead Risk Assessment report.

While this letter will focus specifically on the ANPR for the Lead NAAQS, the CASAC intends to send a separate letter to the EPA Administrator in the near future to address our concerns and elaborate on the deficiencies in the Agency's revised NAAQS review process that the Committee has identified in light of the structure and content of this ANPR.

CASAC's Comments on EPA's Final Lead Risk Assessment and Staff Paper

General Comments

The members of the CASAC Lead Review Panel were unanimous in their praise of EPA's Final Lead Risk Assessment and Final Lead Staff Paper. The Final Risk Assessment report captures the breadth of issues related to assessing the potential public health risks associated with lead exposures; it competently documents the universe of knowledge and interpretations of the literature on lead toxicity, exposures, blood lead modeling and approaches for conducting risk assessments for lead. The Final Lead Staff Paper is also a very well-crafted summary of the important issues associated with interpreting the results from the Final Risk Assessment. The Staff Paper captures the scientific issues and discusses the uncertainties associated with the various assumptions made in the risk assessment. The Staff Paper also conducts a thorough and logical analysis of various options for the NAAQS. The CASAC agrees with the vast majority of the scientific interpretations made in the Staff Paper.

Brief synopses of the Final Lead Risk Assessment and the Final Lead Staff Paper, and a few specific issues that the Panel raised with each of these documents, are highlighted below.

Synopsis and Specific Comments on EPA's Final Lead Risk Assessment

Synopsis:

The Agency's *Human Exposure & Health Risk Assessment (Full-Scale) Document* (Final Lead Risk Assessment report) describes the quantitative human exposure and health risk assessments conducted to inform EPA's current review of the Lead NAAQS. This document represented an update the Agency's *Lead Human Exposure and Health Risk Assessments for Selected Case Studies, Draft Report* (2nd Draft Lead Exposure and Risk Assessments, July 2007) that was reviewed by the Committee in August 2007, and has been updated in response to the CASAC's advice and recommendations in its letter to the Administrator on this topic (EPA-CASAC-07-007, dated September 27, 2007). As noted in the introduction to this Final Lead Risk Assessment report, "risk results are provided in this document without substantial interpretation. Rather, interpretative discussion of these results is provided in the [Final Lead] Staff Paper."

Specific Comments:

The Final Lead Risk Assessment document notes uncertainties associated with the analyses. One major uncertainty that is not discussed well is that associated with quantifying the types of exposures that result in the higher (> 5 µg/dL) PbB levels among children in the U.S. The current approach used in the Final Lead Risk Assessment relies on using the Integrated Exposure Uptake Biokinetic (IEUBK) model for lead in children to estimate the mean and median blood lead levels associated with the various scenarios and then applying a geometric standard deviation (GSD) to quantify plausible variability associated with the distribution of PbB levels for a given exposure scenario. The Lead Panel notes that there is a need for better characterization of the uncertainties associated with the model assumptions related to children's exposures at the upper end of the blood lead distribution (*i.e.*, the higher percentile) and how those exposures may differ from those of the mean/ median percentile. See also the individual written comments of Lead Panel member Mr. Sean Hayes attached in Appendix B of this letter.

Synopsis and Specific Comments on EPA's Final Lead Staff Paper

Synopsis:

EPA's Final Lead Staff Paper concluded that the overall body of evidence on lead health effects clearly calls into question the adequacy of the current primary Lead NAAQS, and provides strong support for consideration of a lead standard that would provide greater health protection for sensitive groups, especially for children. Additionally, the Staff Paper recommends that EPA *not* remove lead from the list of six criteria pollutants and also *not* revoke the NAAQS for lead. Instead, Agency staff recommended that the EPA Administrator consider *appreciably lowering* the level of the current primary standard for lead from the current level of 1.5 micrograms per cubic meter (µg/m^3). Specifically, the Final Lead Staff Paper recommends consideration of a range of levels, from levels that are currently seen in many urban areas across the U.S. (approximately 0.1–0.2 µg/m^3) to the lowest levels evaluated in the Exposure and Health Risk Assessment (0.02–0.05 µg/m^3). In addition, EPA staff recommends either revising the averaging time to monthly or retaining the current averaging time of a calendar quarter.

Specific Comments:

Consistent with the CASAC's previously recommendations to the Administrator in our letter from the Lead Panel's review of EPA's 1st Draft Lead Staff Paper and the Draft Lead Exposure and Risk Assessments documents (EPA-CASAC-07-003, dated March 27, 2007), and reiterated in the Committee's September 27, 2007 letter (EPA-CASAC-07-007) on the 2nd Draft Lead Human Exposure and Health Risk Assessments Document, *the CASAC unanimously affirms EPA staff's recognition of the need to substantially lower the level of the primary NAAQS for Lead, to an upper bound of no higher than 0.2 µg/m^3 with a monthly averaging time.*

With regard to the secondary Lead NAAQS, the Final Lead Staff Paper concluded that the overall body of evidence of lead effects on the environment calls into question the adequacy of the current secondary standard. However, Agency staff also concluded that EPA lacks the relevant data to provide a clear, quantitative basis for setting a secondary lead standard that differs from the primary standard in terms of indicator, averaging time, level or form; thus, the Staff Paper recommends that the EPA Administrator consider setting the secondary standard for

lead equal to a *strengthened* primary standard to provide increased protection against adverse environmental effects. The CASAC had also noted in its previous letters to the Administrator that the level of the secondary Lead NAAQS should be at least as low as the lowest-recommended primary lead standard, such that there is no reversal of the current downward trend in lead concentrations in the environment.

The Staff Paper also recommended that the EPA Administrator consider retaining lead in total suspended particulates (TSP-Pb) as the indicator for lead. The Lead Panel raised issues with the use of TSP or PM_{10} monitors for quantifying concentrations of lead in air. While, historically, the Lead NAAQS has relied on TSP samples for quantifying ambient lead concentrations, the Lead Panel was unanimous in recommending that EPA should transition to PM_{10} sampling for quantifying ambient lead concentrations. PM_{10} is a much more accurate and precisely-measured indicator and represents the fraction of lead that is more relevant for human exposures. In addition, there is a greater availability of PM_{10} samplers throughout the U.S. More detailed recommendations on this topic are provided in our comments in the ANPR monitoring section.

Furthermore, the Final Lead Staff Paper proposes a possible approach of enumerating the number of children above certain blood lead concentrations, similar to that used by the Agency in 1978. Such an approach is inferior to EPA's associated lead risk assessment and would tend to obscure the health benefits of reducing blood lead levels within categories. If used, this underestimation of health risk should be noted, and the CASAC recommends that a threshold of 2 µg/dL be used as the cut-point, because of the evidence of adverse effects at higher levels.

CASAC's Comments on the Agency's ANPR for the Lead NAAQS

Synopsis and General Comments on ANPR for the Lead NAAQS

Synopsis:

The Agency's ANPR for the Lead NAAQS invited public comment on: scientific evidence concerning the health and welfare effects of current and past air emissions of lead that may be found in ambient air, indoor dust, and outdoor soil; current lead exposures and health risks associated with such exposures; and, importantly, *policy options* for addressing lead air-related exposures and associated risks. Specifically, the Agency indicated that, with this ANPR, it was soliciting comment on the *adequacy* of the current lead NAAQS, on potential *revisions* to the standard, and on questions that have been raised with regard to *maintaining* a NAAQS for lead — that is, whether it is appropriate to *revoke* the lead standard or to *remove* (*i.e., de-list*) lead from the list of criteria pollutants. In addition, the ANPR invited comment on issues regarding ambient air quality monitoring for lead, to include sampling and analysis methods, network design, sampling schedule, and data handling methods. The Agency noted that it will consider CASAC recommendations and comments received from the public on the ANPR in developing EPA's proposed decision on the adequacy of the current standards and on any revisions to the Lead NAAQS that may be appropriate; and, furthermore, that the Agency will propose whether to revise or retain the current lead standards by no later than May 1, 2008 (with a target date of March 2008), and take final action by September 1, 2008, pursuant to a Federal court order.

General Comments:

The CASAC notes that the ANPR for the Lead NAAQS adds no new information — and certainly no rigorous analyses of the various options that the Agency is considering — beyond what has already been presented in the Final Lead Staff Paper and the Final Lead Risk Assessment. Furthermore, contrary to the original intent of the review of EPA's NAAQS-setting process, as set forth in the Deputy Administrator's memo of December 15, 2005, the ANPR also failed to "ensure that the best available science [will] guide and inform Agency decision making" — nor does the ANPR adhere to the "highest scientific standards" as stated in the Deputy Administrator's memo of December 7, 2006 (and essentially reiterated in his April 17, 2007 memo) that "the Agency's decisions would be informed by the best available science …. without compromising the scientific integrity [*i.e.*, soundness and transparency] of the process." Finally, rather than making EPA's NAAQS review process more efficient, as envisioned by the Deputy Administrator, the ANPR actually results in a *slowing* of the process by opening up a discussion of options that were already vetted in public and found not to be feasible by both CASAC and Agency staff. As noted above, the ANPR, in effect, puts the NAAQS review process in *reverse*.

Specific Comments on ANPR Sections on Primary Lead NAAQS

Sections III.A (Health Effects Information) & III.B (Human Exposure and Health Risk Assessments):

These sections of the ANPR on the Primary Lead NAAQS contain much good discussion drawn from the Lead Staff Paper, and provide much of the data needed to understand sources of human lead exposure and the use of IQ loss in children as the metric for assessing the effects of lead in this sensitive subpopulation. In the proposed rule for the Lead NAAQS that will follow — or, for that matter, in any ANPR for the NAAQS for a different criteria pollutant — greater emphasis should be placed on including tabular and graphical data of the scientific results that support or underpin the points being discussed. For example, the "roll-up" scenario helps the reader interpret the incremental risks associated with sticking with the current NAAQS and any alternative NAAQS. The incremental risk (*i.e.*, reflected by change in IQ loss) approach helps the reader assess the impact of the various options that are under consideration for a Pb NAAQS.

However, there were several problems identified in the discussion of the primary Lead NAAQS. The ANPR devoted too many pages to describing an alternative to the Agency's peer-reviewed risk assessment, using instead the approach of 1978. In 1978, evidence on the effects of lead on cognitive function was limited to a few studies that showed lower cognitive function in children with "high" lead levels. Reasonably, EPA set the NAAQS with a goal of limiting the number of children with "high" blood lead levels. Necessarily, such an approach recognizes no benefits to lowering blood lead levels within the "not high" category. As described by the Agency's Final Lead Staff Paper and affirmed by the CASAC Lead Review Panel, much more is now known about the dose-response between blood lead and IQ than in 1978. While there is always uncertainty in the dose-response relationship, it should be noted that uncertainty about the slope is not the same as uncertainty that the slope is not zero. Moreover, it is clear that the adverse effects of lead are demonstrable at blood lead levels even lower than 5 µg/dL, as documented by the EPA peer-reviewed risk assessment and by empirical studies.

For example, the ANPR suggests that the slope below 7.5 μg/dL is unreliable because it is based on data from 103 children from one study (Lanphear, 2005). This argument is undercut by several other studies confirming that the relationship of lead exposure is non-linear and persists at blood lead levels considerably lower than 5 μg/dL (Lanphear, 2000; Wasserman, 2003; Kordas, 2006; Tellez-Rojo, 2006). In particular, Tellez-Rojo and co-workers reported that the slope of the association between 24-month blood lead and the 24-month Mental Development Index (MDI) for 294 children who had peak blood lead levels below 5 μg/dL was negative (-1.7 points for each 1 μg/dL increase in blood lead concentration, p=0.01). Collectively, these studies indicate that there is sufficient evidence to support the use of the dose-response relationship from the pooled analysis at blood lead levels < 5 μg/dL (Lanphear, 2005), as described in the Final Lead Staff Paper and previously recommended by CASAC.

The Lead Panel was concerned that the ANPR presented analytical choices, as described below, that may underestimate risks for the adverse effects of lead and the benefits of reducing the Lead NAAQS. In isolation, each of these decisions may not be substantial, but the cumulative impact could result in substantially underestimating the adverse effects of lead and the benefits of lowering the NAAQS for lead. Similarly, these choices would fail to provide an adequate margin of safety, as required by law. The following examples illustrate the major ways that the ANPR underestimated the lead effects and the benefits of alternative lead standards:

- The Clean Air Act requires special attention to susceptible populations. The ANPR notes that there is evidence of increased susceptibility in African Americans and persons with certain genotypes (*e.g.*, ALAD [aminolevulinate, delta-, dehydratase] variants), but it is not apparent that these susceptible populations were considered in EPA's risk assessment.

- Members of the Lead Panel reiterate their previous advice to the Administrator (EPA-CASAC-07-007, dated September 27, 2007) that the Agency use the two-piece linear function for relating IQ alterations to current blood lead levels with a slope change or "hinge" point closer to 7.5 μg/dL rather than the log-linear with low-exposure linearization (LLL) concentration-response function at 1 μg/dL, as recommended in the ANPR. The ANPR argued, on the one hand, that there were too few children to extrapolate below 7.5 μg/dL. As noted above, the Lead Panel disagrees. On the other hand, the ANPR argued that it was not reasonable to see such a dramatic decrement in IQ scores at the lowest levels of exposure (*e.g.*, < 1 μg/dL). Use of the two-piece linear below 7.5 μg/dL, which is based on empirical data, would resolve the concern about steep slope observed with the log-linear results and require fewer assumptions or uncertainties.

- Lead found in "past air" is treated as part of background lead rather than as a component of policy-relevant (air) lead in the risk assessment. This will tend to underestimate the benefits of lowering the NAAQS for lead.

Section III.C (Considerations in Review of the Standard)

In its consideration of the Primary Lead NAAQS, the ANPR combines, presents, and solicits *both* scientific and policy considerations, and in several areas tends to obscure the transition from science to policy. As discussed above, the approach taken in the ANPR for the Lead NAAQS draws heavily from, repeats, or summarizes information by reference only to the EPA's

Final Lead Risk Assessment report and Final Lead Staff Paper, as well as the letters/reports that the CASAC previously sent to the Administrator during this current review cycle for the Lead NAAQS. However, the ANPR fails to convey the scientific basis of the analyses, findings and conclusions contained therein. In its review of the available scientific information, the ANPR should have indicated that: (1) lead would be retained as a criteria air pollutant; (2) the lowering of the Lead NAAQS substantially below the current value is fully-justified; and (3) as discussed below in the section on "Lead Ambient Air Monitoring and Sampling," a new indicator for lead needs to be developed. The policy implications and the Agency's view of these conclusions should then have been discussed in a transparent manner and presented in a strong policy statement.

Rather, the ANPR for Lead tends to undermine the scientific process in EPA's consideration of the primary lead standard. The ANPR frequently notes "limitations and uncertainties" in the available data, analyses, and assessments. Agency staff, on the other hand, recognized these difficulties throughout the Lead NAAQS review process and addressed these unknowns in a scientifically-defensible manner. CASAC has carefully reviewed these analyses, and concurs with the conclusions in the Agency's Final Lead Staff Paper. However, the ANPR fails to carry the discussions and cautions forward and suggests that areas of uncertainty become purely policy issues. While the treatment of uncertainty in policy decision-making should be consistent with the development of those uncertainties in the scientific assessments and be incorporated in an adequate margin of safety, as required by the CAA, the ANPR contains no discussions summarizing either the scientific treatment of uncertainty, the manner in which reviewers should consider those uncertainties, or how EPA intends to address these uncertainties in a margin of safety protective of public health.

Section III.C of the ANPR also conveys *no substantive comparative assessment* of alternative primary lead standards — that is, the point to which the established and vetted scientific evidence should lead — but merely indicates that additional input from anyone would be welcome, without specifying whether that input should be additional data, scientific evaluations, opinions or policy analyses. At best, as twice-noted above, this is moving the process of developing the NAAQS for lead *backwards*, *i.e.*, away from an established scientific foundation, with the ANPR seeming to undermine the clear intent of the Clean Air Act in what it specifies as the particular role of the CASAC.

In regard to the ANPR solicitation of additional public comment as to the sufficiency of the data to warrant the de-listing of lead as a criteria air pollutant, the EPA takes note that all current measurements are below the present ambient standard of 1.5 $\mu g/m^3$. However, in light of evidence identified by the Agency in the 1990 review, the current lead standard is clearly not health-protective. Additionally, this is clearly no guarantee that future air lead levels will remain low. The ANPR also solicits comments on whether a broad range of current Federal and State lead control programs might render the NAAQS unnecessary. The evidence evaluated, and the position of CASAC, clearly indicate that the hazardous air pollutants (HAP) standards under Clean Air Act Section 112 are not appropriate, as these generally apply to individual point sources. Lead is a ubiquitous pollutant, derived from numerous sources, presenting significant air-related exposures in multiple media; and thus is better regulated under CAA Section 108 as a "priority" pollutant. As mentioned above, this issue of de-listing lead was previously considered

by the CASAC on two occasions, and in its summary letters to the Administrator for the associated reviews the Committee unanimously indicated that there is absolutely no scientific justification for an action to de-list. To the contrary, the CASAC has strongly indicated that the current standard needs to be *substantially lowered* (and, in fact, should have been lowered on the basis of existing data many years ago).

Furthermore, the ANPR for the Lead NAAQS contemplates that the U.S. Centers for Disease Control and Prevention (CDC) "action" level for blood lead of 10µg/dL be considered as an acceptable risk level by the EPA Administrator, either as a mean or as a not-to-exceed level. The Lead Panel finds any suggestion of using blood lead action levels as a starting point for a risk assessment to be particularly troubling, in that it begs the question as to why the Agency would even consider allowing children to be sufficiently-exposed to ambient lead to permit PbB levels that require intervention. Surely such an approach — which ignores both the CDC and CASAC determinations that there are adverse health effects at lower blood lead levels — does *not* allow protection of public health with an adequate margin of safety as required by the plain language of Section 109 of the Clean Air Act. Therefore, the Lead Panel concludes that the ANPR document misapplies both the nature and purposes of the CDC's advisory statement on measures to prevent childhood lead poisoning. Specifically, the CDC level of 10 µg/dL PbB is an "action" level, which recommends the initiation of *secondary* prevention measures, not a "risk" level. The CDC, in its most recent statements (CDC 2005, 2007), explicitly declares that adverse health effects of lead occur at PbB concentrations *below* 10µg/dL, but that effective response to sub-10µg/dL blood lead levels requires *primary* prevention methods — which can only occur by significant reductions of ambient air lead levels pursuant to EPA regulations via the NAAQS. Neither of the CDC's lead-related statements indicates that, at sub-10 µg/dL levels, adverse health effects are either non-existent or trivial. Rather, the Center's statements present action levels for the purpose of prioritizing secondary prevention methods: screening, identification of exposure, and intervention after identification. Nowhere in the CDC statements are action levels defined as a "threshold" of blood Pb levels below which there is no harm. Indeed, there are several peer-reviewed papers — with results limited to children whose blood lead was always lower than 10 µg/dL and, in one case, always lower than 5 µg/dL — that report significant associations.

Finally, with regard to the indicator, level, averaging time, and statistical form of a proposed NAAQS for lead, the ANPR fails to either take any position or provide sufficient detail of the position of Agency Staff or the CASAC that would permit a member of the public to understand or evaluate the scientifically-informed decision process by which the Administrator will select from a range of options for the lead standards. The ANPR simply mentions that EPA Staff and the Committee have fulfilled their responsibilities in the process to date and solicits further input on each component. There is no indication that the scientific validity of any evidence presented will be vetted, nor whether potential conflicts of interest among prospective reviewers will be ascertained. *Thus, this ANPR fails as a rigorous policy assessment document that would stand alone as a summary of the current scientific data, and provides no discussion of the range of alternatives for the Lead NAAQS as offered by the Final Lead Staff Paper, and therefore does not provide an adequate basis from which to make sound policy decisions.*

Comments on ANPR Sections on Secondary Lead NAAQS

The Lead Panel unanimously reaffirms its earlier judgments that, as with the primary (public-health based) Lead NAAQS, the secondary (public-welfare based) standard for lead also needs to be substantially lowered. As previously noted, it is critical that the secondary Lead NAAQS be set at a sufficiently-stringent level so as to ensure that there is no reversal of the current downward trend in lead concentrations in the environment. Therefore, at a minimum, the level of the secondary Lead NAAQS should be at least as low as the level of the recommended primary lead standard. Moreover, the Agency needs to give greater priority to the monitoring of environmental lead in the ambient air, as discussed more extensively in the section of this letter that immediately follows. As noted in the ANPR, these conclusions are also fully-supported by EPA staff in the Agency's Final Lead Staff Paper.

CASAC's Comments on Lead Ambient Air Monitoring and Sampling Issues in the Agency's ANPR for the Lead NAAQS

The Lead Panel provides the following comments on the monitoring section of the ANPR for the Lead NAAQS with respect to: (a) sampling and analysis method; (b) network design; (c) sampling schedule; and (d) monitoring for secondary standard.

Sampling and Analysis Method. In its previous comments on EPA's AQCD for Lead, the 1st Draft Lead Staff Paper, and now in this review of the ANPR for the Lead NAAQS, the Panel unanimously recommends that the Agency revise the indicator for lead sampling from TSP to PM_{10}, as measured with a low-volume sampler and analyzed with low-cost multi-elemental analytical methods such as X-Ray Fluorescence (XRF), Inductively Coupled Plasma–Mass Spectroscopy (ICP-MS), or other techniques that offer improved detection limits at the lower concentrations typical of today's ambient air. The detailed rationale for this recommendation is provided in the CASAC letters to the Administrator dated March 27, 2007 and September 27, 2007 (EPA-CASAC-07-003, EPA-CASAC-07-007). See also the individual written comments from Lead Panel members Dr. Barbara Zielinska, Mr. Rich Poirot, and Dr. Donna Kenski found in Appendix B of this letter.

The Agency should also seize this opportunity to transition from TSP to PM_{10}, since the current review indicates a need for a substantial lowering of the lead NAAQS. If a standard is lowered by a factor of 10 to 100, it is unimportant if the indicator measures 10% or 15% less than the indicator selected 30 years ago. The Cavender & Schmidt (2007) analysis does indicate some variability in the average ratios of PM_{10}-Pb to TSP-Pb. However, it also shows average ratios of > 0.60 at all sites, > 0.75 at 20 of 24 sites, and > 0.80 at 18 sites. Rather than needing to arduously establish a large series of site-specific PM10-Pb to TSP-Pb ratios (which would, in essence, constitute "fitting good data to bad"), it would be well within EPA's range of discretionary options to accept a slight loss of ultra-coarse lead at some monitoring sites by selecting an appropriately conservative level for the revised Pb NAAQS. Conversely, it would be a mistake to hold up the old TSP metric as the "gold standard" and only allow newer, better technology if it can reproduce the old, and seriously-flawed, sampler performance. To further explore and discuss these issues, Agency staff and the EPA Science Advisory Board Staff Office are currently discussing a near-term meeting of the CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee.

In response to the Agency's concerns that the new PM_{10} indicator must be tied explicitly to the historic TSP health data, it is the opinion of the Lead Panel that the above arguments may be one way to justify the change, especially given that any minor effect of losing coarse particles is dwarfed by the change in the level of the standard. The Panel unanimously supported the selection of an indicator that can be more robustly measured and thus would be more representative of actual population exposures. (It is also important to note that studies of the health effects of lead are not based on ambient monitoring at all, but rather are based on internal biomarkers of dose, such as blood lead and bone lead.) Finally, a more accurate and precise Pb-PM_{10} indicator would provide a more stable determination of compliance with the new lower Lead NAAQS.

Network Design: The Lead Panel finds the existing Pb-TSP network inadequate in its ability to characterize population exposures, conditions around large sources, and concentrations at typical ambient concentrations in many parts of the county. The issue of how best to design a lead monitoring network that would serve the many goals of air monitoring data collection (while balancing limited resources) is more complicated than the Panel can do justice to in this meeting. Rather, it deserves thorough analysis and is a task that could more appropriately be assigned to the CASAC AAMM Subcommittee. The Lead Panel agrees that the current PM_{10} and National Air Toxics Trends Sites (NATTS) networks could be integrated into a new lead monitoring network, while recognizing that most existing PM_{10} monitors are high-volume samplers that use quartz filters. These samplers are preferable to high-volume TSP, but they have less precise cut-points than low-volume samplers, and the filters are not as clean as Teflon or as amenable to surface beam analytical techniques. Again, the Panel does not recommend any effort to develop site-specific or region-specific adjustment factors to make these measurements more "TSP-like." The one place where Panel members think continued TSP sampling (or more helpfully, collocated TSP and PM_{10}) would be appropriate is near large sources, where ultra-coarse particles are most likely to contribute significant mass. Multiple size fractions can provide a better understanding of exposures, of lead's movement from a source through the environment, and the influences of various source types and meteorological conditions on the distribution and deposition of lead.

Sampling Schedule: If the form of the lead standard is changed to a monthly averaging time, the sampling frequency should be increased to once every three days (1-in-3) or even more often (another point in favor of PM_{10}, which can be collected with automated sequential samplers). However, in the interests of reducing filter-sampling efforts, sampling frequency could be adjusted depending on concentrations; sites with consistently low concentrations could operate on a one-in-six-day (1-in-6) schedule, and sites that are closer to the Pb NAAQS could sample more frequently to better characterize the mean. The Lead Panel discourages the use of longer sampling times (48 or 72 hours) or compositing of samples, since these actions limit the utility of the data for other purposes.

Monitoring for the Secondary NAAQS: The Lead Panel supports the excellent idea of supplementing the rural/remote $PM_{2.5}$ Pb measurements from the Interagency Monitoring of Protected Visual Environments (IMPROVE) network with a smaller "sentinel" network of PM_{10}-Pb samplers. The IMPROVE program already collects PM_{10} samples and these samples — from a subset of sites that might be periodically rotated — could be at least subject to multi-elemental

XRF analysis that would provide useful information on both fine and coarse lead as well as other components of coarse particle composition.

In closing, the CASAC acknowledges the distinction between science and public policy in the NAAQS-setting process. However, it is essential that policy choices be based both on *sound scientific data and supporting analyses* and on *independent, expert assessment* thereof. Additionally, the process for the review of the NAAQS policy options and the associated information must be open and transparent — and should certainly reflect the results of the analytical efforts of the Agency's own scientific and technical staff. In the past, this in-depth analysis has been presented as a policy assessment in the Agency's Final Staff Paper. *The Committee still needs this rigorous policy assessment of scientific and technical information, both now and in the future, to be able to properly advise the EPA Administrator on the NAAQS.* Accordingly, the CASAC looks forward to working with the Agency to effectively and appropriately implement a suitable process for NAAQS review that is scientifically-sound and transparent and will enable the Committee to properly fulfill its statutory obligations under the Clean Air Act, with the goal of protecting public health with an adequate margin of safety and protecting the public welfare.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

Appendices

NOTICE

This report has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively-located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the SAB Web site at: http://www.epa.gov/sab.

Appendix A – Roster of the CASAC Lead Review Panel

U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
CASAC Lead Review Panel

CASAC MEMBERS

Dr. Rogene Henderson (Chair), Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Ellis Cowling, University Distinguished Professor At-Large, Emeritus, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

Dr. James D. Crapo [M.D.], Professor, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. Douglas Crawford-Brown, Director, Carolina Environmental Program; Professor, Environmental Sciences and Engineering; and Professor, Public Policy, Department of Environmental Sciences and Engineering, University of North Carolina at Chapel Hill, Chapel Hill, NC

Dr. Donna Kenski, Director of Data Analysis, Lake Michigan Air Directors Consortium (LADCO), Rosemont, IL

Dr. Armistead (Ted) Russell, Georgia Power Distinguished Professor of Environmental Engineering, Environmental Engineering Group, School of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. Jonathan Samet [M.D.], Professor and Chairman, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

PANEL MEMBERS

Dr. Joshua Cohen, Research Associate Professor of Medicine, Tufts University School of Medicine, Institute for Clinical Research and Health Policy Studies, Center for the Evaluation of Value and Risk, Tufts New England Medical Center, Boston, MA

Dr. Deborah Cory-Slechta, Professor, Department of Environmental Medicine, University of Rochester School of Medicine and Dentistry, Rochester, NY

Dr. Bruce Fowler, Assistant Director for Science, Division of Toxicology and Environmental Medicine, Office of the Director, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention (ATSDR/CDC), Chamblee, GA

Dr. Andrew Friedland, Professor and Chair, Environmental Studies Program, Dartmouth College, Hanover, NH

Dr. Robert Goyer [M.D.], Emeritus Professor of Pathology, Faculty of Medicine, University of Western Ontario (Canada), Chapel Hill, NC

Mr. Sean Hays, President, Summit Toxicology, Allenspark, CO

Dr. Bruce Lanphear [M.D.], Sloan Professor of Children's Environmental Health, and the Director of the Cincinnati Children's Environmental Health Center at Cincinnati Children's Hospital Medical Center and the University of Cincinnati, Cincinnati, OH

Dr. Samuel Luoma, Senior Research Hydrologist, Emeritus, U.S. Geological Survey (USGS), Menlo Park, CA

Dr. Frederick J. Miller, Consultant, Cary, NC

Dr. Paul Mushak, Principal, PB Associates, and Visiting Professor, Albert Einstein College of Medicine (New York, NY), Durham, NC

Dr. Michael Newman, Professor of Marine Science, School of Marine Sciences, Virginia Institute of Marine Science, College of William & Mary, Gloucester Point, VA

Mr. Richard L. Poirot, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

Dr. Michael Rabinowitz, Geochemist, Marine Biological Laboratory, Woods Hole, MA

Dr. Joel Schwartz, Professor, Environmental Health, Harvard University School of Public Health, Boston, MA

Dr. Frank Speizer [M.D.], Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. Ian von Lindern, Senior Scientist, TerraGraphics Environmental Engineering, Inc., Moscow, ID

Dr. Barbara Zielinska, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

SCIENCE ADVISORY BOARD STAFF

Mr. Fred Butterfield, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC, 20460, Phone: 202-343-9994, Fax: 202-233-0643 (butterfield.fred@epa.gov)

Appendix B – Written Comments from Individual CASAC Lead Review Panel Members

This appendix contains the preliminary and/or final written comments of the individual members of the Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel who submitted such comments electronically. The comments are included here to provide both a full perspective and a range of individual views expressed by Panel members during the review process. These comments do not represent the views of the CASAC Lead Review Panel, the CASAC, the EPA Science Advisory Board, or the EPA itself. The views of the CASAC Lead Review Panel and the CASAC as a whole are contained in the text of the letter to which this appendix is attached. Panelists providing written comments are listed on the next page, and their individual comments follow.

Panelist **Page #**

Dr. Deborah Cory-Slechta

These comments in regard specifically to the ANPR concur with those offered by other Panel members on the content of the document.

1. First, no specific options are ever proposed that could elicit serious systematic deliberations from the community at large, as per the stated intent of the change in process that has been evoked.
2. Nor is it clear how the information that would be obtained from this new process would be used and judged. Would information from non-experts be given the same weight as those of experts in the field? Does preponderance of opinion count? My service as a Panel member on the Lead NAAQS Panel is premised on lack of conflict of interest. Will information obtained from sources who might have financial interest in the outcome be given the same weight as those stakeholders who sustain the exposures? The ANPR repeatedly makes reference to levels of uncertainty in the effects of blood lead levels at <10 µg/dl, but what level of certainty would be sufficient? Since this would be a subjective judgment, how might it be related to financial conflicts of interest?
3. It remains difficult to consider how any loss of IQ could ever be acceptable in the context of human health protection and to be without public health significance. I remain of the mind set that this is a slippery slope and that 20 years from now, these documents will be read by people wondering what on earth could these people have been thinking?
4. In addition, the lack of any full economic analysis of the costs associated with lead exposure and its consequences as a component of these documents is a highly significant omission. Such an analysis, which should include the costs of all the health consequences, both for children and adults, and the long-term effects of early academic failure for children and its ability to result in sustained academic failure should be weighed in the deliberations. The focus strictly on IQ point loss is misleading at best and thus does not allow a full consideration of all of the consequences of any policy decision.
5. The document conveys a bias in its request for information. For example, in its solicitation of information on the primary standard, it requests comment on delisting, revocation and adequacy of the current standard, but does not specifically, in the same sentences, request comments on the inadequacy of the current standard, as consistent with CASAC recommendations and the OAQPS Staff paper.
6. It seem apparent that the intent of the change in process imposed during the Lead NAAQS review has been to downgrade input and recommendations provided by CASAC and thereby diminish public health protection. It certainly leaves this panel member wondering why they are spending time providing any advice to the Administrator. Likewise, the current process serves to undermine the careful and considered deliberations of its own EPA staff.

Dr. Ellis Cowling

Ellis Cowling
North Carolina State University
January 3, 2008

Individual Comments Prepared in Connection with the December 12 and 13, 2007 CASAC Review of the Advanced Notice of Proposed Rule Making (ANPR) and the November 2007 Staff Paper for Pb NAAQS

Before dealing with my specific assignment with regard to the Secondary (public-welfare based) NAAQS Standards for Pb, permit me to offer the following general comments on: the **importance of EPA's role in helping eliminate childhood lead poisoning in the United States by 2010,** and the **structure and content of the ANPR for the Pb NAAQS** in the context of the new processes and procedures for NAAQS reviews.

EPA's role in "eliminating childhood lead poisoning" in the United States

As indicated in my individual comments on January 27, 2007 and again on July 23, 2007 regarding the USEPA's implementation of the *Lead Renovation, Repair, and Painting Rule*, it was an inspiration to learn that many different agencies of our federal Government had established a very noble goal for multi-agency cooperation and collaboration in:
"eliminating childhood lead poisoning [in the United States] by the year 2010!"

At the same time, it was very disappointing to learn how little the USEPA had done during the several years after this interagency goal was established during the early 1990s to do its part together with other federal agencies to help fulfill this very noble national goal.

As the members of our CASAC Lead Panel look forward to the time it will take for EPA to implement its *Lead Renovation and Repair Rule*, we could not help but wonder why it was not until February 2007 that CASAC was asked to review two separate documents – the *Draft Assessment Plan in Support of the Lead Renovation and Repair Rule* and *An Approach for Estimating Children's Health Risk (IQ) Changes Associated with Dust Lead Generated by Renovation, Repair, and Painting Activities* – when the goal of our government is "eliminating childhood lead poisoning by 2010" – then 3 years away and now only 2 years away!

We commend the present administration of the USEPA for undertaking their presently renewed interest and actions with regard to lead pollution and poisoning and hope that the Agency will in fact now do its important and appropriate part – together with other federal agencies – and thus help our country make further progress toward our self-declared national goal of "eliminating childhood lead poisoning – [hopefully] by 2010," but if not by then "as soon thereafter as possible. **Better late than never!**

The references listed below describe important parts of the reasons why the currently proposed actions and reports regarding lead poisoning of children in the United States are so long overdue.

References:

1) Childhood lead poisoning prevention. Too little, too late. B P Lanphear. J Amer Med Assn. 2005 May, 293(18):2274-2276.

2) "Cater to the children": The role of the lead industry in a public health tragedy, 1900-1955. G Markowitz and D Rosner. Am J Public Health. 2000 January; 90(1):36–46.

General Comments on the Advanced Notice of Proposed Rulemaking for Pb NAAQS

As our CASAC Lead Panel gathered in Washington DC on December 12 and 13, 2007 to meet and discuss our individual review comments on the Advanced Notice of Proposed Rulemaking for the Pb NAAQS, once again we could not help but wonder if the form and substance of the ANPR was in fact intended to facilitate continuing delay and lack of timely action in fulfilling the noble goal of "eliminating childhood lead poisoning [in the United States]."

In this context, permit me to offer the following general comments on the **ANPR for the Pb NAAQS** and its relationship to two other sources of insight about the Pb NAAQS:

1) The detailed and firmly stated conclusions and recommendations with regard to both the Primary (public-health based) NAAQS for Lead and the Secondary (public-welfare based) NAAQS for Lead developed by the staff in EPA's Office of Air Quality Planning and Standards (OAQPS) in their *2007 EPA Staff Paper for the Pb NAAQS,* and

2) The similarly detailed conclusions and recommendations prepared over the past two years by the CASAC Lead Panel and summarized in our two most recent letters to the Administrator of EPA (EPA-CASAC-07-003 dated March 27, 2007 and EPA-CASAC-07-007 dated September 27, 2007) following careful Peer Reviews of earlier assessment documents on these same Primary and Secondary NAAQS for Lead.

I agree with the general comments made during our CASAC meeting on December 12 and 13 by essential all of my expert colleagues on our CASAC Lead Panel. We all are greatly puzzled and disturbed about:

1) The intent and purposes of these three separate sources of insight about the adequacy (or inadequacy) of the present identical Primary and Secondary NAAQS for lead, and possible changes in the indicator, level, statistic form, and averaging time of alternative NAAQS standards,

2) Presentation in the ANPR of the carefully reasoned and very congruent science-based conclusions and recommendations of both OAQPS and CASAC – as though both of these organizations were merely two additional "interested parties" in offering advice and counsel with regard to final decisions about the NAAQS for Pb and their important role in "eliminating childhood lead poisoning" and protecting ecosystems from further poisoning by both current atmospheric deposition and redistribution of historically deposited lead in the United States.

3) What is expected to be gained from our CASAC Lead Panel Review of the ANPR on December 12 and 13 – beyond what has already been communicated through CASAC's recent letters to the Administrator of EPA following careful Peer Reviews of earlier assessment documents on these same Primary and Secondary NAAQS for Lead.

4) How the additional comments received from the CASAC Lead Panel after our meeting on December 12 and 13, the already finalized conclusions and recommendations in the OAQPS Staff Paper for Pb NAAQS, and the comments being solicited through the ANPR from other federal, state, and local government agencies, public interest groups, industry and trade associations, and individual citizen will be weighed, evaluated, and assessed during the final rule making process.

Joel Schwartz summarized our CASAC Lead Panel's collective puzzlements very well when he wrote:

> "I agree with the comments of Paul Mushak that this document summarizes the risk assessment that OAQPS did, … but then ignores the recommendations of OAQPS, …and blithely asks for comments on a range of standards from zero to infinity. This is really not acceptable. The Clean Air Act requires the administrator to set standards for a pollutant that "may reasonably be anticipated to endanger public health," using criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of a pollutant in ambient air…".
>
> "The range of possibilities proposed for comments ignores the comments of CASAC on what those effects are, at what levels, ignores the Staff Paper summary of those effects at different levels, and ignores the risk assessment."

Comments on Replacement of the OAQPS Staff paper with a Policy Assessment and Rulemaking document in the form of an Advanced Notice of Proposed Rule Making

In my opinion, the ANPR for lead is not consistent with the high scientific principles outlined in Deputy Administrator Marcus Peacock's original memo of December 7, 2006 (and repeated again in his follow-up memo of April 17, 2007) where he outlined his high hopes and principled aspirations for the new NAAQS review processes as follows:

> **"I believe these changes will help improve the efficiency of the NAAQS review process while ensuring that the Agency's decisions are informed by the best available science and broad participation among experts in the scientific community. These improvements will help the Agency meet the goal of reviewing each NAAQS on a 5-year cycle as required by the Clean Air Act without compromising the scientific integrity of the process. It is imperative that the NAAQS process continue to adhere to the highest scientific standards to ensure adequate protection of public health and welfare."**

As outlined below, the ANPR for Pb is not consistent with the Deputy Administrator's hopes and written assertions about:

"… ensuring that the Agency's decisions are informed by the best available science,"
"… broad participation among experts in the scientific community,"
"… without compromising the scientific integrity of the process," and

"It is imperative that the NAAQS process continue to adhere to the highest scientific standards to ensure adequate protection of public health and welfare."

The information contained in the ANPR for Pb is presented in two distinctly different ways:

1) Carefully reasoned analyses of scientific evidence and insights developed since the last review to indicate if the current public-health based and current public-welfare based NAAQS for lead are adequate, or if alternative levels, indicators, statistical forms, and averaging times are needed to protect public health with an adequate margin of safety and to protect public welfare.

   (These parts of the ANPR are consistent with the publicly available and well documented consensus findings and recommendations contained in the November 2007 OAQPS Staff Paper and in both the March 27, 2007 and September 27, 2007 CASAC letters to the Administrator of EPA.)

2) Much less carefully reasoned descriptions of uncertainties, alternative views, and/or possible alternative courses of action that might be considered by the Administrator of EPA in making his final court-ordered decisions about the current NAAQS for lead in September 2008.

   (These parts of the ANPR are not consistent with the publicly available consensus findings and recommendations contained in the November 2007 OAQPS Staff Paper and in the March 27, 2007 and September 27, 2007 CASAC letters to the Administrator of EPA and thus are not consistent with the high principles of scientific integrity outlined in the Deputy Administrator's memorandums of December 7, 2007 and April 17, 2007.)

Comments about My Specific Assignment

As requested by our CASAC Chair, Dr. Rogene Henderson, my specific comments about the ANPR are focused primarily on the six ***Areas in Which EPA Solicits Comments*** with regard to the Secondary (public-welfare based) NAAQS Standard for Pb.

As we all are aware, EPA promulgated the present identical Primary (public-health based) and Secondary (public-welfare based) National Ambient Air Quality Standards for Lead on October 5, 1978. These standards were established at a level of 1.5 micrograms per cubic meter of air, measured as Pb in total suspended particulate matter (Pb-TSP), not to be exceeded by the arithmetic mean concentration averaged over a calendar quarter.

The six ***Areas of EPA Solicitation*** deal with the following issues related to the Secondary NAAQS standard for Pb. My comments are presented in ordinary type (or in ***bold face italic***

type in the case of important quotations from published documents) after each of these important Areas of Solicitation is presented in ordinary **non-italic bold type**.

1) The questions of delisting and revocation.

These two questions have been very thoroughly considered and discussed by both CASAC in its March 2007 letter to Administrator Johnson and also by OAQPS staff in their November 2007 Staff Paper. In fact, the March 2007 CASAC letter contains a very detailed and carefully reasoned separate section titled "**Scientific Basis for Continuing or De-listing the Lead NAAQS."** This letter contains the following firmly stated overall conclusions regarding the questions of delisting and revocation:

"The unanimous judgment of the CASAC Lead Panel is that lead should not be de-listed as a criteria air pollutant, as defined by the Clean Air Act, for which primary (public-health based) and secondary (public-welfare based) NAAQS are established, and that both the primary and secondary NAAQS air standards should be lowered substantially."

"***It is also recommended that future monitoring of lead exposure be conducted with low volume PM_{10} samplers rather than with total suspended particulate (TSP) samplers, and that the averaging time be decreased from seasonal to monthly."***

"If lead were de-listed as a criteria air pollutant, would it be appropriately regulated under the Agency's Hazardous Air Pollutants (HAP) program? The answer is "No." The HAP program regulates according to use of maximum achievable control technology (MACT) and is appropriate for point sources. However, the most widespread source of airborne lead throughout the nation is the historically-deposited lead along roadways. Thus, this source of airborne lead could not be regulated under the HAP program."

"The large environmental burden of historically-deposited lead is currently decreasing. Accordingly, the goal should be to set the secondary Lead NAAQS such that there is no reversal of the current downward trend in lead concentrations in the environment. The limited funds available for monitoring environmental lead should be focused on this critical task."

Exactly these same questions of delisting and revocation also were very critically examined in the OAQPS November 2007 Staff Paper. The final carefully reasoned conclusions of EPA staff are also stated very clearly:

"For reasons discussed above, staff concurs with CASAC with regard to consideration of Pb in the environment today and the adequacy of the current standard. Accordingly, we suggest that there is a need for the Administrator to consider a revision of the current standard to provide increased protection against reasonably anticipated adverse environmental effects."

"In conclusion, staff concludes that in the absence of information on which to base independent recommendations for the secondary standard consistent with a reduction in the level of the primary standard (Section 5.5.4) would provide increased protection against adverse environmental effects. Accordingly staff recommends that the

Administrator consider a revised secondary standard set identical to the indicator, averaging time, form, and level of a revised primary standard."

2) Whether the evidence suggests that adverse effects are occurring, particularly near point sources, under the current standard.

Here too both CASAC and OAQPS staff have thoroughly considered the question of whether adverse effects are occurring, particularly near point sources. Both organizations agree that although there are few if any catastrophic damages to aquatic or terrestrial ecosystems that can be unequivocally be attributed specifically to Pb pollution, as opposed to Pb acting in concert with other stress factors, the general conclusion from the available scientific evidence is that adverse effects are occurring, especially near point sources and that the current identical primary and secondary NAAQS for Pb need to be strengthen.

3) The role of deposition of Pb from current sources and the availability of this Pb to ecological receptors.

Most air emissions from current Pb sources are dispersed into the environment in the form of particulate matter that is transported over both short and long distances. Thus Pb particles are deposited onto the leaves, shoots, and stems of agricultural crops, forest and shade trees, and natural vegetation at low and high elevations throughout the United States as well as directly deposited onto soils and surface waters in natural and man-made lakes, streams, ponds, reservoirs, and estuaries throughout our country. From these initial deposition sites, Pb is generally absorbed, adsorbed, or chemically bound to organic matter from which it is only very slowly transported deeper into soil layers and eventually incorporated into sediments. Thus air emissions from current sources are readily available to a wide variety of ecological receptors that include all the living plants, domesticated and wild animals, and both beneficial and harmful insects and microorganisms as well as the physical components of both aquatic and terrestrial ecosystems.

Both CASAC and OAQPS staff have summarized current scientific understanding of the role of atmospheric deposition of Pb from current sources and the availability of this Pb to ecological receptors and how this knowledge should be considered in relationship to the adequacy of the current secondary standard for Pb and needs for consideration of alternative indicator, averaging time, form, and level of a revised secondary standard.

4) The adequacy of the current standard and the rationale upon which such views are based.

Please note once again the firmly stated summary conclusions of both CASAC and OAQPS staff (see the discussion under Item 1 above) with regard to the adequacy of the current secondary NAAQS standard for Pb and the recommendation from both organizations that both the primary and secondary NAAQS air standards for Pb should be decreased substantially. The principal rationale for recommending that the secondary standard be set at least as low as the proposed primary standard is that:

"***The large environmental burden of historically-deposited lead is currently decreasing. Accordingly, the goal should be to set the secondary Lead NAAQS such that there is no reversal of the current downward trend in lead concentrations in the environment."***

5) The option of a reduction in the secondary standard consistent with any reduction of the primary standard that would provide increased protection against adverse environmental effects.

As stated in the discussion under item 4 above, the principal rationale for recommending that the secondary standard be set at least as low and the proposed primary standard is that:

"***The large environmental burden of historically-deposited lead is currently decreasing. Accordingly, the goal should be to set the secondary Lead NAAQS such that there is no reversal of the current downward trend in lead concentrations in the environment."***

6) Additional information pertaining to and comment on the considerations described above, as well as on other views with regard to the elements of a secondary standard for Pb, and the rationale upon which such views are based.

The ANPR, CASAC's March 27 and September 27, 2007 letters to Administrator Johnson, and the November 2007 OAQPS Staff paper on the NAAQS standards for Pb are essentially congruent in that all three documents summarize compelling scientific evidence that current atmospheric lead concentrations and deposition — combined with a large reservoir of historically-deposited lead in soils, sediments and surface waters — continue to cause adverse environmental effects in aquatic and/or terrestrial ecosystems, especially in the vicinity of large emission sources. These effects persist in some cases at locations where current airborne lead concentrations are below the levels of the current identical primary and secondary lead standards.

Thus, from an environmental perspective, there are convincing scientific reasons to both retain lead as a regulated criteria air pollutant and to lower the level of the current secondary standard.

Since concentrations of historically deposited lead in soils throughout the U.S. (averaging 0.5 to 4 g/m^2 of land area) are changing only slowly — with a half-life exceeding a century — these concentrated deposits of lead are expected to remain accessible for exchange with the atmosphere and the rest of the biosphere into the foreseeable future. Fires, changes in land use, or climatic events such as regional dust storms could mobilize significant quantities of lead that would be harmful both to human health and ecosystems downwind. This potential for harm is not adequately recognized in the 1st Draft Lead Staff Paper and the Draft Lead Exposure and Risk Assessments technical support document, but is a concern that warrants careful continued monitoring in the future.

In addition, I recently reexamined the magnitude of the reservoir of "historically deposited lead" and found that -- 0.5 to 4 grams per square meter of land area translates into 4.4-35.7 pounds of lead that is available for potential redistribution from every acre of land

area in this country! This simple recalculation adds significance to the CASAC assertion in the March 2007 CASAC letter to Administrator Johnson that:

"Fires, changes in land use, or climatic events such as regional dust storms could mobilize significant quantities of lead that would be harmful both to human health and ecosystems downwind."

Among these several potential causes of atmospheric redistribution of lead, wild fires in forest and grassland areas – which are occurring with increasing frequency and intensity in recent decades in many parts of the US – are potentially very important for both human health and ecosystem health and stability.

The EPA is also encouraged to identify the necessary funds to support needed continuing research on the ecological effects of airborne lead pollution and to consider developing alternative secondary standards such as critical loads for lead, which may be different from primary standards in indicator, averaging time, level or form.

Finally, although the ANPR, CASAC's March and September 2007 letters to Administrator Johnson, and the November 2007 OAQPS Staff Paper for Pb do not provide a clear quantitative basis for identifying a specific lower level at which a more protective secondary Pb NAAQS should be set, there are no reasons to expect that humans are uniquely sensitive to lead pollution among the millions of plant, animal, insect, and microorganisms with which we share our life on this planet. ***Therefore, at a minimum, the level of the secondary Pb NAAQS should be at least as low as the lowest-recommended primary Pb standard.***

Dr. James Crapo

Review Comments: EPA's Advance Notice of Proposed Rulemaking for the NAAQS for Lead

James D. Crapo, M.D.
Professor
National Jewish Medical and Research Center
Denver, CO 80206

The ANPR for the NAAQS for Lead as released by the EPA December 17, 2007 is a severe disappointment and raises substantial questions regarding the viability of the revised NAAQS Review Process and the intent of the Agency to used this process to appropriately meet the requirements of the Clean Air Act. The ANPR for lead failed to meet the Agency's obligation to consider the "best available science" and provide an advance notice of, and rationale for, a justifiable range of standards that the agency is considering for rule making.

The ANPR for Lead contained only a restatement of the Agency's Final Lead Risk Assessment report and the Agency's Staff Paper along with the statement that the Agency would consider all options for its eventual rule making for this air criteria pollutant, including delisting lead. This does not constitute an advance notice of the agency's assessment of the science in this field and its thinking regarding how the NAAQS for lead should be revised to conform to the requirements of the Clean Air Act. One is left to assume that the Agency plans to make a closed door decision on a final rule after the scientific and public review is completed, thereby ignoring their responsibility to conduct this process in a more open fashion and provide an advance notice of the agency's assessment of the scientific and public policy issues that will frame the final decision.

I would applaud the quality of the Agency's work on the Final Lead Risk Assessment document and the Agency's Staff Paper on Lead. Both were well done and correctly reflected the marked evolution of the science in the field of lead toxicity. These documents correctly identified the substantial adverse risk of even low levels of lead on neurocognitive function in children and the obvious need for a marked tightening of the current lead standards. The documents also identified the central role that air lead plays in the movement of lead between environmental reservoirs and the need to maintain a strict air quality standard for lead as a central mechanism to control exposures of sensitive populations (i.e., children). While the ANPR lists findings and conclusions found in the Agency's Staff Paper, it does not provide any insight into the Agency's assessment of these findings and conclusions.

The current review of the Lead NAAQS is the first time that the revised NAAQS is being implemented. It is essential that this process be done correctly in order to establish credibility for the Agency and for the process it will use to meet its legal obligations under the Clean Air Act. I would recommend that the Agency accept the failure of the current Lead ANPR to meet even minimum expectations and to redo this document. The revised document should consider the critical scientific and policy issues and provide a range of standards that the Agency is actively considering for the eventual rule. This range of standards should be defended in the

ANPR by showing that it can be supported by high quality science and that it considers health risks to sensitive populations as required by EPA's legislative mandate.

Dr. Douglas Crawford-Brown

Comments on the Lead Human Exposure and Health Risk Assessments for Selected Case Studies (ANPR), Volume I.

Doug Crawford-Brown, December, 2007

This review focuses largely on Section III B of the ANPR document and the associated Volume I and appendices.

General Remarks

I am generally supportive of the approach taken by the authors in this assessment. The methodologies used are sophisticated and complex, capturing the major issues associated with what is perhaps the most difficult set of exposure pathways to model of any of the NAAQS due to the wide range of sources of lead in the environment. Because of this complexity, I support the idea of examining some selected case studies rather than attempting to produce a distribution of risks in the entire U.S. population, and I support the particular cases the authors have selected. The cases cover a reasonable range of exposure scenarios and include a significant number of people in the U.S.

I remain unclear as to how the results in the tables at the end of Section III B – the results concerning the NUMBER of people with a BLL or an IQ loss – are to be used by the Agency in making a final decision on the NAAQS. I suppose the conclusion that can be drawn is that the numbers of people affected are by no means insignificant (tending to be in the hundreds of thousands), and that these numbers would be even larger if the Agency were to perform the same kind of assessment over the entire United States rather than just for the case studies. And these numbers are presented in the context of other tables that report the median and 95^{th} percentiles of the BLL and IQ loss, which provides a range of considerations the Administrator might take into account in making a final decision. I simply was struck by the lack of any clearly stated decision criteria to be employed in interpreting the tables at the end of Section 3 III, but can understand if those criteria are being left to the discretion of the Administrator. As the tables stand, they demonstrate that any decision will be made in the face of results that show that the existing NAAQS is associated with significant IQ loss to a significant number of people in urban areas and near smelters located in diverse regions of the United States. It would improve the ANPR to show not just numbers of people affected in the case studies, but the fraction affected.

However, there is a problem I see in interpreting the results of the tables at the end of this section. While the risks appear significant, the large majority of those risks must be due to sources that are not impacted by the NAAQS, or at least are not completely modeled in the assessment. The tables show what I believe to be very small reductions in the 95^{th} percentile IQ loss (or even median IQ loss) as the NAAQS is progressively lowered all the way down to 0.02. There are two possible interpretations of this result. The first is that a more stringent NAAQS will have little impact on improving public health because the large majority of the risk is coming from sources unaffected by a NAAQS (an indication of the success the Agency has had with past regulatory action). The other interpretation is that this finding is an artifact of the

current inability to fully model the effect of lowered air concentrations on exposures through soil, indoor dust, etc. The claim could be made that the differences in the results as the NAAQS are lowered are significantly understated in the tables (i.e., that the benefits of regulation are understated). Both interpretations have merit here. The problem is that the latter one, the one that would support a more stringent NAAQS for lead, can't be determined one way or the other from the current assessment. I will say that the authors have done a good job of pointing to this issue in the document, so it hasn't simply been ignored. And I have no suggestions as to how the problem can be removed; it seems to me inherent in the current limitations on the state of the science in modeling non-air exposures resulting from past releases.

On the issue of the various exposure-response functions, I can't support the use of the stratified analysis with two separate slopes. I understand the reasoning that there might be two mechanisms at play at two different concentrations, but I just can't find any biological justification for a discontinuous curve. And as the curves currently stand, one is left with the odd situation (not called out in the text) that there is an intermediate range of exposures surrounding the cut-point where it looks as if a small increase in exposure leads to a decrease in IQ loss. This is an artifact of having the two separate slopes with no attempt to provide a single model over the entire range of exposures. The issue is hidden in Figure 5-2 of Volume I by the fact that the authors have chosen to force the two parts of the curve to meet (in both the 7.5 and 10 µg/dL curves). But I am not sure that this is how the modeling was done. Unless I am misreading that Volume, the C-R function used in the modeling was actually a piece-wise model with an IF-THEN-ELSE structure (IF BLL<7.5, THEN slope = X, ELSE slope = y). So there seems to me to be a disconnection between the computational form of the model and the picture shown in Figure 5-2. But absent having the code in front of me, I can't be sure this is the case. If it is, I suggest de-emphasizing this approach. I also suggest that Tables 3 and 4 contain a footnote letting the reader know which models constitute the Low and High C-R function estimate.

On a related note, I am supportive of the claims on pages 57 and 58 that the models that have undergone the extensive development and statistical diagnoses should have top priority in the assessment. At several points in the ANPR, the authors then mention that the log-linear model form should enjoy greater "confidence". I can't, however, see any place in the assessment where the idea of "confidence" plays a role formally. And this mention of increased confidence doesn't appear again in the tables. So, I am not convinced that this claim will have any impact on conclusions drawn by the reader or the Administrator. The authors might consider some way to give this judgment of confidence more of a role in interpreting the tables of results.

This assessment of IQ loss, and the claim that there is no threshold, places the assessment more in line with probabilistic risk assessments such as for cancer rather than in the older non-cancer, threshold, assessments. In the case of regulating for reduction of cancer risk, there is a need to specify an unacceptable level of risk, giving rise to the "fuzzy bright line" concept that generally plays itself out as a range of target values between 1E-6 and 1E-4. I kept wondering throughout the ANPR what the analogue is for IQ loss. The tables present estimates of the number of people with an IQ loss above 1 and an IQ loss above 7, but I can't find a coherent explanation as to why these are the relevant values defining anything like a "fuzzy bright line". I am not saying they are the wrong values, I just don't understand the implications of these values for anything like quality of life. In the case of cancer risk, the Agency did a reasonable job of looking at lifetime

excess incidence of disease that is accepted in different occupations, and used this as basis for establishing target levels of risk to be deemed unacceptable. Something akin to that is needed here, or at least will be needed when a numerical value for a NAAQS is established and presented for public comment.

The authors have chosen, in my mind, the appropriate exposure measure from the list of possibilities (concurrent, etc.). I doubt the results would change significantly if the others were used, but it might improve the document by at least including the results of sample calculations in which the same case study is assessed through these 4 different measures (or at least the two that Lanphear et al found most predictive). This would help the reader see that the results are not extremely sensitive to this choice.

I remain supportive of the proportional roll-up and roll-down approach used in the assessment, although it will introduce errors due to the fact that the impact of a revised NAAQS on non-air pathways is not being modeled directly. But given this caveat, the roll-up and roll-down procedures are the best available at the moment.

I also remain supportive of the post-processing approach to incorporating inter-subject variability into the assessment. The choice of a lognormal distribution is appropriate, as it agrees reasonably well with existing data on variability of the biological parameters going into the relationship between exposure and BLL. There remains some minor concern that they are assuming that the "central tendency" values they calculate are equal to the medians of a lognormal distribution, without any evidence that they are in fact medians rather than means or just some kind of "representative typical" value (as is often the case in such regulatory assessments, typified by NATA). But that is a minor quibble and in any event it is made routinely both in risk assessment in general and in EPA assessments in particular.

On the issue of uncertainty, the authors have chosen not to employ a formal statistical approach, and have instead provided results under a range of different C-R models. I support this idea in principle, because it would not be feasible at present to place such a complex computational system into a full, nested, uncertainty-variability framework. However, I think the uncertainties in characterizing exposure, and in the exposure-to-BLL conversion, are at least as large as those associated with the C-R functions. As a result, the document should make it clear that the uncertainties described are a lower bound estimate on uncertainties (and then make it clear that this uncertainty can cut both ways).

On Page 73 of the ANPR, the authors note that the uncertainties and limitations in the Secondary Lead Smelter case study are large. The closing sentences in this bullet appear to suggest that this analysis should not be used. Is that what the authors intend to convey?

Finally, I note that the authors have, for the most part, responded to all of my concerns with the first draft assessment, and most of the concerns raised in the CASAC review overall. There remain areas where the science needs to be improved, especially with respect to non-air exposure pathways that reflect "past" exposures, but the authors have done what I believe is the best assessment possible given these current limitations and complexities. I was especially pleased to see the complete dropping of calculations at the 99.5^{th} percentile.

Mr. Sean Hays

Individual Review Comments
By: Sean M. Hays
Date: December 19, 2007

Comments on Final Lead Risk Assessment and EPA Staff Paper

I commend the EPA for providing the incremental changes in blood lead levels associated with the various NAAQS scenarios. As I have commented before, the incremental changes in blood lead levels are far more certain and informative than the predicted absolute blood lead levels. In my opinion, these incremental changes in blood lead (and thus IQ decrements) between current levels and the various NAAQS options should be relied upon for setting the NAAQS.

Providing the "roll-up" scenario is very helpful and informative for NAAQS decision making. It is important to see what could happen if the NAAQS is set at a level that allows for levels of air lead to increase above those occurring today.

The final risk assessment notes many uncertainties associated with the analyses. One major uncertainty that is not discussed well is related to uncertainties associated with quantifying the types of exposures that result in the higher (> 3 - 5 µg/dL) PbB levels among children in the United States. The current approach used in the Final Lead Risk Assessment relies on using the Integrated Exposure Uptake Biokinetic (IEUBK) model for lead in children to estimate the mean/median blood lead levels associated with the various scenarios and then applying a geometric standard deviation (GSD) to quantify plausible variability associated with the distribution of PbB levels for a given exposure scenario.

The Final Lead Risk Assessment notes on page 4-17 that "pathway apportionment of blood Pb levels for higher population percentiles is specified to be the same as that estimated using the central tendency estimate of blood Pb in an exposure zone." In other words, if air lead is thought to contribute ten percent (10%) of total lead exposures for the central tendency of the U.S. population, this estimate is also used for the higher population percentiles of PbB. Since the goal of any lead risk assessment will be to reduce the blood lead for the higher percentiles, knowledge of the exposure sources for these higher percentile PbB levels and the potential to impact these exposures via the Lead NAAQS is critically important. The current Final Lead Risk Assessment does not provide any assessment or assurances that the alternative NAAQS will impact the PbB levels among the upper percentiles beyond those predicted for the mean/median percentiles. I still have uncertainties about whether lowering the NAAQS below current exposure levels will meaningfully impact the levels of lead in children who already have blood lead levels above 5 µg/dL (the population of children most at risk of developing neurological effects). Since it appears there are no data to fill this gap, this issue should be identified and highlighted as a data gap and research need.

The other major uncertainty that exists is the shape of the dose-response curve for children with blood lead levels below approximately 5 µg/dL. The EPA has provided a range of

slopes (both linear and non-linear) to help bound the variability or uncertainty in the dose-response relationship relating children's concurrent blood lead levels with IQ decrements. I agree with the use of the various models as it is unclear which model provides the best fit (since EPA was unable to independently validate the model fits to the data from the Pooled International Analysis).

Comments on ANPR

Not having expertise in the policy aspect of setting the NAAQS, I find it difficult to comment on the ANPR as a tool for setting the ANPR. However, I find the ANPR to read somewhat of a two-handed report. One the one hand it carefully summarizes the EPA final risk assessment and staff paper, and then on the other hand it offers other alternatives and discussions of science that were already passed off as not being supported or supportable by the science as deemed by the risk assessment, staff paper, and opinions of the CASAC. In addition, when discussing the various options, the ANPR fully characterizes the uncertainties noted by EPA and CASAC for the various issues with the risk assessment, but does not fully characterize the uncertainties with the new options being offered in the ANPR which were eliminated from consideration by EPA and CASAC. It is unclear how expanding the universe of options and interpretations at this late in the process helps to advance the policy options for setting the NAAQS.

Other specific comments include:

- On page 118 of the ANPR, it is stated that CASAC recommended 1.0 – 1.4 µg/dL or lower to be considered as an estimate of the non-air component of blood Pb. I do not agree with this estimate nor do I understand the basis for such an estimate. This estimate may be fine for the median child, however it may grossly underestimate the non-air contribution among children with much higher blood lead levels. This distinction needs to be made clear.
- On page 65 of the ANPR, it is stated that "inclusion of indoor lead Pb as a component of "other" indoor air (and consequently as a component of "past air" exposure) represents a source of potential high bias in our prediction of total exposure and risk associated with past air because conceptually, exposure to indoor paint Pb is considered part of background exposure." I agree this biases the "past air" contribution to total Pb exposure. Pb from paint should not be attributed to "past air".
- On page 67 it is stated that a "probabilistic exposure model" was used to generate distributions of blood lead concentrations for the various scenarios. The Agency should be careful not to characterize what they did as a probabilistic effort. Use of a GSD on top of estimates of the mean does not constitute a probabilistic effort.

Dr. Donna Kenski

Comments on the NAAQS for Pb ANPR
Donna Kenski
December 11, 2007

As a new member of CASAC, I came to this panel very late in the process of reviewing the Pb standard. My *a priori* view was that we'd made wonderful progress in controlling lead and that maybe it was time to retire the standard, since EPA's direction to the states has been to retire the monitors. The Staff Paper quickly set me straight. The new health effects data reviewed in that document make an absolutely convincing case that the standard must significantly lowered from the current level in order to protect at-risk populations. The ANPR, however, failed to convey the tone of the staff paper and also failed to present any concrete options or preferences on EPA's part for the direction of the rulemaking with respect to anticipated level or averaging time. It seems to have summarized most of the science and data analysis of the staff paper but failed to include the logical conclusions that were, for the most part, presented there. Instead, it asks CASAC again for its opinions on issues we have already weighed in on. Consequently, my responses to the specific solicitations for comment below reiterate some of the advice that panel members have discussed and documented in their deliberations and letters to the Administrator (e.g., Henderson, Sept. 2007).

Monitoring considerations:

On the issue of variability of collection efficiency of the high-volume TSP sampler: The ANPR and the staff paper fail to make a compelling case for continuing to use the high-volume TSP sampler as the FRM. In light of the clearly established need to lower the level of the standard and make more frequent measurements at additional sites, EPA should take this opportunity to make low-volume PM10 sampling on Teflon filters the new FRM. It offers significant improvements in precision, allows for sequential sampling, allows for analyses of multiple species, and makes it possible to integrate Pb measurements made in existing networks that are already making PM10 metal measurements like NATTS and IMPROVE (not all of these PM10 measurements are currently low volume).

The Staff Paper and the Cavender/Schmidt memo made it clear that PM10 and TSP lead are generally highly correlated. The instances where they were not well correlated is most likely due to the inefficient and variable collection of large particles by the TSP sampler. Some of these poorer relationships were based on a small number of data points, many at concentrations close to the detection limit for the TSP FRM. The range of proposed levels (0.02 to 0.5 $\mu g/m^3$) is sufficiently broad that the selection of PM10 vs. TSP FRM has a minor impact in comparison. The average Pb-PM10/Pb-TSP ratio was 0.8, with all sites examined being above 0.6. So a level of 0.03 for PM10 would be as protective as a level of 0.05 for TSP at most sites. The sensible approach would be to choose a more conservative (lower) level of the standard and use a method to monitor that, while collecting slightly less Pb mass, offers significant monitoring advantages and makes it possible to collect the additional high-quality data necessary to make stronger assessments of Pb impacts on public health. The very large particles that will be missed by the PM10 are the same ones collected with the least reliability by the TSP method.

Retain TSP or require around large sources? As stated above, I think retaining TSP is unnecessary because a PM10 indicator could be sufficiently protective, based on the data presented in the Staff Paper and Cavender memo, and offers numerous advantages. That said, I like the idea of continuing to collect TSP (although a low-volume method would be preferable) in a few places, including around large sources, because there is much value in collocated measurements of the various size fractions. Multiple size fractions can give us a better understanding of exposures, of lead's movement from a source through the environment, and the influences of various source types and meteorological conditions on the distribution and deposition of lead. More important than what kind of monitoring is a requirement for any monitoring—PM10 or TSP—around large sources (but see comments on network below).

Appropriateness of using Pb-PM10 data as a surrogate for Pb-TSP: As noted above, I think low volume PM10 would be the appropriate indicator, not TSP. Making PM10 a surrogate for TSP is merely trying to make a more precise and well-defined measurement match a less precise and poorly defined measurement, which is the wrong approach.

Appropriate range of concentrations for an FEM demonstration: Clearly FEM demonstrations should be made across a range of concentrations that represent real-world conditions. Presuming a switch from TSP to PM10, a range of 0.01 $\mu g/m^3$ to 0.2 $\mu g/m^3$ should cover current ambient Pb-PM10 concentrations.

Adequacy of current lab analysis methods for use at alternative NAAQS levels considered in Staff Paper: A lower level of the standard, preferably one with an accompanying PM10 indicator, should be supported with a change in lab analysis method, or a requirement for a minimum detection limit that permits concentrations at typical ambient levels to be accurately quantified. At current ambient Pb-TSP or Pb-PM10 levels, a detection limit of 0.01 $\mu g/m^3$ is too high. As noted in Sec. 2.3.2.5 of the Staff Paper, 57 of 129 non-source-oriented monitors reported more than 50% of their raw data below the MDL. In order to support future reviews of the NAAQS and assess exposures to Pb, the monitoring network must do a better job characterizing these low concentrations. A method like ICP/MS has a detection limit that is sufficiently low and permits the quantitation of multiple metal species on the filter, another consideration that should be weighed in determining the appropriate choice of indicator and FRM.

Adequacy of current Pb-TSP network and need for additional sites to determine compliance with current or revised Pb NAAQS: Serious deficiencies in the monitoring network must be addressed. The fact that only 2 of the 27 largest Pb point sources have a monitor within 1 mile is appalling. Two of the sources on the list of 27 reside in a state with no Pb monitors at all. How can this be??? By allowing the nation's lead monitoring network to be dismantled, EPA has made a grave error in judgment. The new standard could address this in part by requiring monitoring around point sources (can this be made a condition of operating permits?) EPA could conduct the necessary analyses to determine what facility size or emission rate would require monitoring and how far from the fenceline is acceptable. Expanded monitoring for population exposure and to support future health risk assessments is also necessary. EPA's goals for monitoring are much broader than merely NAAQS determination.

As stated in the recent PM Draft Integrated Review Plan, "monitoring networks provide data that serve a wide variety of purposes as part of an iterative process in managing air quality. These include: (1) determining compliance with the NAAQS; (2) characterizing air quality status; (3) supporting air quality analyses used to conduct assessments of exposure, health risks, and welfare effects; (4) developing and evaluating emissions control strategies; and (5) measuring overall progress for the air pollution control program." All of these are necessary goals that need to be accommodated so that we don't go through another NAAQS review with wholly inadequate data.

But expanded monitoring has to be funded, and hopefully not at the expense of other monitoring programs. Yet another reason for moving to PM10, which would allow the NATTS monitors to take up some of the burden. In pondering the question of where to monitor for lead under a new NAAQS, I find that the issue of network design is more complicated than can be addressed adequately here. It deserves a much more thorough analysis and careful deliberation that could appropriately be assigned to the CASAC Ambient Air Monitoring and Methods Subcommittee, as Rich Poirot has suggested. Hasty decisions are likely to be regretted.

Options for improving the coverage of the Pb network: As noted above, there are many, many options, and the design of an adequate network that would provide sufficient information to support NAAQS determinations and also support exposure and risk assessments for the next review needs more attention than I can address here. To do this properly requires careful analysis. Of the options laid out in the ANPR, none are wholly satisfactory. Some combination of source monitors, population monitors, and rural monitors is needed, and taking advantage of the existing PM10 network would be great, although most are not low-volume samplers.

Appropriateness of sampling options and suggestions for others: The concept of a sampling frequency that increases as concentrations approach the NAAQS is clever. It reduces the sampling burden (and expense) where concentrations are low, and assures that as concentrations approach levels of concern, we collect enough data to assess concentrations accurately. I like this option best. Multi-day samples (48-hr, 72-hr) and composited samples are satisfactory for assessing attainment but less so for supporting other potential uses of the data.

Conventions for interpreting NAAQS: The proposed conventions are fine.

Value and appropriateness of use of IMPROVE Pb-PM2.5 data for assessing trends: Yes, it is a great idea to analyze some of the IMPROVE PM10 filters for Pb (and other metals at the same time). Adopting a PM10 indicator makes this a no-brainer.

Reference: Henderson, R. (Sept. 27, 2007) Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Administrator Stephen L. Johnson. Re: CASAC Review of the 2nd Draft Lead Human Exposure and Health Risk Assessments.

Dr. Bruce Lanphear

Comments on ANPR
Clean Air Scientific Advisory Committee December 12th-13th, 2007

The general tone of ANPR is one of complete disregard for the CASAC Panel recommendations and a failure to provide any margin of safety. The fact that "EPA is seeking comment and supporting information about whether it would be appropriate to determine that Pb emissions no longer contribute to air pollution that may reasonably be anticipated to endanger public health or the extent to which reductions in the ambient air Pb standard would benefit public health" at this late stage (page 114), makes me wonder why the CASAC Panel has been meeting for the past two years and providing advise to US EPA Administrator Johnson.

The ANPR also raises other fundamental issues about low-level lead toxicity that have largely been resolved. For example, the fact that the ANPR is soliciting comments on the appropriateness of using a mean or individual target blood lead value 10 μg/dL as the foundation for deriving a level for the primary lead standard (see page 148) is troubling and misguided for a federal agency that purports to protect the publics' health using most recent and relevant scientific evidence. The CDC clearly recognizes that the 10 μg/dL is an action level that is triggered for an individual child at the same time they clearly recognize that there is no evidence of a threshold for the adverse effects of lead on children's intellectual ability.

The ANPR consistently recommends alternatives that underestimate the effect of lead or the benefit of reducing air lead standards, thus failing to provide any margin of safety.

- Consistent with the 1978 NAAQS, the CASAC Lead Review Panel considers that the primary lead standard should be set so as to protect 99.5% of the population from exceeding substantive IQ loss (~1-2 IQ points). Due to uncertainties in estimating the 99.5% of the populations, the 95th percentile is reported as the estimate of the high end of the distribution (page 122). While it may not be possible to estimate the 99.5%, relying on the 95th percentile to make decisions about the lead standard will inevitably fail to protect 99.5% of the population.

- The ANPR ignored emerging but consistent research indicating that sub-populations of children with various polymorphisms (e.g., DRD4 7-repeat) are more susceptible to lead toxicity than children without the DRD4 7-repeat (Froehlich, 2007).

- Using a ratio of 1:5 rather than 1:10 for air lead

- Use of the log-linear with linear extrapolation at 1 μg/dL rather than the two-piece linear estimate recommended by CASAC Panel. The ANPR argued, on the one hand, that there were two few children to extrapolate below 7.5 μg/dL. On the other hand, they argued that it wasn't reasonable to see such a dramatic decrement in IQ scores at the lowest levels of exposure e.g., < 1 μg/dL. A more logical choice would have been to use the two-piece linear below 7.5 μg/dL because the linear extrapolation was based on actual

data. Moreover, as described below, there are other studies with over 200 children having blood lead levels < 5 μg/dL that confirm the non-linear relationship (Tellez-Rojo 2006).

Page 58: The ANPR was concerned that the relatively few children who had peak blood lead levels less than 7.5 μg/dL (n=103). Still, other studies corroborated the results of the pooled analysis (see, for example, Tellez-Rojo 2006). Moreover, a host of other studies confirm that the relationship at lower blood lead levels is non-linear (Lanphear, 2000; Canfield, 2003; Wasserman, 2003; Schnaas, 2006; Kordas, 2006). Thus, we have considerable confidence that lead exposure is associated with adverse effects at the lowest measurable levels of lead in blood; the only question is the size of the effect.

While the effect for each of these decisions in isolation would not result in a large difference in the estimated IQ reduction or the predicted benefit of alternatives NAAQS for Pb, it is troubling that the cumulative effect of the decisions described in the ANPR fail to provide a margin of safety.

On page 79, there is discussion about significant uncertainty at lower blood lead levels (e.g., below 5 μg/dL) for concurrent blood lead levels. The uncertainty is not whether there are effects below 5 μg/dL or that there is an inverse association of lead with IQ, but the size of the effect. Although it is reasonable to be concerned that the low-linear model may not be ideal at the lowest levels of exposure, the two-piece linear estimate < 7.5 μg/dL serves as a reasonable estimate that provides a built-in margin of safety that is otherwise ignored in the ANPR.

It is important to consider differing opinions, but it is questionable to treat the opinions of a commentator that has a clear conflict of interest (e.g., the National Association for Battery Recycling) as equivalent to the recommendations of the CASAC Panel. In several places in the ANPR, it notes that there are differing opinions and that the dramatic reductions in air lead raise questions about whether it is still appropriate to maintain a NAAQS for lead or retain lead as a criteria pollutant. If these differing (and conflicted) views are treated as equal with the CASAC Panel, it undermines the Federal Advisory Committee Act that restricts members who have conflicts of interests from serving on the CASAC Panel (see, for example, p. 111, 129 and 131).

I was struck by the US EPA's recognition that there are important limitations in the design of, and data and methods employed in, the exposure and risk analyses in a passive voice. To be completely candid with the public, it might have read, "EPA recognizes that it has failed to generate studies and monitoring data to ensure that the public is protected against lead toxicity."

Page 146: I was struck by the comment that there is "increasing uncertainty with regard to the magnitude and type of effects at levels below 5 μg/dL". This makes it sound like, despite considerable evidence about adverse effects below 5 μg/dL, we know less and less about the effects below 5 μg/dL. Or, if we only did less research there would be less uncertainly about the magnitude and type of effect at blood lead levels bellow 5 μg/dL. The evidence is quite clear that there is no apparent threshold; that is certain. It is also quite clear that the effects appear to be greater for a given increment in exposure at the lower levels of exposure.

Dr. Paul Mushak

PRE-MEETING COMMENTS: THE USEPA PB NAAQS ADVANCE NOTICE OF PROPOSED RULEMAKING (ANPR)

CASAC Pb NAAQS Panel Member: Paul Mushak, Ph.D.
December 8, 2007

My comments, per the request to the Panel from Chairperson Dr. Henderson, deal with the ANPR exclusively. Per Dr. Henderson's lead discussant assignments, I focus comments on Section III, The Primary Standard, and particularly on Section III.C of the ANPR, *Considerations in Review of the Standard.*

I. GENERAL AND SECTIONAL COMMENTS

A review of the ANPR and an accompanying "Fact Sheet" allows a number of conclusions, notwithstanding the review being limited by the time constraints posed by late release of the ANPR relative to the CASAC 12/12-13/07 meeting in Washington.

The ANPR represents an impressive effort on the part of multiple groups. I do have a number of comments about the document's potential for causing confusion, however. First, the ANPR is not the notice of proposed rulemaking but many in the public may not get the distinction from proposed rulemaking. It is, rather, a multi-part invitation to the regulatory dance for ambient air Pb standard review. The invitation, I fear, is organized in a way that will appear quite confusing to stakeholders, the general public, the media, and those in the scientific community not directly involved in the Pb NAAQS review over the past several years.

The ANPR proposes no specific air Pb NAAQS or range of NAAQS for Administrator selection. The section on the Primary Standard considerations, including policy options, Sec. III.C, says a considerable amount about where the overall process is, i.e., OAQPS exposure/risk assessments and CASAC Panel recommendations, but says nothing explicit that prioritizes the thinking of the Agency about what NAAQS selection options are really in the running. It only says where things might go in a proposed rulemaking of a NAAQS.

Specifically, while ANPR made good use of the OAQPS Exposure/Risk Assessments and Staff Paper analysis, this document did not pay appropriate attention to the Staff Paper's sets of conclusions and recommendations. The ANPR document simply indicated it was taking note of the OAQPS conclusions and recommendations. It did so by burying the reference to it in the document. Reviewers or other readers can rightfully ask "How many EPAs are there?" One has produced a full Staff Paper with recommendations for NAAQS selection, while the other has seemingly relegated the OAQPS full Staff Paper to the status of some sort of submission from an interested party.

The ANPR requests comment on a document which structurally resembles no regulatory creation ever seen before and a structure that likely will not appear as such again. The

document's contents embody the transition from the conventional review process with its production of Staff Papers and CASAC Panel peer reviews to ANPRs which cut out the Staff Paper and attenuate the traditional role of CASAC Panels for criteria pollutants mandated by statute. Consequently, this Pb ANPR invites comments at a seeming preliminary level on something which has already matured to a Staff Paper and almost two years of CASAC Pb NAAQS Panel review submissions to the Administrator.

I assume it was the call of EPA's policy office to continue with a Pb NAAQS ANPR alongside a full Staff Paper mandated by court order rather than opting for the ordered Staff Paper and leaving the maiden voyage of the ANPR approach to some other criteria pollutant that has no court challenge and no deadline date certain. Having issued both a Staff Paper and an ANPR, the Agency has two products which basically use the same information. The Agency is stitching an extra toe (ANPR) to an intact and fully functional foot (OAQPS Staff Paper and multiple CASAC Panel reviews).

The health, scientific and broader public, not to mention the various stakeholders, will find it difficult to reconcile a preliminary ANPR that only invites comment on Agency work and findings so far with a final Staff Paper that says here are our NAAQS conclusions, recommendations, and options for air lead based on (1) OAQPS' extensive scientific and policy considerations and (2) the serial recommendations from extensive peer review by the principal reviewers, the CASAC Pb NAAQS Panel.

A critical concern is how an ANPR, however well done, would play out in the overall NAAQS decision-making process when it comes time to propose a Pb NAAQS or a range of NAAQS.

— In the present case, we have an ANPR whose extensive and reasonably well-prepared sections are such because they directly benefited from the work done by others via the Staff Paper and the CASAC Panel reviews.

— To what extent does that continue in the lead standard case after solicited comments via ANPR are received and assimilated?

— How much relative weight will be given to the Staff Paper's and CASAC Panel's recommendations versus recommendations of non-Agency or non-CASAC Panel parties? The ANPR does note that those submitting comments will presumably have to provide a credible basis for their comments. Is it not appropriate for EPA to spell out clear criteria for scientific support needed for outside parties in offering their comments so they can be ranked with the scientific database being used in the Agency efforts so far?

— In future criteria pollutant regulatory rule making, will the associated ANPRs be as comprehensive and transparent as this one for Pb?

II. SPECIFIC COMMENTS ON THE ANPR DOCUMENT

The invitations for comment in the ANPR do so with an odd, repetitive semantic style of "Some might conclude..." "Some might not conclude...," etc. This is a rather unusual style in my experience with these matters, whatever the novelty of the ANPR approach in transition from the classical methodologies for criteria pollutants. The style presents no ranking or weighting to be accorded input on the basis of expertise, freedom from bias or official roles in the NAAQS review process. It may be true that "Some may say A, while some may say B," but B may be totally incorrect owing to lack of expertise, absence of arms-length exercise of judgments, existence of an agenda, or all three.

Nowhere in Sec. III.C do I find a coherent tabular compilation, with associated contexts, rationales and evidence, that lays out even a broad range of those Pb NAAQS offered in the final Staff Paper and the two CASAC Panel's Letters to the Administrator. Such one-stop reading would help clarify things immensely. These options on the basis of policy or whatever should not be scattered and buried in the dense text. The reviewer or any other interested reader will not harvest a clue, from the present language, about what EPA will eventually consider seriously *even within an extreme range of options*. They may de-list; then again, they may not. They may keep the obsolete current standard; then again, they may not. They may adopt a fully protective stance with regard to IQ loss; then again, they may not. And so forth down the line.

As noted already, a significant part of the ANPR draws heavily from, repeats, or summarizes information in the OAQPS Risk Assessments, the OAQPS Staff Paper and the several CASAC Panel Administrator Letters and attachments therein. These documents and the dependency on them in the ANPR would serve, collectively, to anticipate a strong argument presented in the policy part of Section III.C for (1) retaining Pb as a criteria pollutant and (2) lowering the Pb NAAQS substantially below the current value.

This has not occurred in Sec. III.C. There is a serious disconnect between the new evidence and its assessments and the relative treatment in Sec. III.C of the various options for the NAAQS. Sec. III.C conveys no real comparative assessment of alternative NAAQS values in terms of where the established and vetted scientific evidence should take the ANPR's thinking. For example, Sec. III.C leaves open the option of delisting and, barring delisting, keeping the present air lead standard at 1.5 $\mu g/m^3$ averaged quarterly.

Within the ANPR are several items on which I provide more detailed comment below.

A. Potential U.S. Child Health Consequences of Retaining the Current Air Pb Standard

Retention of the current air Pb NAAQS as one of EPA's eventual proposed options for action in this preliminary ANPR obliges EPA to consider the consequences to child health. The data are available to do so.

The CASAC Pb NAAQS Panel has already presented its conclusions in its Administrator Letters about the issues of delisting Pb as a criteria pollutant and the arguments for promulgating a NAAQS much lower than the current one. I will quantify some of the concerns here.

I am particularly concerned about the ANPR not ruling out an eventual NPR setting forth a rationale for keeping the current air Pb standard of 1.5 μg/m^3. EPA has attempted to model through "proportional roll-up" methods the simulated consequences of air lead at the current NAAQS with respect to fractional distributions of impacts. I agree with OAQPS' Risk Assessment effort that there is considerable uncertainty associated with this. I do not agree that it is highly unlikely that general, ambient urban air Pb values will ever re-attain levels near or at the current standard since achievement of such high levels would derive from point sources.

A better approach is a revisiting of the historical record. In this, I follow up and elaborate on Dr. Joel Schwartz's earlier meeting comments about the nature and extent of toxic lead exposures in U.S. children in earlier years. The Pb exposure record of past decades shows retaining the current standard would be potentially catastrophic to the environmental and developmental health of young U.S. children and the health of other national risk groups.

— Setting standards for toxics such as lead in air cannot be based on what a particular national, regional, or stratified expression of that substance's level in the environment happens to be at some isolated time, nor on simulations of hypothetical returns to some previously high value. The process hinges on the full regulatory and public health record for that substance. All Federal agencies entrusted with regulating toxic substances via diverse statutes have adhered to this prescriptive dictum. Besides EPA, these include the FDA, HUD, and the USDA.

— Specifically, current air Pb levels in the U.S. cannot be taken as a permanent environmental feature of U.S. air quality. They are simply a reflection of the present processes for lead's entry or reentry into the ambient atmosphere. As such, they are subject to abrupt changes in U.S. technological and/or industrial activity using lead. I do not agree with the ANPR's assumption that return to past air Pb levels would be highly unlikely. We should be mindful that discussions of lead control in the 1920s, such as they were, did not anticipate the enormous adverse child health consequences of the introduction of leaded gasoline in the U.S.

— Re-promulgation of the current primary air Pb standard or promulgation of an even weaker one would simply mean there is no *de-facto* regulatory barrier to the introduction or re-introduction of lead sources and ambient atmospheric emissions that would expose millions of American children to lead at toxic levels, as happened in the 1970s.

— Alternative regulation of air Pb as a hazardous air pollutant under Sec. 112 of the CAA would not be as effective for control as a criteria pollutant process. The CASAC Panel put forth reasons for this and made this explicitly clear in past communications to EPA.

— In the late 1970s, the nationwide U.S. air Pb values (as maximum quarterly averages) for the years 1978 and 1979 were around or even below the current air Pb standard, 1.5 μg/m^3. The national values were 1.67 and 1.36 μg/m^3 respectively (see, e.g., USEPA, 1994).

— In the period 1976-1980, corresponding to the above air Pb values, the NHANES II survey (Annest and Mahaffey/USDHHS, 1984, Table 4; US EPA, 1986 Criteria Document, Ch. 11, Table 11-2, Mahaffey et al., 1982) showed that:

— The arithmetic and geometric means of blood lead (Pb-B) for U.S. children 6 mos. to 5 years of age were 16.0 and 14.9 μg/dl in the 1976-1980 time respectively. The great majority, 87.8%, of children in this age band at that time had Pb-Bs of 10 μg/dl or higher. The tally of U.S. children in this age band was 17 million (rounding), meaning 15 million children had Pb-Bs at or above this value. A significant fraction of these children, 20.5%, had Pb-Bs at or above 20 μg/dl, or a total of 3,500,000 children (rounding).

— The arithmetic and geometric means for black children 6 mos.-5 years of age were 20.9 and 19.6 μg/dl, respectively, while this age block of white children showed 14.9 and 14.0 μg/dl, respectively. Virtually all U.S. black children (97.5%) had Pb-Bs at or above 10 μg/dl, while the corresponding percentage figure for white children was 85.5%. The tally of black children in this age band was 2,600,000 (rounding), meaning over 2,500,000 black children had Pb-Bs at or above this value.

— For a total of 13,600,000 white children (rounding), 11,600,000 of these had Pb-B at 10 μg/dl or higher. A majority of black children, 51.1%, had Pb-Bs 20 μg/dl or higher. With a total base of 2,600,000, 1,340,000 black children had a Pb-B of 20 units or higher. White children had lower prevalence, 18.1%, of Pb-B 20 μg/dl or higher, but the much greater population base meant higher tallies at 20 μg/dl and higher, i.e., 2,460,000 (rounding) white children.

— The major source of the above-described greatly elevated Pb-B values was direct and indirect air Pb exposures, the latter as dusts and fallout onto soils. We know this from the quantitative features of time trend correlational analyses of ambient air Pb and declines in Pb-B.

Illustrative Refs for 1970s Pb Exposures:

Annest JL, Mahaffey K. 1984. Blood lead levels for persons ages 6 months-74 years: United States, 1976-1980. Hyattsville MD: National Center for Health Statistics, U.S. Department of Health and Human Services. Series 11, No. 233.

Mahaffey KR, Annest JL, Roberts J, Murphy RS. 1982. National estimates of blood lead levels: United States, 1976-1980: association with selected demographic and socioeconomic factors. N. Engl. J. Med. 307: 573-579.

U.S. EPA. 1986. Air Quality Criteria for Lead, 4 Vols. EPA 600/8-83/028bF. Research Triangle Park, NC: Environmental Protection Agency, Ch. 11, Vol. III.

U.S. EPA. 1994. National Air Quality and Emissions Trend Report, 1994. Report No. EPA 454/R-95-014. OAQPS, RTP, NC. Appendix Table A-9.

B. Gaps in Regulatory Policy Options in ANPR Sec. III.C.

The ANPR accepts that there is no documented "safe" level for lead exposures indexed as Pb-B in children. It accepts, as do virtually all other expert consensus public documents on the topic, the huge database for human populations showing lead is a non-threshold toxicant in children. Characterization of lead as a non-threshold toxicant has obvious regulatory policy implications for its control.

— The ANPR does not go the next obvious step and discuss the question of whether lead needs to be regulated the way EPA regulates other non-threshold toxicants, for example, the toxicants classified as likely or established human carcinogens. I am not saying that lead bears toxicological and mechanistic analogy with human carcinogens, only analogy with this class of toxicants in terms of the clear need for harmonization of regulatory rationales and methodologies for all non-threshold toxicants.

— EPA may in fact take the view that lead is theoretically a threshold toxicant but that threshold has not yet been revealed. However, the issue remains: if lead is a threshold toxicant it has an extremely small window in which to exhibit this characteristic. The window is now so small that the potential range for a claimed threshold becomes a dose-response distinction without a toxicological difference from non-threshold toxicants.

— Regulation of lead in air or elsewhere as a non-threshold toxicant retains in a more stringent way the suite of policy questions of what non-threshold toxic endpoint and its numerical value are to be determinative for control and at what risk management level, i.e., what frequency of toxic occurrence within a risk group is to be acceptable.

— The upshot of the above that the nature of lead as a non-threshold toxicant clearly requires that any selected air Pb NAAQS be as low as possible.

C. Use of CDC Statements in the ANPR

The various CDC Statements on childhood lead poisoning appear to occupy a central position in the general thinking in the ANPR, but EPA's grasp of these Statements appears to be tenuous at best. It is necessary to put CDC Statements in context in terms of their scope and purposes for use by regulatory agencies for lead control and to avoid misuse.

CDC Statements, contrary to implied or expressed interpretations and roles given them in the ANPR, were and remain highly flexible prescriptive instruments for addressing the problem of childhood lead poisoning in the U.S. and elsewhere. Every incarnation and iteration of the CDC Statements has made two characterizations of the Statements explicit. First, there was and is every expectation that the nature and advisory utility of the Statements would change as the science changed. For example, the CDC April, 1978 Statement, which was used in the derivation of the 1978 and current NAAQS primary standard of 1.5 μg/dl, stated that (p. 1, Introduction):

"The CDC recognizes that there will doubtless be further development in this field which may alter or redefine our current understanding."

The 1985 Statement (p. 1, Introduction) noted:

> "The revised recommendations in this 1985 Statement reflect current knowledge concerning screening, diagnosis, treatment, follow up, and environmental intervention for children with elevated blood lead levels."

The second aspect of all Statements, including the 2007 version, was the use of the Statements to eventually effect primary lead poisoning prevention for children in the U.S. and elsewhere. Furthermore, this ultimate goal of primary prevention was presented in print to the public health and clinical communities for more than 30 years. We clearly see this in the evolution of the prescriptive language of successive Statements which simply translates as 'it is much easier to prevent than to treat.'

The 1978 Statement (p. 1, Introduction) notes:

> "The ultimate preventive goal is identification and removal of lead in the environment before it enters the child. Until this occurs, screening, diagnosis, treatment, and environmental management will continue to be necessary public health activities."

The 1985 Statement (p. 1, Introduction) notes:

> "Clearly, the goal is to remove lead from the environment of children before it enters their bodies. Until this goal is reached, screening, diagnosis, treatment, and environmental management will continue to be necessary public health activities."

The 1991 Statement (pp. 1-4, Introduction) notes:

> "Primary prevention efforts (that is, elimination of lead hazards before children are poisoned) must receive more emphasis as the blood lead levels of concern are lowered [p.1]."

> "Primary Prevention. Efforts need to be increasingly focused on preventing lead poisoning before it occurs. This will require communitywide environmental interventions, as well as educational and nutritional campaigns. [p.3] "

> "The focus of prevention efforts, therefore, must expand from merely identifying and treating individual children to include primary prevention....[p.4]"

The 2005 Statement (p. ix, Preface) notes:

> "The data demonstrating that no "safe" threshold for blood lead levels (BLLs) in young children has been identified highlights the importance of preventing childhood exposures to lead. It confirms the need for a systematic and society wide effort to control or eliminate lead hazards in children's environments before they are exposed. This emphasis on primary prevention, although not entirely new, is highlighted here and is clearly the

foremost action supported by the data presented in *A Review of Evidence of Adverse Health Effects Associated with Blood Lead Levels < 10 µg/dL in Children.* "

The CDC 2007 Statement (MMWR 56: 11/2/07, p. 1), in advising how clinicians are to deal with Pb-B values < 10 µg/dl, essentially iterates parts of the 2005 Statement from which it drew considerable information.

CDC presented the CDC Statements of 1975, 1978 and 1985 as tabulated Pb toxicity risk advisories for *secondary prevention of childhood lead poisoning.* That is, the focus was to be on identification of the frequency and nature of lead exposures in U.S. children where the mechanisms are *post-hoc* in nature: children are identified as to toxic lead exposures after they have sustained such toxic lead exposures.

However, developmental neurotoxic effects in children appear to be persistent and may be irreversible to some significant extent. Once such effects are expressed, whether recognized or not, they are not easily reversed (Rogan et al., 2001; Rosen and Mushak, 2001).

Refs:

Rogan WJ, Dietrich KN, Ware JH et al. 2001. The effect of chelation therapy with succimer on neuropsychological development in children exposed to lead. N. Engl. J. Med. 344: 1421-1426.

Rosen JF, Mushak P. 2001. [Editorial]. Primary prevention of childhood lead poisoning--the only solution. N. Engl. J. Med. 344: 1470-1471.

The October 1991 CDC Statement presented prescriptive language that was transitional in nature, combining elements of both secondary and *primary prevention mechanisms*. Primary prevention deals with prevention of the toxic lead exposures in the first place.

The August, 2005 and November, 2007 Statements clearly state that adverse health effects in children occur below 10 µg/dl. These Statements acknowledged the huge growth in the database for low-level lead poisoning in the global literature from 1991 to the present. The 2005 and 2007 Statements render the 14 to 16 years-old 1991 Statement irrelevant to doing quantitative health risk assessments for lead in children now.

The latter two Statements preserved the value of 10 µg/dl as the action level for earliest intervention in terms of a prioritization rationale. Nowhere in the 2005 and 2007 Statements does CDC say that effects in children below 10 µg/dl are trivial, merely that BLLs in this range require primary prevention through the various agencies entrusted with such primary prevention, to include EPA.

More specifically, the CDC material shows EPA needs to recognize one obvious fact about the need for primary prevention methods spelled out in the 2005 and 2007 Statements. Primary prevention methods to address the toxic effects of lead at Pb-Bs <10 µg/dl require the actions of regulatory agencies such as EPA, not advisory agencies such as CDC. Ambient air Pb

through direct and indirect pathways poses adverse health risk to children and EPA is in the business of regulating air lead so as to prevent such adverse health risks through the primary prevention modality of continued ambient air Pb reduction.

D. Adequacy of CDC Statements in Meeting Section 109, CAA Requirements

The ANPR seems to dance around the issues of adequate health protection and adequate margins of safety expressed in Section 109 of the CAA with legalisms rather than convincing health science. It needs to address 109 with the latter.

Secondly, there is no explicit or causal quantitative linkage between values presented in CDC Statements and the requirements of Sec. 109 in the Clean Air Act. The "action" levels of those earlier CDC Statements employing secondary prevention methods are not values that provide adequate protection of human health with adequate margins of safety. They were meant to be and remain as triggers for prioritizing secondary lead poisoning prevention strategies: screening, diagnosis, treatment, and environmental management.

The CDC risk categories, with their successive reductions in earliest levels of concern for Pb-Bs, do not scientifically satisfy nor are they synonymous with these Sec. 109 requirements.

<u>Refs for CDC Use of Statements and Reference Values</u>

U.S. DHEW/CDC. 1975. Increased Lead Absorption and Lead Poisoning in Young Children: A Statement by the Centers for Disease Control. Atlanta, GA: U.S. Department of Health, Education and Welfare.

U.S. DHEW/CDC. 1978. Preventing Lead Poisoning in Young Children: A Statement by the Centers for Disease Control. Atlanta, GA: U.S. Department of Health, Education and Welfare. April.

U.S. DHHS/CDC. 1985. Preventing Lead Poisoning in Young Children. A Statement by the Centers for Disease Control. Atlanta, GA: U.S. Department of Health and Human Services. January.

U.S. DHHS/CDC. 1991. Preventing Lead Poisoning in Young Children. A Statement by the Centers for Disease Control. Atlanta, GA: U.S. Department of Health and Human Services. October.

U.S. DHHS/CDC. 1997. Preventing Lead Poisoning in Young Children. A Statement by the Centers for Disease Control. Atlanta, GA: Department of Health and Human Services. November.

U.S. DHHS/CDC. 2005. Preventing Lead Poisoning in Young Children. A Statement by the Centers for Disease Control and Prevention. Atlanta, GA: Department of Health and Human Services. August.

U.S. DHHS/CDC. 2007. Interpreting and Managing Blood Lead Levels <10 μg/dL in Children and Reducing Childhood Exposures to Lead. Recommendations of CDC's Advisory Committee on Childhood Lead Poisoning Prevention. MMWR 56: 1-14; 16.

Mr. Rich Poirot

Post-Meeting Comments on (monitoring section of) 12/07 Pb ANPR, R. Poirot, VT DEC

I was disappointed by the overall form and content of the Pb ANPR – both as a guide to policy decision-making for revising the current (1978) Pb standards, and more generally as a harbinger of how the new NAAQS review process may be conducted in the future. Nearly as much space is devoted to summarizing and justifying the logic and rationale for the 1978 standards and 1990 decision not to revise them, as is provided to summarize and synthesize the new scientific information that is relevant to the current NAAQS review. In discussing the current review, the ANPR presents – and specifically seeks comment on - such a broad range of policy options for all aspects of a revised (or de-listed) Pb NAAQS, that its difficult to see how it informs the public on the Agency's intentions for rule-making, or solicits useful new information to inform that rule-making. The resulting general 'public opinion survey' also provides an inherently difficult target for scientific review, and raises questions about the future role (if any) of CASAC review at this point in the NAAQS process.

Carefully considered, thoroughly documented EPA staff recommendations and associated CASAC comments are often presented as a sort of "extreme" low bound to an open-ended range of policy options, for which alternative viewpoints of "some" or "others" are presented in the ANPR without documentation, justification or attribution of authorship. We learn that "questions have been raised" regarding the option of delisting Pb as a criteria pollutant, but not by whom or for what purpose. After explaining why the CDC action level of 10 µg/dL BPb is used to identify individual at-risk children for follow-up remedial action, and should clearly not be "misinterpreted as a definitive toxicological threshold", the ANPR then proceeds, bizarrely, to request comments on the use of this screening level as a (misinterpreted) "foundation for deriving the level for the primary Pb standard", because "some" might consider this appropriate. The ANPR also features a very heavy emphasis on 'limitations and uncertainties' in all sections (the words "limitations", "uncertainty" or "uncertainties" appear a total of 136 times in the ANPR), but provides few if any quantitative assessments of these uncertainties for context.

By contrast, the final Pb Staff paper was clearly written, intelligently reasoned, thoroughly documented, and should provide a useful basis for Agency decision-making. It was difficult to imagine reviewing the current ANPR, without benefit of this focused Staff Paper. Nor can I imagine how future ANPRs - without benefit of preceding Staff Papers - can effectively present the recommendations of technical staff and CASAC, along with the contrasting anonymous opinions of some and others. If open-ended ANPRs of this nature are contemplated for future NAAQS reviews, they should be issued at the beginning, rather than at the end, of the review process, and the Staff Paper should be retained as a critical step in the NAAQS review process.

Pb Indicator and Considerations for Ambient Monitoring

In previous comments on the Pb CD and 1st draft Staff Paper, the CASAC Pb Panel had encouraged the Agency to consider revising the indicator for Pb sampling from TSP to low volume PM_{10} (with provisions for low cost multi-elemental analytical methods like XRF and ICP-MS). Reasons for this recommendation (from Henderson, 2007) included:

"Most other TSP sampling was discontinued after PM_{10} standards were promulgated in 1987. TSP samplers capture particles with an imprecise and variable upper particle cut size in the range of approximately 30 to 50 microns on fiberglass filters which are not well-suited for analysis by inexpensive, multi-elemental surface beam techniques like particle-induced X-ray emission (PIXE) or X-ray fluorescence (XRF). Consequently TSP sampling by imprecise samplers is primarily conducted only for lead analysis and these filters are rarely analyzed for other species. If Lead NAAQS monitoring was based on (low-volume) PM10 sampling on Teflon filters, the resulting data would be correlated with TSP lead, as suggested by limited data in the 1st Draft Lead Staff Paper, but would have substantially improved sampling precision. The Lead Panel recognizes that either monitoring system would be subject to variability based on location, particularly near sources. Other advantages of low-volume PM_{10} sampling include:

1. Focus on those biologically-relevant particles that, when inhaled, are deposited in the thoracic region;

2. Larger spatial-scale representativeness for population exposures to monitored particles which remain airborne longer;

3. Could utilize more widespread PM_{10} and "air toxics" metals sampling networks, leading to collection of more data at lower costs;

4. Potential for inexpensive multi-elemental analysis by XRF or PIXE would provide useful supplemental metals information for health effects studies and source apportionment;

5. Potential for automated sequential PM_{10} samplers (not available for TSP) would be especially useful if sampling frequency is increased from once every six days; and

6. Weighing filters would provide useful information on PM_{10} mass; and, if collocated with $PM_{2.5}$ Federal Reference Methods (FRM), could provide needed information on $PM_{10-2.5}$ mass and speciation."

The Pb Panel had acknowledged that PM_{10} sampling could exclude some ultra-coarse particle (>10 um) Pb that had previously been captured by TSP samplers (and that may or may not become ingested), but that given the needs to substantially reduce the level of the standard and to increase the sampling frequency for a shorter-term monthly standard, the low volume PM_{10} Pb measurements, with greater accuracy and precision, lower detection limits, and potential for automated sample collection with lower cost and more useful multi-elemental analysis, would be a preferable method for future monitoring. The Pb panel also suggested that, if necessary, an "adjustment factor" might be applied to reduce the level of a PM_{10} standard to account for ultra-coarse Pb not captured by the PM_{10} samplers, as it was expected that PM_{10} Pb would represent a large fraction of, and be highly correlated with TSP Pb.

One minor criticism of the Final Staff Paper is that prior CASAC suggestions on approaches the Agency might consider in changing the Pb indicator from TSP to PM_{10} are presented in the Staff Paper as "requirements" rather than "recommendations". For example, at the bottom of p 5-25

and top of p. 5/26, it's stated that "CASAC recognized…that a scaling of the NAAQS level would be needed to accommodate the loss of very large coarse-mode Pb particles, and that concurrent Pb-PM10 and Pb-TSP sampling would be needed to inform development of scaling factors…" (emphasis added). I think the previous CASAC intent was to suggest that such approaches could help inform a judgment about an appropriate revised indicator, rather to suggest that a detailed quantitative analysis would be a necessary prerequisite.

In the 12/07 ANPR and associated support documents, the Agency presented an evaluation of the limited available collocated TSP and PM_{10} Pb data (Cavander and Schmidt, 11/26/07) from which it is concluded that no single PM_{10}:TSP ratio could be developed that would accurately predict TSP Pb for all US locations, although it did appear likely that such ratios might be developed for individual sites based on future site-specific measurements. An additional evaluation of precision and bias of existing TSP Pb data (Camilier and Rice, 2007) demonstrated that the average precision of TSP Pb measurements (averaging 12% $\pm$ 19%) and sampling bias were not substantially poorer than for some other NAAQS FRMs (although it should be noted that this analysis excluded 21% of measurements which were below MDL of 0.01 $\mu g/m^3$, and also showed much poorer relative precision at the lower concentrations more typical of actual current population exposures.

Based on these analyses, the Agency continues to advocate retention of the TSP Pb indicator, although it does request comments on various related issues and options, including:

- whether the variability of the TSP sampler warrants discontinuation of its usage as the Pb indicator,
- the appropriateness of using Pb-PM_{10} data as a surrogate for Pb-TSP,
- a perceived need to tighten the Pb FEM demonstration requirements (which currently call for testing over a [1970s - type] range of Pb concentrations of 0.5 to 4 $\mu g/m^3$) to better reflect the much lower current concentrations,
- the need to add source-oriented Pb monitoring near many of the largest Pb emitters which are not currently monitored,
- the desirability of various network options including population-based sampling, source-oriented sampling, a combination of these approaches, and/or utilization of the current PM_{10} network if an acceptable regional or site-specific correlation of TSP-Pb and PM_{10}-Pb can be established.

Regarding sample frequency, the Agency suggests and seeks comments on a wide range of options including:

- 1-in-6 day, 1-in-3-day, 1-in-1 day sampling, perhaps with increased sample frequency for sites with higher concentrations,
- increased sample duration – from 24-hour to 48 or 72-hour or longer,
- allowing for sample compositing (analyzing sequential samples together), and
- allowing for multiple samplers at one site.

Regarding Pb monitoring in rural areas to compare with secondary NAAQS - which is presumed to be equal to the primary NAAQS (what a surprise!), comments are requested on the appropriateness of using rural/remote $PM_{2.5}$ Pb measurements from the IMPROVE network –

possibly supplemented with a smaller "sentinel" network of TSP-Pb or PM_{10}-Pb samplers, to track spatial and temporal patterns of Pb concentration and deposition in non-urban areas.

I continue to strongly encourage the Agency to **transition away from TSP sampling with the clear goal of using low-volume PM_{10} Pb sampling in the near future**. The Agency has recently specified low volume PM_{10} sampling as a component of the new FRM for coarse particles ($PM_{10-2.5}$), and so there will be an expansion of population-oriented sites using this method and collecting (elementally clean) Teflon filters amenable to low cost multi-elemental analysis methods for Pb and other species indicative of emission sources and other health risks. At the same time, the Agency and the States are also expanding their sampling efforts for "toxic air contaminants", including Pb and other metals. The consensus method for NAATS metals sampling is low volume PM_{10} with associated ICP-MS analysis. In addition to the large savings in costs and human resources that would be realized if Pb NAAQS sampling were harmonized with these established and expanding programs, there are other good reasons why a transition to PM_{10}-Pb NAAQS sampling would be timely.

The current Pb standard was established in 1978, and based on sampling using 1950's technology. Pb is somewhat unique among the criteria pollutants in that it has more or less "skipped" a mid-term review cycle. Twenty years ago, there was clear evidence in the 1986-90 review to support both lowering the level of the 1978 NAAQS (from 1.5 to 0.5 to 1 $\mu g/m^3$) and also shortening the averaging time from quarterly to monthly (adding further stringency). But as the Agency chose an alternative, aggressive multi-media Pb emission reduction strategy, ambient air concentrations declined in most areas to well below the level of the antiquated NAAQS. Subsequently, Pb sampling was discontinued at many sites, since it is labor intensive, provides no useful information on sources or other pollutants, and revealed concentrations "safely" below the NAAQS. The current review provides compelling evidence of a need for a further substantial lowering of the standard, which in turn poses an especial challenge for monitoring, since the current network lacks sufficient size and orientation to focus on either populations or current sources. The continued use of 1950's sampling technology poses additional obstacles, as TSP samplers are not suited for automated sequential sampling, and the labor-intensive filter collections are not suitable to analyses for other pollutants. The TSP samplers collect a variable and unspecified mix of respirable air pollutants and coarse mode dust, and by inclusion of unknown fractions of ultra-coarse Pb containing particles, promote an FRM which – by definition – can't represent population exposures over areas extending much beyond monitoring locations at any sites where TSP-Pb differs significantly from PM_{10}-Pb. Measurements that are heavily influenced by ultra-coarse particles (where TSP-Pb differs from PM_{10}-Pb) have micro-scale spatial representativeness, and would be extremely sensitive to the exact height of the sampler inlet above the ground. It should also be noted that 2-meter separation requirements for TSP Hi-Vols, combined with the absence of sequential TSP samplers (requiring multiple samplers for monthly means) may render TSP-Pb sampling impossible at many existing monitoring sites.

This would be an opportune time to make or initiate a transition from TSP to PM_{10}, since the current review indicates a need for such a substantial lowering of the NAAQS - to the range suggested in the Staff Paper of between 0.1-0.2 $\mu g/m^3$ to as low as 0.02 to 0.05 $\mu g/m^3$. If a standard is lowered by a factor of 10 to 100, it is unimportant if the indicator measures 10% or 15% less than the indicator selected 30 years ago. The Cavander & Schmidt (2007) analysis

does indicate some variability in the average ratios of PM_{10}-Pb to TSP-Pb. However, it also shows average ratios of > 0.60 at all sites, > 0.75 at 20 of 24 sites, > 0.80 at 18 sites. Some of the extreme high or low individual sample ratios (ranging from 0.04 to 11.9 at 1 site) or poor correlations are not reflective of true PM_{10} to TSP Pb ratios, but likely the result of poor quality monitoring practices or inaccuracies in the TSP measurements - which are generally > those for hi-vol PM_{10} and >> those for low volume PM_{10} (not available for this analysis). Rather than needing to arduously establish a large series of site-specific PM_{10}-Pb to TSP-Pb ratios (fitting good data to bad), I think it would be well within the Agency's range of discretionary options to consider a slight loss of ultra-coarse Pb at some sites in selecting an appropriately conservative level for the revised NAAQS. Conversely, I think it would be a mistake to hold up the old TSP metric as the "gold standard" and only allow newer, better technology if it can reproduce the old, seriously flawed sampler performance.

As observed in the ANPR, TSP samplers have a variable and poorly characterized upper particle cut size – of "between 25 and 50 um depending on wind speed and direction". In Figure 1 below, I've plotted the Hi-Vol TSP collection efficiency data reported by Wedding et al. (1977) cited in the ANPR. These wind tunnel measurements were taken with a single Hi-Vol at a wind speed of 4.6 meters, but with the slanted shed roof of the sampler at different orientations with respect to the wind direction. The lower blue curve represents sampling with the ridge of the shed roof aligned parallel to the WD, while the red curve represents sampling with the ridge of the shed roof aligned perpendicular to the WD. Note both how poorly defined (not sharp) the collection efficiency is for larger particles and how greatly it varies with wind direction. At sites which have a high fraction of ultra-coarse Pb, the TSP Hi-Vol is a lousy way to measure it.

Those relatively few sites that actually have large contributions of ultra-coarse Pb also clearly have large, nearby coarse mode (industrial process or fugitive dust) emissions, but how much coarse Pb is measured (and any measure of the sampling precision) is strongly dependent on wind speed and sampler orientation. The Agency would be better off prescribing and enforcing specific control technologies for those large dust sources, than requiring (& greatly expanding) an extensive national monitoring network to accommodate the occasional extreme cases. Conversely, if ultra-coarse Pb is a widespread problem of concern, the Agency should develop appropriate methods to accurately characterize those dust particles. "Whatever it is that the TSP sampler happened to collect today" is not a sufficiently clear definition.

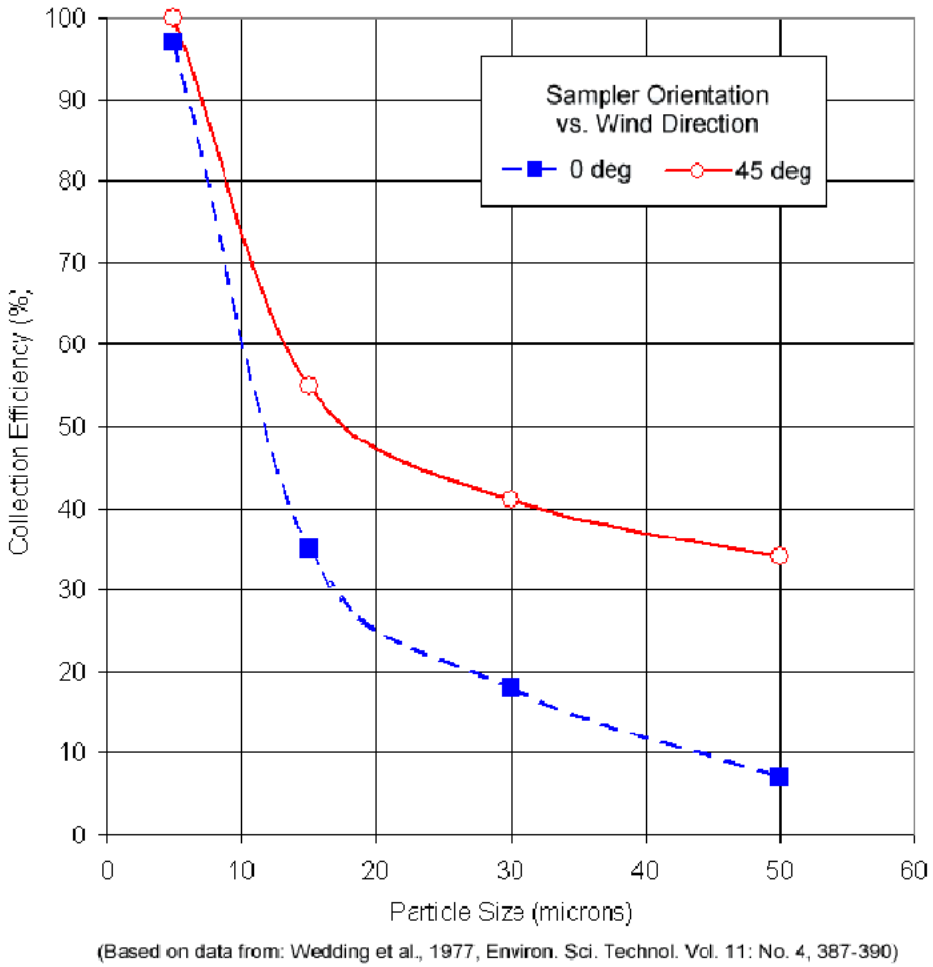

Figure 1. TSP Collection Efficiency vs. Particle Size and Sampler Orientation at 4.6 m/s Wind Speed

It should also be noted that Pb in ultra-coarse particles is not deposited in the lower respiratory tract, and inefficiently deposited (especially during nasal breathing) in the upper respiratory tract – from which only a fraction is ultimately ingested. Ultra-coarse particles are also inefficiently exchanged between outdoor and indoor air and so contribute less effectively to Pb loadings on indoor surfaces than does fine particle air lead. The Staff Paper argues (p. 5-25) that "nonrespirable Pb in the environment may, at some point, become respirable through weathering or mechanical action." But by this "logic", we should also use TSP samplers to determine compliance with PM_{10} and $PM_{2.5}$ standards. The variability of TSP sampler cut size, the higher MDL associated with TSP-Pb sampling, and the relatively poor precision at lower Pb concentrations all contribute to variability in the TSP-Pb indicator. So a PM_{10}-Pb indicator would have the added advantage of providing a more stable metric for compliance determination, as well as a more representative metric of population exposures to support future health studies and risk assessments.

It is recognized that the Agency may lack the time to develop a new Pb FRM for the current NAAQS review cycle. But at the same time, it would be an unfortunate waste of scarce

resources to require a large expansion of the TSP-Pb sampling network. One option might be for the Agency to simply designate low volume PM_{10}-Pb as an FEM – having first taken into consideration the slight, occasional loss of ultra-coarse Pb in setting the (slightly conservative) level of the standard. Another possible variation on this might be to require TSP-Pb sampling only at sites which exceed standards with the new PM_{10}-Pb FEM. Another option might be to designate two separate Pb NAAQS, one based on the current TSP-Pb FRM indicator and one based on a new PM_{10}-Pb FRM indicator – allowing either method to be used for attainment compliance determination, but perhaps requiring both methods at sites which exceed either standard. Alternatively, the Agency might specify TSP sampling at source-oriented locations and PM_{10} at population-oriented sites. The latter could be used for compliance determination, while the former might be used to trigger additional monitoring or control requirements if "action levels" are exceeded. Possibly the Agency should seek advice from the CASAC AAMM Subcommittee to develop recommendations for appropriate Pb FRM, FEMs and network design strategies. That Subcommittee had previously reviewed EPA's National Ambient Air Monitoring Strategy – at a time when the currently implied large expansion of a Pb sampling network was not envisioned. Unless new funds are provided, any new sampling needs to be paid for by reductions in existing programs.

Regarding the Agency's request for comments on the suitability of using the current PM_{10} network for Pb sampling if adequate regional or source-specific PM_{10}-Pb/TSP-Pb correlations could be established – I would prefer this to a large expansion of the TSP-Pb network, regardless of whether acceptable correlations are developed. However, a large fraction of current PM_{10} sites use hi vol PM_{10} samplers, equipped with quartz filters. The particle cut size for these hi vol PM_{10}s is much more clearly defined than for TSP, but is not as sharp as for low vol PM_{10}, nor are the quartz filters as clean as Teflon or as amenable to surface beam analytical techniques.

Regarding the request for comments on changes to the Pb FEM certification requirements, I agree that there should be accuracy and precision performance specifications tested within a range of Pb levels more representative of today's ambient concentrations than the 0.5 to 4 $\mu g/m^3$ range in the current FEM specs. But I think FEM certification need not (& should not) require statistical equivalency to the flawed TSP method (or perhaps might allow equivalency to be determined under test conditions which do not include high levels of ultra-coarse Pb.

Regarding sample frequency, the move to a monthly averaging time provides another reason to switch to PM_{10} samplers, as they are available in automatic sequential sampling configuration. Sample compositing or sample collection over prolonged multi-day periods is useful only for "bright line" compliance determination (for a pollutant, in this case, for which there is no bright line for effects). But the aggregation produces information of limited value for source attribution or effects studies. I would also like to encourage, however, that every effort is made to avoid a need for high frequency, filter-based sampling. I would imagine a large portion of the difference between monthly and quarterly averages could be described as a "statistical issue." That is there's an average or median ratio of monthly max to quarterly max, and data from most sites will fall within a fairly narrow range of that ratio over time. Only a relatively few sites near extremely episodic emission sources will have month/y/quarterly ratios that consistently fall well above the average. When concepts like the "2^{nd} highest monthly max" and/or "the 3 year average" are introduced to provide some stability in the compliance metric, the difference

between monthly and quarterly is reduced to more of a scaling factor. I would think some metric reflective of the "episodicity" of the daily sample values (perhaps the standard deviation or ratio of the 98^{th} to 50^{th} percentile) could be used to supplement a quarterly mean in a way that sites with much higher monthly values could be targeted for increased sample frequency, while a majority of sites might get by with 1-in-3 sampling, or even 1-in-6 day sampling at sites that consistently fall below standards.

Regarding the request for comments on Pb monitoring in rural areas to compare with secondary NAAQS (and which would also help define regional background, transport and trends), I think its an excellent idea to supplement the rural/remote $PM_{2.5}$ Pb measurements from the IMPROVE network with a smaller "sentinel" network of PM_{10}-Pb samplers (no TSP-Pb please), The IMPROVE program already collects PM_{10} samples and these samples – from a subset of sites that might be periodically rotated – could be at least subject to multi-elemental XRF analysis which would provide useful information on fine and coarse Pb as well as other components of coarse particle composition.

References

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Wedding, J. B., A. R. McFarland and J. E. Cermak (1977) Large Particle Collection Characteristics of Ambient Aerosol Samplers, *Environ. Sci. Technol.* 11: No. 4, pp 387-390.

Dr. Michael Rabinowitz

Review by Michael Rabinowitz of
"Lead: Human Exposure and Health Risk Assessments for Selected Case Studies" and
"Review of the National Ambient Air Quality Standards for Lead: OAQPS Staff Paper"
(October 2007)"

November, 2007

General Comments:
These two documents are the fruits of years of labor of groups of well-funded and co-coordinated workers. In its current form I think it provides a sufficient basis for the Administrator to set an appropriate air standard, taking into account a vast amount of older and newer information. At this stage, I can think of nothing to add to or take out of the text, aside from some small items below.

I would like to again stress that to achieve a lead-safe environment not only must lead in air (and water) be regulated, but the burdens of lead paint, still in homes, and lead accumulated in outdoor areas, whether from old exhaust, paint, or industrial sources, all need to be addressed.

Although I raise some fairly minor points below, and I am without the benefits of hearing from my panel colleagues, I see no reason not to approve these documents in their present form.

Minor Remarks
Might this document have a useful "Executive Summary"? pages 3-21 to 3-23 and 5-41-46 might serve as a good start.

Page 2-8 line 3 Yes, indeed. You could actually point to a Feb 1972 publication of EPA's fuel additive regulations which resulted in the reduction of lead in gasoline which were to start in January 1977. {California lead the way}

Page 2-23 Figure 2-7 In my draft the middle (average lines) were not visible.

Page 3-18 Section 4.4.2 I understand that this section is suppose to show how lead can make other health problems worse. But it was not clear to me how lead makes diabetes worse. This section needs to be clarified and expanded or eliminated. Also, the 3 groups of adults (hypertensives, diabetics, and kidney patients) may not be separate. Diabetes, hypertension, and kidney disease often co-occur in the same individual. I suggest just focusing on hypertension, where the case is clearest.

Dr. Armistead (Ted) Russell

Comments of Dr. Armistead (Ted) Russell
Georgia Power Professor of Civil and Environmental Engineering
Georgia Institute of Technology, Atlanta, GA

on

EPA's Advance Notice of Proposed Rulemaking (ANPR) on the NAAQS for Lead

December 6, 2007

The lead staff paper is very responsive to our deliberations, and I was quite pleased with what is there. The ANPR, on the other hand, raises some concerns looking to a future where the ANPR replaces the Staff Paper. The ANPR says rather little new, but regurgitates the findings of the Staff Paper and CASAC comments. I trust, and hope we get reassurance, that the future ANPRs will really be more like the current Staff Paper, not the current ANPR.

We also received a memo from Cavender and Schmidt on the comparison of PM10 and TSP lead at collocated monitors. I would like to thank them for providing this information. I must admit, the data raises some questions about the TSP monitoring, and makes me wonder what is happening at some of the TSP monitors (I have a bias towards using PM10 in that I think the inlet is better characterized, PM10 monitors are more ubiquitous, having the additional metals will provide more information in the long run, and they provide a better characterization of area-wide lead exposures). I actually think that this analysis further argues towards using PM10 monitoring as it makes me a bit more leery of the TSP monitoring. I disagree with the idea of adding a delta (e.g., one standard deviation) to make a change to PM10 conservatively protective. I generally don't like such arbitrary changes. Going to a tighter standard and going to PM10 at the same time will be both more protective and better in the long run from a monitoring perspective. While I might prefer monthly averaging, the difference between this and quarterly averaging is relatively minor, so I might just suggest we show a preference towards monthly, but not be overly emphatic about such.

In regards to the level of the standard, I view that the staff paper has captured the range of where I might fall, and given that I will not be present for the final discussions I hesitate to be overly specific at this time as those discussions might fine tune my suggestions.

In regards to the secondary standard, and what is said both the ANPR and Staff Paper, I might suggest that we enshrine the various comments made by Rich [Poirot], [Dr.] Ellis [Cowling] and others about the lack of data how ever many years ago, and that little has been done to alleviate that inadequacy. It is quite apparent that their words will be just as applicable five years from now. I trust that our furry, scaled, leafed and single-celled friends will reap benefits from tightening of the primary standard in the mean time.

Dr. Jonathan M. Samet

Review Comments: EPA's Advance Notice of Proposed Rulemaking (ANPR)

Jonathan M. Samet, MD, MS
Professor and Chair
Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health

General Comments:

Having reviewed the staff paper and the ANPR for lead, I was left concerned by a process that had left the ANPR as an isolated document, lacking any links to either the Criteria document or the Staff Paper. Additionally, the peer review that had been provided by CASAC, as well as comments by the public to date, were not acknowledged to a sufficient extent. I recognize that this ANPR represents the first that the Agency has developed and that it is linked still to the prior process involving a Criteria Document and Staff Paper, now set aside in terms of the new ISA model. Nonetheless, this ANPR cannot stand as the model for developing a National Ambient Air Quality Standard (NAAQS).

The ANPR reads as though there was not sufficient certainty with regard to the health effects of lead and the need for a standard that would be protective of public health. Rather, it appears to take a seemingly "neutral" stance, appropriate only if the evidence were in equipoise, hardly the case. The role of CASAC is diminished as a commenter, as is the Agency's own staff which has synthesized the evidence through the Criteria Document and the Staff Paper. This ANPR is an unacceptable result of a process that should be evidence-based, but has clearly gone off course and lost its links to a substantial body of evidence.

Specific Comments:

1. Handling of uncertainty: On reading the document, I was troubled by the manner in which uncertainty was handled and emphasized. The obvious truism, that uncertainty is greater at the lower end of the dose-response relationship, received excessive emphasis, without adequate interpretation. The document failed to adequately call attention to how the points on the dose-response curve at which effects have been observed with certainty has become increasingly lower, and guideline values have followed.

2. With regard to the handling of susceptibility, the ANPR addressed some of the groups that may be at risk. Meriting greater emphasis are those persons, primarily inner-city children, who are at risk for higher levels of exposure in general. There is potential that additional exposure from airborne lead will move them into a range of much greater risk.

Dr. Joel Schwartz

Review of ANPRM for Lead

General Comments:

I am concerned that there are continuing choices made, each for understandable reasons, all of which have the effect of biasing downward the estimated health effects of lowering the standards, and which in net, constitute a large downward bias. For example:

1. The effects of decreased renal function are difficult to quantify, but they are not zero. Why not either a crude attempt to bound them, or a fuller discussion when reporting the estimated benefits.

2. The effect of air lead on food lead is ignored, despite evidence that it is an important source. The old CD had some estimates, based on a period of higher air lead. The expected value of uncertainty is not zero. Why not a sensitivity analysis assuming 40% of food lead is from air deposition?

3. Past air is treated as part of background, not part of air. Again, a downward bias. And there are measures to control this source. I understand there are technical limitations, but again, a sensitivity analysis, which, for example, attributes 15% of indoor dust to “past air”, and makes some assumptions about turnover rates, would avoid the impression that there is a desire to understate effects.

4. There may not be time to quantify the blood pressure benefits, but it should be noted that when that has been done in the past, e.g. the RIA for lead in gasoline and the RIA for the water lead rule, the magnitude of the benefits was of the same order as the magnitude of the cognitive benefits in children. Thus this decision alone likely cuts the estimated health benefits in half. This needs to be discussed, with reference to the previous RIAs.

5. A back of the envelope estimate of the effects of lead exposure on criminal behavior, using estimates of the economic costs of crime, suggest that again a potentially large benefit is being ignored.

I agree with the comments of Paul Mushak that this document summarizes the risk assessment that OAQPS did, summarizes the risk assessment, but then ignores the recommendations of OAQPS, buries them, and blithely asks for comments on a range of standards from zero to infinity. This is really not acceptable. The Clean Air Act requires the administrator to set standards for a pollutant that “may reasonably be anticipated to endanger public health”, using criteria that “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of a pollutant in ambient air..”. The range of possibilities proposed for comments ignores the comments of CASAC on what those effects are at what levels, ignores the Staff

Paper summary of those effects at different standard levels, and ignores the risk assessment. It seems, in fact, to ignore science. Are we now doing faith-based risk assessment?

While the Clean Air Act requires special attention to susceptible populations, and the ANPRM notes that there is evidence of increased susceptibility in Blacks and persons with certain ALAD variants, there is no place in the ANPRM where this is specifically addressed in the risk assessment or proposal for comments.

The ANPRM notes that CASAC reviewed the science and said that it was clear that air pollution by lead still had public health impacts, slides by the Staff Paper and Risk Assessment documents which quantitate adverse effects on children's IQ, and asks for comments on whether it would be appropriate to determine that air lead no longer has any public health impact. "We take not of the views of CASAC summarized above… We recognize, however that there may be differing views on interpreting or weighing the available information. "If CASAC is just another interested party to submit comments, what are we doing at this meeting? This is precisely the issue that has already been addressed by the statutory reviewer of science for EPA air standards, addressed by OAQPS in its Risk Assessment and Staff Paper documents, and again reviewed by CASAC. Either CASAC is the committee that reviews the "differing views" or it is not. If this change in status has happened for CASAC, then I believe that we need to inform the Congressional Committee's that authorized CASAC in the clean air act that this has occurred, so that they can determine whether this was their legislative intent.

HAPs are focused on major stationary sources, and are inadequate to control emissions from a variety of smaller sources which become relevant when we stop focusing on smelters.

Specific Comments
P19. States that 5 is the level at which there are significant effects reported, arguing that levels below that may not need protection. But this is a distortion of the literature. Restricting analyses only to Blood Lead levels below 7, Lanphear has reported a significant association, which makes it highly unlikely that levels below 5 have no effect. Indeed, the bulk of the literature indicates that the slope of the blood lead-IQ dose response curve increases as we get to lower blood lead levels, rather than decreasing to zero.
If NHANES 2003-04 and has reported the median, then the 95^{th} percentile must "exist", contrary to the note on this page. Given a set of data, it must have a 95^{th} percentile, and the data clearly exist if the median has been published. CDC may not have published it, but that does not prevent EPA from asking them for the number.

P26. footnote 13. Duh! Of course uptake of lead in **solution** is greater than uptake of lead from food, some of which may be non-soluble.
However, this page seems to ignore the role that air lead plays in lead in food. Content of lead in red wine in France dropped considerably when lead was banned as a gasoline additive, because of lower deposition on the skins of the grapes. Lead content of white wine, where the skins are quickly removed, had always been lower. Hence the dichotomy between dietary lead and air lead being proposed is flawed.
P33. Should note that there have been several publications since the close of the CD which continue to report significant associations of lead < 10 µg/dL and IQ, and continue to report

steeper slopes at lower levels (e.g. Tellez-Rojo 2006, Lanphear 2007). It should also note that if a threshold existed, one would expect slopes to decrease as we limited the sample to subjects with lower and lower blood lead.

P47 should note a recent publication (Jain et al 2007, EHP) which provides further support for the association of lead exposure with ischemic heart disease, not just blood pressure.
P 57. Again, an assumption is made about the shape of the dose response that, based on the data, appears unlikely. If there were a threshold below which the dose-response became zero, then in repeated analyses that excluded blood lead concentrations above certain levels, one would expect the slope to decrease. This is not observed, rather the opposite is observed—a steeper slope at low levels. It is one thing to assume that as we go to levels outside of the realm of the Lanphear study the slope stops increasing. It is another to assume direction of change in slope suddenly reverses, and the slope plummets to zero. I agree that when we have no data, we need to make an assumption—but this one seems mathematically implausible. Further, there is other circumstantial evidence that suggests it is not likely. Analyses of bone lead concentrations from inhabitants of the Southwest desert in the US from circa 1100 show much lower bone lead concentrations than in modern Americans. These bone lead concentrations are consistent with blood lead concentrations well below 0.1 µg/dL. Hence the range of blood lead we are talking about for this extrapolation is still about an order of magnitude higher than background concentrations.

p.59 The argument is made that the slope below 7.5 from Lanphear is unreliable because a)it comes predominantly from one study; and b) it includes only 103 children. This argument is undercut by the subsequent publication of Tellez-Rojo (Pediatrics, 2006) of an analysis of a cohort of 294 children, whose blood lead concentrations never exceeded 10 µg/dL. This study reported a significant association in 294 children in two birth cohorts (not in the Lanphear pooled analysis) in Mexico City whose blood lead concentration never exceeded 10 µg/dL. The slope of the association between 24 month blood lead and 24 month MDI, when restricted to blood lead concentrations never exceeding 5 µg/dL was -1.7 points/µg/dL, and highly significant (p=0.01). When 90 children whose blood lead concentrations had exceeded 10 µg/dL but otherwise met all inclusion criteria were analyzed, a smaller slope was found at the higher dose. Hence, a significant association is found in another large cohort of children who never exceeded 10 µg/dL, it is significant when restricted to children who never exceeded 5 µg/dL, and this study also confirms the nonlinear shape of the dose-response reported by Lanphear. This study should be cited in the ANPRM, and its support for the Lanphear study should result in a modification of the argument on p59 that support for the Lanphear analysis is “dissipated”, which incidentally elicits an image of a bedraggled Bruce, slumped over a bar. I attach a PDF of the study for convenience.

P 59. The discussion of dose response makes much of the fact that the loglinear function has undergone more extensive sensitivity analysis than any other, and uses this to justify the log-linear function *with linearization at the low dose*. However, this argument seems logically inconsistent. First it argues that the most convincing evidence is for a *nonlinea*r relation with the slope of the dose-response curve constantly increasing as one goes to lower blood lead levels. Then it argues that the slope must be *linear* below the bottom of the blood lead levels observed in the study. But if all the evidence says we have a nonlinear relation, what is the justification for

suddenly linearizing it? What that is saying is “everytime we test for a linear association, the evidence is against us, so let’s insist on it where there is not enough evidence to show we are once again wrong”. Anything is possible, but is this really the most likely?

Addendum to Comments on EPA’s ANPR for the Lead NAAQS

Dr. Joel Schwartz

December 14, 2007

The ANPRM has many pages devoted to elucidating an alternative to the peer reviewed risk assessment, using instead the approach of 1978. In 1978, the evidence on the effects of lead on cognitive function was limited to a few studies showing lower cognitive function in children with “high” lead levels. Reasonably, EPA sent the ambient standard with a goal of limiting the number of children with “high” blood lead levels. Necessarily, such an approach recognizes no benefits to lowering blood lead levels within the “not high” category, or within the “high” category.

We know much more about the dose-response between lead and IQ now than we knew in 1978. The CASAC has reviewed the CD and the Staff Paper and expressed itself on that issue. While there is always uncertainty in the dose-response relationship, it is clear that it is continuous, not a step function, and that it persists to concentrations well below 5 µg/dL. Therefore, the proposed approach is a step backward and inconsistent with the science. Merely substituting a level of 5µg/dL or 2 µg/dL for the earlier level does not remedy this defect, and ignores the substantial health benefits from lowering ambient concentrations that has been documented by the peer reviewed risk assessment, most of which does not involve children moving from one category to another.

Dr. Frank Speizer

Pre-meeting Comments on ANPR for Lead dated December 5, 2007

Submitted by Frank E. Speizer, MD
12/11 /07

General Comment: Although the idea of replacing the Staff paper with this ANPR was only approximately accomplished as we transition from the "old style" to this new approach because of the court ordered Staff paper, and because of what we have here I for one have to congratulate the court for its fore-wisdom for insisting on a Staff paper. The format of this ANPR is extremely disappointing. In sum it simply restates what has come before in the form of a staff paper, and whether CASAC agreed or did not agree with what was previously produced, and what CASAC has recommended and then goes on to solicit further comment, presumably from CASAC again and the public. If we did not have a Staff paper it is not clear that the ANPR would have sufficient scientific input to make any statement that resulted in a position that could be criticized one way or another. I would have expected the ANPR to come to some conclusion rather than restating the case, and by presenting the argument as it has simply leaves open to the Administrator the option for doing anything he wants, without scientific justification. Separate from this process we will need to revisit what the role of CASAC will be in the future as well as what will bind the Administrator in using scientific data with a margin of safety to make a NAAQS. I as others on the committee have already suggested recommend that we send not only a response to this ANPR but a separate letter, addressed not only to the Administrator, but also SAB and potentially the Congressional oversight committees of our concerns with the execution of the changes in the standard setting process and the degree to which the process appears **not to be working.**

Paraphrase of areas in which EPA is soliciting comments

Primary Standard, Section III, C—Adequacy of the Current Standard.

1. Question of delisting. Pp 114, 131. The whole question of delisting was previously considered by CASAC and unanimously on two occasions (documented in the appendices to the staff paper in which we responded to the Administrator) **rejected.** To raise it again can only be to solicit potentially biased responses from individuals and groups with potential and real conflict of interest. Furthermore CASAC considered whether the other Federal agencies were sufficient to provide adequate protection. We rejected that and unless compelling argument can be brought forward in some open forum I would recommend we reject it again. This all raises a potential issue for future NAAQS procedures, when the ANPR is supposed to replace the Staff paper. It is not clear that since the public had the opportunity already to have input into the process that lead to the CASAC summaries without repeating what has already been said by CASAC isn't the Administrator essentially stepping backwards and redoing what has already been done either with or without a Staff paper? Is the Administrator aware of other data that has not already been considered? If so shouldn't that be part of the ANPR? What will be the procedure for vetting the additional information that comes into the administrator's office? Will it meet the Federal

Guideline of a Federal Advisory Committee if it is not vetted though CASAC? These are serious procedural issues that the current offered approach of the ANPR by specifically soliciting additional input at this stage of the process creates.

2. Understanding the decline ratio for air-to-blood ratio. Pp120. I believe the data reported in 1986 and the summary suggested in the CASAC panel letter clearly indicted what the ratio implied. EPA seems to be asking for new or additional data to help them understand further what we have written. Again, I think we need to refer them back to our previous comments.

Elements of the Standard

1. Indicator. Pp135, 136. The exercise performed by Cavender and Schmidt dated as Memo 11/26/07, suggest that there is generally a high correlation between TSP and PM10; it is the case that there are significant discrepancies. At this point in time I think this means that we have to continue to go with the concept of all particles contribute to the risk. More research is obviously needed to sort this out. Further side by side studies that take into account potential confounders and risk modifiers may increase our knowledge as to factors influencing the deltas seen between TSP and PM10; however, in that research it will also be important to look as course and fine fractions as well. For now I would recommend staying with the TSP system but could be persuaded otherwise.

2. Averaging time and Form pp143. CASAC has previously indicated a preference for a monthly average because of the evidence that blood Pb concentrations related to shorter time scales and therefore this would be more protective than the current quarterly scale. This was the recommendation that was rejected by the Administrator in the previous round of lead standard setting. In making the recommendation again, CASAC indicated that a second highest monthly would be acceptable. We now have some predictive data as indicated in Appendix table 5.A. The table is quite informative in predicting what might be seen and there clearly are regional differences in terms of potential for non-attainment of new standards below 0.5. Selecting from that table it would appear for the total country were TSP Pb are measured that an acceptable level of attainment for levels of exposure below 0.50 might be in the range of 75-85%. To obtain such levels one must move to somewhere around 0.20 with any of the averaging times of max quarterly, max monthly or 2nd max monthly.

3. Level pp148. The entire argument suggesting because CDC uses 10µg/dl as a monitoring level is simply wrong. The CDC level is an action level not a risk level. The data presented and fully discussed in both the CD and the Staff paper clearly demonstrates important health effects at or below the 5µg/dl and to even raise this issue and ask for comments is to mislead the public.

Dr. Ian von Lindern

COMMENTS: THE USEPA LEAD NAAQS ADVANCE NOTICE OF PROPOSED RULEMAKING (ANPR)

CASAC Panel Member: Ian von Lindern, P.E.,Ph.D.

December 24, 2007

General Comments

The Staff Paper and the ANPR both include synthesis analyses of the NAAQS process to this point. As a result, it is important that the flow of information, the assumptions and underlying strategies of the analyses, and the interpretations forwarded to the Administrator and the public be objective, transparent and consistent. In that regard, there are candid discussions missing from these documents. There is concern that the message carried forward to the Administrator does not inform policy makers, or the public, of the consequences of the Agency's failure to adequately regulate lead in air over the last fifteen years.

The regulatory exercise that the EPA and CASAC are currently engaged in evaluates the costs and benefits of the various alternative scenarios in addressing contemporary lead exposures. This is clearly a difficult and challenging task, largely due to lack of data regarding sources, transport mechanisms, and exposures throughout the nation. This lack of pertinent data can be traced to EPA's decision to not update the NAAQS in 1991, followed by suspension of monitoring and collection of characterization data.

In hindsight, EPA would have been well-advised to have lowered the NAAQS to a protective level consistent with observed ambient concentrations. In that case the monitoring programs would, likely, have not been abandoned. Failure to recognize this shortcoming could result in repeating that mistake in 2008 and eliminating the NAAQS, or adopting a NAAQS that simply certifies current conditions.

The base of information for the 2008 decision-making process was developed in the AQCD. Those data and findings were forwarded to the Risk Assessment document, where analyses were performed to evaluate the potential risk to human health and welfare across the nation. Those results and findings were then interpreted and evaluated and Staff conclusions and recommendations were captured in the OAQPS Staff Paper. CASAC has followed, evaluated and provided input throughout this process and staff has been attentive to and responsive to CASAC's comments and suggestions. Staff did an excellent job under the circumstances presented, and the Staff Paper recommendations are reasonable and appropriate. Staff has also done a good job of summarizing and presenting CASAC's views, conclusions and recommendations. Based on the outcome of these documents, the recommendations made by CASAC in past letters to the Administrator should stand as presented and that the Staff Paper is adequate for use in assessing the NAAQS.

However, those same conclusions do not extend to the ANPR. This document seems to be a meatless version of the Staff Paper, with no real conclusions or recommendations. No standard is proposed, no position is taken on whether the standard should be retained, there is vague mention of, perhaps, deleting the standard, noting that lead compounds are included in HAPs, and no tentative Agency position is provided. It seems to be a solicitation for input on whether the Agency should agree or disagree with its own Staff and Scientific Advisors. The Agency should either agree or disagree with its staff and advisors, tell the public why, espouse a proposed course of action, and then solicit comment on that position.

This is critically important with the lead NAAQS because the agency failed in 1990 to act on Staff and CASAC recommendations and that decision, unfortunately, had unintended adverse effects for the Nation's health, and for the NAAQS process. The current analyses could be interpreted to indicate the numerous children have suffered cognitive decrements and the Agency has little idea of the extent of deleterious exposures in most of the country.

Perhaps the most important function of the ANPR is to convey the status of air lead regulation to the public and underscore the policy the Agency is using to protect the health and welfare. This document fails to convey the poor state of knowledge regarding lead in air, the Agency's role in allowing the knowledge base to deteriorate, the uncertainties resulting from that lack of knowledge, the likelihood that there is insufficient information available to consider deleting the NAAQS, and that large margins of safety may be appropriate to assure protectiveness in the development of the revision.

The Agency has failed in the last fifteen years in one of its primary missions to characterize the extent and severity of this priority pollutant's exposures in the U.S. The deleterious effects of lead have always been underestimated and now, from a health perspective, there may be significant damage ongoing to susceptible populations. Consequently, the Agency must now reassess the significance of lead exposures without adequate data and greater uncertainty. Twenty years ago lead was among the best characterized priority pollutants in terms of exposure and response relationships. As a result, the current NAAQS was adopted with an atypically low margin of safety incorporated in the standard. Such a low margin cannot be justified by the state of knowledge today.

This lack of data was first noted in the initial AQCD reviews by CASAC. Almost no useful emissions or ambient air data were available in the peer-reviewed literature in 2005. CASAC urged EPA to use the Agency's own resources and the trade and professional literature to augment the knowledge base. The Staff did find some useful information and included this in the AQCD. However, there certainly was not sufficient data to conduct a "national" risk assessment and Staff opted to develop pilot risk assessments for three source-type situations. At the risk assessment stage, CASAC was again critical of this approach, urging that a "national" perspective risk evaluation be conducted. Staff made an admirable effort to accommodate this request in the urban analyses presented in the final Risk Assessment.

Despite the success of this effort, this risk assessment should be recognized as largely a modeling exercise utilizing numerous assumptions, often based on decades old data and empirical relationships derived from environmental regimes that no longer exist in the U.S. This approach

was necessary and had to be undertaken because the data do not exist to address this problem more appropriately. With regard to these shortcomings, the discussions do not sufficiently convey the lack of information and unknowns associated with the knowledge base of lead in the air, as documented in the AQCD.

Nevertheless, these analyses show that there is substantial indication of significant deleterious health effects (IQ decrements greater than 1 point) ongoing in, presumably, many areas of the country. These were effects that were suspected in 1990 and it was recommended that a margin of safety be incorporated into an NAAQS strategy to protect against this possibility. That was not implemented. The default margin of safety inherent in the 1978 Primary NAAQS, was clearly inadequate. This leads to a potential interpretation– that, despite phenomenal lead exposure declines in other media, some children were likely harmed in the interim, and little data were collected to support conducting a "national" risk assessment when the Agency was forced in Court to reconsider the NAAQS.

The status today as summarized, but not explicitly made clear, in these documents is:

The 1978 Standard is clearly non-protective. A one to two order of magnitude reduction should be considered requisite to an effective health protective strategy.

The emissions and ambient air database is insufficient to characterize the extent of potentially deleterious exposures across the U.S. Large urban areas are largely uncharacterized with respect to both area and point sources. There was not even sufficient data to characterize a single secondary source in the country for this risk assessment. Hypothetical data and combinations of data from different sites and time periods had to be synthesized for the secondary source risk analyses.

The primary source analysis relies on an area that has been de-populated and remediated, but continues to show substantial risk. The maximum (or worst case) situation developed in the primary smelter application seems to be about 50% of the current NAAQS. This result seems to derive from a combination of the ratio between the quarterly and annual average, *and* the current geographic disposition of population relative to the smelter in Missouri. The ultimate result is that potentially worst case exposures and estimated IQ decrement are possibly underestimated by a factor of, perhaps, 1.5 to 2 times. Were the 1.5 km sub-area repopulated to previous decade densities, a substantial portion of the childhood population would exhibit unacceptable risk levels, in the current NAAQS and current conditions scenarios.

As a result, exposures are likely underestimated, due to lack of monitoring and coverage which the Risk Assessment and Staff Paper admit for the urban cases, but seem less articulated in the ANPR. Nevertheless, the pilot studies as presented indicate both urban and point source communities are at risk of substantial harm.

A critical issue that has been seemingly ignored throughout this process is the potential non-representative nature of the database that is being used as it might apply for *future* applications. All emissions and most of the ambient data are from the 2002-2005 era at best. This was an era of relatively low lead production and use in the U.S. The emissions picture and particularly, the

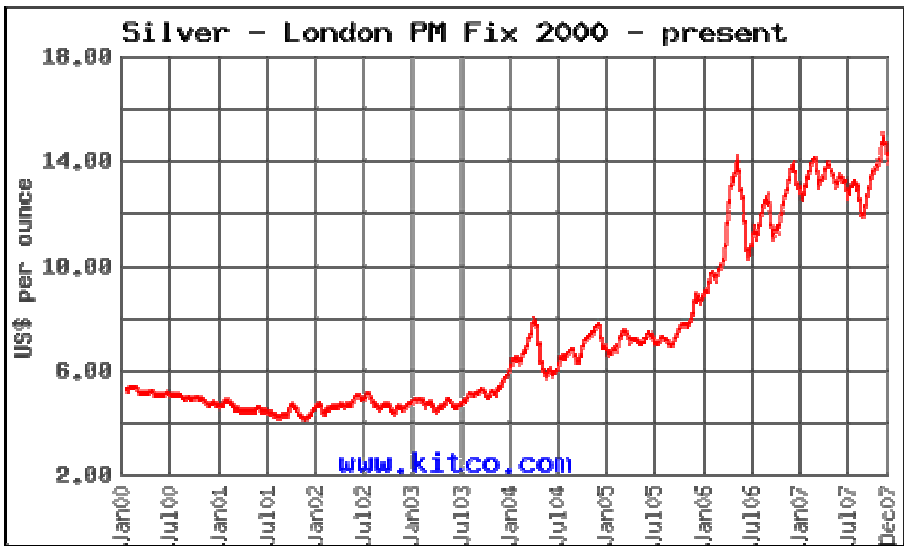
spatial characterizations and peak-to-mean ratios, used in the roll-up and roll-down calculations were based on an industry in a minimal production and use mode.

There are suggestive data that indicating the possibility that this trend may reverse and that potential increases in point source emissions be considered. Base metal prices have exploded since 2005, first in copper and zinc and, in the last year, by silver and lead. Recent metals exchange prices are appended below. Production has increased, mining and milling operations are being rehabilitated, and substantial legislative lobbying for considerations in several forums supporting revival of the industry in the U.S. are underway; much of it for national security reasons. Significant damage to some of the nation's infrastructure is occurring due to base-metal shortages and copper thievery. The energy crisis in petroleum is leading to even more demand for these metals.

The country's mining and metal-refining and fabrication industries need to know what the rules will be, what level of controls will be required, and where EPA believes there are ongoing and significant ambient air lead risk. The current standard and state of knowledge are both inadequate to this task.

Reliance on HAPs seems questionable at this time. The documents only note that HAPs is applicable. No presentation is provided regarding the effectiveness of a technology based standard being protective in the case of this ubiquitous contaminant. The EPA has not evaluated, and for the most part does not know, the extent of deleterious exposures, where current sources are located, how these impact local airsheds, the sources that need to be controlled, nor the level of control required. Had EPA revised the NAAQS to those levels considered to be of concern in the 1990's and monitored accordingly, analyses of potential HAPs applicability could be undertaken. Unfortunately that database is probably lagging the imposition of a new standard and appropriate monitoring by 3 to 5 years.

Few if any of these issues are discussed in the ANPR.



Silver (source London Metals Exchange 12/4/07)

Copper $US/tonne (source London Metals Exchange 12/4/07)

Zinc $US/tonne (source London Metals Exchange 12/4/07)

Lead $US/tonne (source London Metals Exchange 12/4/07)

Post-meeting responses to Pb ANPR – Areas in which EPA solicits comment

The EPA invites general, specific, and/or technical comments on all issues discussed in this ANPR, including issues related to the Agency's review of the primary and secondary Pb NAAQS (sections III and IV below) and associated monitoring considerations (section V below). EPA also invites comments on all information, findings, and recommendations presented in this notice (section VI below). [pp. 23-24, section II.D.]

Specifically, EPA solicits comments on …

Primary Standard – Approach for Current Review {III.C.2 - p. 112}

… on the appropriate weight to be placed on the results from these *{quantitative exposure/risk}*assessments in evaluating the adequacy of the current primary standard and in considering alternative standards.

These risk assessments are appropriate and should be given substantial weighting as these are the best that can be accomplished under the circumstances. Despite the success of this effort, this risk assessment should be recognized as largely a modeling exercise utilizing numerous assumptions, often based on decades old data and empirical relationships derived from environmental regimes that no longer exist in the U.S. This approach was necessary and had to be undertaken because the data do not exist to address this problem more appropriately. With regard to these shortcomings, the discussions do not sufficiently convey the lack of information and unknowns associated with the knowledge base of lead in the air, as documented in the AQCD.

… on a number of aspects of the design of the assessments and interpretation of the assessment results, including in particular:

(1) the appropriateness of rolling up ambient Pb concentrations to simulate just meeting the current standard for areas in which current concentrations are well below the level of the current standard;

The emissions picture and particularly, the spatial characterizations and peak-to-mean ratios, used in the roll-up and roll-down calculations were based on an industry in a minimal production-mode. There is suggestive evidence that production of base metals and use of lead in consumer products may increase in the foreseeable future. As EPA has indicated that it may entertain retaining the current standard, take no action as occurred in 1991, or develop a new standard between the current levels and the current NAAQS, analyzing the potential impacts under the current standard seems requisite.

Moreover, should the Agency delete the NAAQS, and develop a HAPs/technology-based approach and rely on other media controls to reduce risk, emissions and ambient concentrations; this would likely increase exposures in areas where new or expanding industries locate. As such, consideration of the impacts of increased ambient concentrations should be included in the decision-making process.

(2) the use of a proportional method to roll-up and roll-down Pb concentrations to simulate just meeting the current and alternative standards;

The methodology should be consistent with the above, but acknowledge the inherent uncertainties, and should bias the analyses toward protectiveness with an appropriate margin of safety. It should also be explicitly noted that the risk assessments are based on current

source, receptor and population configurations. These do not emulate worst-case scenarios that would be used in compliance evaluations for NAAQS pollutants. Should new sources be developed, the roll-up analyses presented in the risk assessments likely under-estimate exposures for the determining allowable emission rates under a NAAQS scenario. Additionally there is no discussion in any of the documents relating to how potential impacts would be addressed in a HAPs-multi-media strategy.

(3) the categorization and apportionment of policy-relevant exposure pathways and policy-relevant background, particularly with regard to exposures related to historically deposited Pb from leaded gasoline and from Pb paint; and

Lead is, and will continue to be, a multimedia multi-source ubiquitous contaminant. Multiple effects must be considered in any attainment strategy. Staff has done as good an analysis as can be provided, given the scarcity of data. Should the Agency find that these sources in whole produce unacceptable risk levels, then a coordinated strategy to reduce exposures should be developed. Control of both recent and past lead will be requisite. Presumably, the effort required for the latter will diminish over-time, as the older sources are removed or stabilized. Control of current sources will be an ongoing obligation.

(4) the weight to be given to risk estimates derived using various concentration-response functions.

The model form recommended by CASAC should be given the most weight as it provides a margin of safety appropriate to the state of knowledge. The results from the other functions should help frame the margin of safety incorporated into the development of the control strategy. Please see the CASAC's conclusions.

… on the approach of considering exposures and risks resulting from the ingestion of historically emitted Pb that may now be present in indoor dust and outdoor soil (e.g., that associated with past use of Pb in gasoline or Pb paint) impacted by ambient air Pb as being policy-relevant for the purpose of setting a NAAQS.

Consideration of these exposures is requisite to establishing a protective health strategy. Remediation of past sources may be an effective element in an eventual compliance strategy. As a result, failure to consider these sources or relying on a technology-based standard only addressing current sources would not be efficient or effective.

Primary Standard–Adequacy of the Current Standard {III.C.3 - pp. 114, 120, 131, 132}… and supporting information on the issue of whether it would be appropriate for EPA to determine that emissions of Pb no longer contribute to air pollution that may reasonably be anticipated to endanger public health.

Because the Agency has little knowledge of the extent of exposures currently in the U.S., EPA could only make this determination if it required that all lead emissions be reduced to zero.

… and supporting information on the extent to which reductions in the ambient air Pb standard would benefit public health.

The risk assessment developed indicates that current lead levels in particular areas likely contribute to an IQ decrement in children living in these areas. The extent of continuing exposures in urban areas and the possibility that lead emissions may increase in the future indicate that this effect may manifest in other communities. Lowering or preventing these exposures and consequent neuro-cognitive effects would be beneficial. The difficult question is how beneficial in relation to other risks and expenditures. Please see the CASAC's conclusions.

… on data or studies that may help inform our understanding of this important parameter *{the air-to-blood relationship}*.

Several studies have addressed this factor and Staff has done a good job of identifying and comparing these results. It seems clear that the ratios reported all have site-specific and study-specific considerations related to a host of factors common to the ubiquitous lead exposures. The approach used in 1978, clearly underestimated this ratio for air quality regimes that followed and has been inappropriate for decades, CASAC has advised using 1.5 and addressing the uncertainty through applying an appropriate margin of safety.

… on whether the broad range of current multimedia Federal and State Pb control programs, summarized above in section II.C, are sufficient to provide appropriate public health protection in lieu of a Pb NAAQS.

Several non-air programs implemented by various entities have resulted in major reductions in lead exposures from non-air sources, and decreases in re-entrained or fugitive source emissions. As a result the baseline lead level (from non-air sources) has declined dramatically, as noted. CASAC estimated this reduction as decreasing typical mean blood lead levels from 12 µg/dl to 1-1.4 µg/dl. Exposures and blood lead levels in some areas, however, remain higher as residual lead continues to circulate in the environment. Significantly less reduction, however, has been due to lead in air since the 1990s. Most of the reductions in lead emissions were achieved by curtailment of industry associated with the economics of mineral industry and consumer goods that utilize lead. No analyses have been presented in any of the documents regarding the possibility of increased lead output and emissions.

… on delisting, revocation, and the adequacy of the current standard and the rationale upon which such views are based.

There is overwhelming evidence of the adverse effects of lead at blood low-levels noted for young children in the U.S. today. Lead is an ubiquitous contaminant present in several media involved in air-related transport and transformation processes. There is an overwhelming absence of emissions and ambient exposure data available to assess how many U.S. children at at-risk today. The EPA should not consider deleting the NAAQS simply because the Agency has neglected to monitor.

Primary Standard – Elements of the Standard– Indicator {III.C.4.a - pp. 135, 136}

… on previous Agency conclusions that the health evidence indicates that Pb in all particle size fractions, not just respirable Pb, contributes to Pb in blood and to associated health effects.

The Agency should continue to assess and monitor all size fractions through direct or surrogate methods.

… and information that would help inform such analyses *{of Pb particle size relationships}* and the Agency's views on the indicator for the primary Pb NAAQS.

Please see the CASAC's conclusions.

Primary Standard - Elements of the Standard– Averaging Time and Form
{III.C.4.b - pp. 143}

… on a range of options, including the recommendations in the Staff Paper that include changing the averaging time to monthly, with a form of maximum or second maximum, as well as retaining the quarterly averaging time.

Please see the CASAC's conclusions.

… on the options of changing the form to apply to a three-year period as well as retaining a single-year period.

Please see the CASAC's conclusions.

… on these ranges of averaging times and forms as well as views and related rationales that might support alternative options.

Please see the CASAC's conclusions.

Primary Standard - Elements of the Standard –Level
{III.C.4.c-pp. 143, 148, 149, 150, 160, 161}

… on a wide range of possible options … range from lowering the standard, to the levels recommended by CASAC and the OAQPS Staff paper or lower, as well as on other alternative levels, up to and including the current level, and the rationale upon which such views are based.

Lead should be retained as a criteria air pollutant; (2) the lowering of the Lead NAAQS substantially below the current value is fully-justified; and (3) a new indicator for lead should be developed. Please see the CASAC conclusions.

… on the appropriateness of using a mean or individual target blood Pb value of 10 µg/dL as the foundation for deriving a level for the primary Pb standard.

Totally inappropriate, please see the CASAC's conclusions.

… on mean target blood Pb levels as well as other factors that would be important in applying the 1978 framework *{using the current evidence}.*

The new standard should recognize the benefits of lowering blood lead levels across the entire population, as well as preventing threshold concentrations for the most-exposed individuals. Please see the CASAC's conclusions.

… on the definition and appropriate values for this parameter *{the nonair (background) contribution to total blood Pb}*

The NAAQS compliance strategy should consider all sources of lead, coordinate with other federal, State and local programs effecting reductions in other media and include past-air impacts and exposure reduction strategies directly in the NAQQS.

… and supporting information regarding the air-to-blood ratio and differences in the available estimates.

Please see the CASAC's conclusions.

… on all of these factors *{important to application of 1978 framework}*

… on the 1978 standard setting framework and on alternate approaches and the factors that are relevant to those approaches.

Please see the CASAC's conclusions.

… on levels of IQ loss considered to be significant from a public health perspective.

Please see the CASAC's conclusions.

… on the magnitude of IQ loss associated with exposures to ambient Pb by the pathways categorized as "recent air" in the risk assessment described in this notice that are considered to be significant from a public health perspective.

Please see the CASAC's conclusions.

… on the approach of adopting a public health policy goal of limiting policy-relevant air exposure such that the incremental blood Pb level (and the associated resulting IQ loss) are below a specified level (e.g., to a magnitude of 0.5 or 1 μg/dL, or other alternative values).

Please see the CASAC's conclusions.

Dr. Barbara Zielinska

THE US EPA LEAD NAAQS ADVANCE NOTICE OF PROPOSED RULEMAKING (ANPR)

Comments on Section V: Considerations for Ambient Monitoring.

Barbara Zielinska

My general comment regarding the Pb ANPR is that if this document is designated to replace the Staff Paper in the future, I would expect it to be more conclusive and not only limited to a restatement of the Agency's Staff Paper findings and CASAC recommendations. Specifically, one would expect some sort of justifiable recommendations as to the indicator, level, statistical form, and averaging time of the standard and not only an invitation for all interested parties to submit their recommendations. After all, this document was formulated after several years of gathering and synthesizing new scientific information on this subject and at this stage the Agency should be able to formulate some conclusions regarding the range of the Pb standard. Saying that all policy options are still on the table, from delisting Pb as a NAAQS, keeping the present level of 1.5 $\mu g/m^3$ or going down to 0.02 $\mu g/m^3$, is like starting the whole process all over again.

My specific comments are limited to Section V, Considerations for Ambient Monitoring, as requested by Dr. Rogene Henderson. For this Section, the Agency invites comments regarding (a) sampling and analysis method; (b) network design; (c) sampling schedule; (d) data handling; and (e) monitoring for secondary standard.

Regarding (a), the CASAC Pb Panel had strongly encouraged the Agency in its previous letter to the Administrator (Henderson, 3/27/07) to consider revising the indicator for Pb sampling from TSP to low volume $PM_{10.}$ The current ANPR and associated support documents (memos by Cavender and Schmidt 11/26/07, and Camalier and Rice, 11/29/07), reviewed the collocated Pb-TSP and Pb-PM_{10} data and evaluated the precision and bias of the Pb-TSP monitors. Although the high-volume TSP methods have an average precision of 11.7 % with a standard deviation of 18.6 %, it is evident from Figure 1 of Camalier and Rice memos, that at the relevant ambient concentrations below 1 $\mu g/m^3$ this precision is much worse (and this is after exclusion of 21% of measurements which were below MDL of 0.01 µg/m3). The memo comparing Pb-TSP and Pb-PM_{10} data also shows that the relation between these two measurement methods is much worse at lower concentrations (below 0.03 $\mu g/m^3$). Both, the average sampling bias (based on the flow audits) and the bias for lab analyses were low (in the range of 1%), so they do not contribute significantly to the overall precision of Pb-TSP monitors. These pieces of information taken together indicate some problems with TSP monitors. The variability of TSP sampler cut size, the higher minimum detection limit (MDL) associated with TSP-Pb sampling, and the relatively poor precision at lower Pb concentrations all contribute to variability in the TSP-Pb indicator. In my opinion, PM_{10} samplers are preferred over the much less reliable, old technology, TSP samplers. PM_{10} samplers' inlet is much better characterized, they are used in many sampling locations and they are utilized for many other measurements, including a suite of elements, in addition to Pb. The TSP monitors are used for lead only and they have been discontinued in

many sampling locations. I do not recommend retaining hi-volume Pb-TSP monitors, neither investing in the development of low-volume, sequential Pb-TSP samplers.

The memo "Summary of method detection limits" by Rice, indicates that the current FRM analytical method (based on atomic absorption) has the highest MDL. Since this MDL was estimated for high-volume TSP samplers, if the low-volume samplers are to be used in the future, the analytical MDL would be even higher (per m^3). For these reasons, I would rather recommend more sensitive and widely used analytical methods, such as XRF or ICPMS. Clearly, ICPMS has a superior sensitivity of 0.00001 $\mu g/m^3$ (for high volume samples). However, XRF (which is less expensive) may be sufficient for the lowest alternative NAAQS – based on my experience, the MDL for the equivalent high-volume sample would be 0.005 $\mu g/m^3$

Regarding (b), I favor the option number 4: to utilize the current PM_{10} network. I'm not particularly concerned about finding an acceptable regional or site-specific correlation of Pb-TSP and Pb- PM_{10}, since I do believe that Pb-TSP are much less accurate than Pb- PM_{10} and I don't think that the Pb-TSP method can serve as a "golden standard", especially if the Pb NAAQS will be tightened considerably. Since PM_{10} monitors may not be currently located near the large Pb emission sources, the additional monitors may be utilized at these specific sites. Also, since Pb levels and particle size ranges are expected to be higher near major Pb emission sources, Pb-TSP monitors can be used, in addition to Pb-PM_{10} to establish the equivalency factor for these specific sites. There are only a few such major Pb emission sources in the U.S. anyway.

Regarding (c), sampling schedule, if the monthly averaging period is selected, the sampling frequency should be increased from 1-in-6 to at least 1-in-3 sampling schedule. This would yield sufficient amount of samples per averaging period with 75% completeness. However, I'm not feeling very strongly about monthly averaging period. I think quarterly averaging period could be acceptable as well, especially at sites that consistently fall below the standard.

Regarding (d), data handling, I assume that that the third bullet should specify that 50% of the expected number of samples is needed for a month to be considered complete, if daily sampling schedule is adopted. Otherwise, for 1-in-3 sampling schedule, 75% should be required.

Regarding (e), monitoring for the secondary NAAQS, I think that the Pb-$PM_{2.5}$ data from the IMPROVE network should be utilized to track changes in ambient Pb concentrations in rural and remote areas. Since it is very likely that in these remote locations nearly all (if not all) Pb is present in the PM size range below 10 µm, PM_{10} monitors can be used to develop the relationship between Pb- PM_{10} and Pb- $PM_{2.5}$. Likewise, the data from the National Water Quality Assessment (NAWQA) and Geochemical Landscape project should be used to track the concentrations of Pb in water bodies and soil, respectively.