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NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT  
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OFFICE OF  
RESEARCH AND DEVELOPMENT

October 29, 2018

**MEMORANDUM**

**SUBJECT:** Clean Air Scientific Committee Review of the External Review Draft Integrated Science Assessment for Particulate Matter

**FROM:** John Vandenberg, Ph.D. /s/  
Director  
National Center for Environmental Assessment  
Research Triangle Park Division (B243-01)

**TO:** Aaron Yeow, M.P.H.  
Designated Federal Officer  
Clean Air Scientific Advisory Committee  
EPA Science Advisory Board Staff Office (1400R)

The External Review Draft *Integrated Science Assessment for Particulate Matter* (hereafter referred to as this draft ISA) prepared by the U.S. Environmental Protection Agency's (U.S. EPA) National Center for Environmental Assessment – Research Triangle Park Division (NCEA-RTP) as part of EPA's ongoing review of the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for particulate matter was released on October 15, 2018. Electronic copies of the ISA and other documents referenced below are available for download at <https://www.epa.gov/isa>. I am requesting that you provide this memo to the Clean Air Scientific Advisory Committee (CASAC) for peer review of this document.

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**OVERARCHING REVIEW CONTEXT**

On May 9, 2018, then EPA Administrator, Mr. Scott Pruitt, provided principles and guidance for NAAQS reviews in a memorandum titled, [Back to Basics Process for Review of the National Ambient Air Quality Standards](#). This memorandum set out five principles for EPA to observe in future NAAQS reviews:

- (1) Meet statutory deadlines;
- (2) Address all CAA provisions for NAAQS reviews;
- (3) Streamline and standardize the process for development and review of key policy-relevant information;
- (4) Differentiate science and policy judgments in the NAAQS review process; and
- (5) Issue timely implementation regulations and guidance

In the context of **Principle 2**, the memorandum poses a standardized set of charge questions to CASAC to frame the entirety of the NAAQS review. These questions are provided below as a backdrop to this review:

- What scientific evidence has been developed since the last review to indicate if the current primary and/or secondary NAAQS need to be revised or if an alternative level or form of these standards is needed to protect public health and/or public welfare? Please recommend to the Administrator any new NAAQS or revisions of existing criteria and standards as may be appropriate. In providing advice, please consider a range of options for standard setting, in terms of indicators, averaging times, form, and 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.
- Are there areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS? Please describe the research efforts necessary to provide the required information.
- What is the relative contribution to air pollution concentrations of natural as well as anthropogenic activity? In providing advice on any recommended NAAQS levels, please discuss relative proximity to peak background levels.
- Please advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.
- Do key studies, analyses, and assessments which may inform the Administrator's decision to revise the NAAQS properly address or characterize uncertainty and causality? Are there appropriate criteria to ensure transparency in the evaluation, assessment, and characterization of key scientific evidence for this review?

### **ISA CONTEXT:**

**Purpose of this draft ISA:** The purpose of this draft ISA is to identify, evaluate, and summarize scientific information on the health and welfare effects associated with particulate matter (PM). This draft ISA is intended to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare, which may be expected from the presence of [a] pollutant in the ambient air” [Clean Air Act, Section 108; 42 U.S.C. 7408(b)]. This draft ISA integrates the scientific evidence for review of the primary (health-based) and secondary (welfare-based) NAAQS for particulate matter, and provides draft findings, conclusions, and judgments on the strength, coherence, and plausibility of the evidence. It is important to note the evaluation of welfare effects focuses on non-ecological effects because the ecological welfare effects are being considered in a separate assessment as part of the review of the secondary (welfare-based) NAAQS for oxides of nitrogen, oxides of sulfur, and particulate matter in the [Integrated Science Assessment for Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter \(Ecological Criteria\)](#).

**Process for ISA Development:** The overall process for ISA development, including criteria used to identify relevant studies, aspects considered in judging the overall weight of evidence, and the framework for causality determinations, are described in the [Preamble to the Integrated Science Assessments](#), which is attached and available to the public at NCEA's website (<https://www.epa.gov/isa>) and in the Health and Environmental Research Online (HERO) database. The Preamble to the ISA is a companion document to the draft PM ISA, and it reflects development and refinements based on peer review and public comment for prior ISAs.

**Organization of the ISA:** The Preface within the draft PM ISA outlines the legislative requirements and history of the reviews of the primary and secondary PM NAAQS, describes the purpose and presents an

overview of the ISA, and the process for developing the ISA. The Executive Summary is intended to provide a concise synopsis of the key findings and conclusions for a broad range of audiences. Chapter 1 presents an integrated summary of the overall conclusions and characterizes available scientific information on policy-relevant issues. **Principle 3** of the Back to Basics Memo stipulates, “the Agency shall identify more efficient ways to conduct a thorough scientific assessment of the relevant air quality criteria for each review, focusing on comprehensive synthesis of the relevant science for each pollutant. CASAC has frequently identified reducing the length and complexity of the ISA as a key process improvement for streamlining NAAQS reviews.” Taken together, the Executive Summary and Chapter 1 address this Principle by providing a comprehensive synthesis of key findings.

The information presented in Chapter 1 is supported by detailed information on the relevant evidence spanning scientific disciplines that directly informs the causality determinations: atmospheric chemistry, ambient concentrations, and measurement and modeling of ambient concentrations of PM (Chapter 2); exposure to particulate matter (Chapter 3); dosimetry of particulate matter (Chapter 3); health effects of short-term and long-term particulate matter exposures (Chapters 5 - 11); and populations and lifestyles potentially at increased risk of particulate matter-related health effects (Chapter 12); and welfare effects (Chapter 13). The final ISA, in conjunction with additional technical assessments, will provide the scientific basis for the U.S. EPA’s decisions regarding the adequacy of the current primary and secondary standards for PM.

**Development Timeline for the ISA:** The U.S. EPA initiated this review of the primary (health-based) and secondary (welfare-based) PM NAAQS on December 3, 2014 (79 FR 71764), which requested the submission of recent scientific information on specified topics. EPA conducted a workshop—from February 9 to 11, 2015 to gather input from invited scientific experts, both internal and external to EPA, as well as from the public, regarding key science and policy issues relevant to the review of the primary and secondary NAAQS (79 FR 8644 and 79 FR 71764). These science and policy issues were incorporated in EPA’s *Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter* which was available for public comment (81 FR 22977) and discussion by the CASAC via publicly accessible teleconference consultation (81 FR 13362). The *Final Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter* was released December 6, 2016 (81 FR 87933).

In the context of **Principle 4**, the memo stipulates: “The Agency should establish a clearer distinction between the purely scientific findings of the ISA and the wider range of policy concerns that the Administrator must consider in making judgments about requisite standards. In addition, EPA should request CASAC to distinguish clearly between its scientific and policy advice, and to focus on core questions when providing advice to the Administrator under the Clean Air Act.”

### **SUPPLEMENTAL CHARGE QUESTIONS FOR SCIENTIFIC REVIEW OF THE ISA**

To supplement the standardized charge questions, and guide the scientific review of this ISA, the EPA has identified these areas for CASAC review and comment:

- The Executive Summary is intended to provide a concise synopsis of the key findings and conclusions of the PM ISA for a broad range of audiences. Please comment on the clarity with which the Executive Summary communicates the key information from the PM ISA. Please provide recommendations on information that should be added or information that should be left for discussion in the subsequent chapters of the PM ISA.
- Chapter 1 presents an integrated summary and the overall conclusions from the subsequent detailed chapters of the PM ISA and characterizes available scientific information on policy-relevant issues. Please comment on the usefulness and effectiveness of the summary presentation.

Please provide recommendations on approaches that may improve the communication of key findings to varied audiences and the synthesis of available information across subject areas. What information should be added or is more appropriate to leave for discussion in the subsequent detailed chapters?

- To what extent is the information presented in Chapter 2 regarding sources, chemistry, and measurement and modeling of ambient concentrations of PM clearly and accurately conveyed and appropriately characterized? Please comment on the extent to which available information on the spatial and temporal trends of ambient PM concentrations at various scales has been adequately and accurately described.
- Chapter 3 describes scientific information on exposure to ambient PM and implications for epidemiologic studies. To what extent is the discussion on methodological considerations for exposure measurement and modeling clearly and accurately conveyed and appropriately characterized? Please comment on the extent to which the discussion regarding exposure assessment and the influence of exposure error on effect estimates in epidemiologic studies of the health effects of PM has been adequately and accurately described.
- Chapter 4 characterizes scientific evidence on the dosimetry of PM. To what extent does the discussion clearly and accurately convey the dosimetry of inhaled PM and the processes of deposition, clearance, retention, and translocation?
- Please comment on the identification, evaluation and characterization of the available scientific evidence from epidemiologic, controlled human exposure, toxicological and associated human exposure and atmospheric sciences studies and the application of information from these studies to inform causality determinations and uncertainty characterizations for human health outcomes.
  - Chapters 5 – 11 present assessments of the health effects associated with short-term and long-term exposure to PM. The discussion is organized by PM size fraction, exposure duration, broad health effects (e.g., asthma, ischemic heart disease, etc.), and scientific discipline. Please comment on the characterization of the evidence within these chapters.
  - Please comment on the portrayal and discussion of the biological plausibility evidence presented at the outset of Chapters 5 – 11 and the extent to which: (1) the organization adequately captures the current state of the science with respect to potential pathways by which PM could impart health effects, and (2) as currently constructed, inform causality determinations.
- Chapter 12 evaluates scientific information and presents conclusions on factors that may contribute to specific populations or lifestyles being at increased risk of a PM-related health effect. Please comment on the extent to which the available scientific evidence from epidemiologic, controlled human exposure, and toxicological studies been integrated to inform conclusions on populations and/or lifestyles potentially at increased risk of a PM-related health effect. Is there information available on other key factors that is not included in the draft PM ISA that inform differential risk that should be added?
- Please comment on the identification, evaluation and characterization of the available scientific evidence from studies of PM on non-ecological welfare effects of visibility impairment, climate, and materials and the application of information from these studies, as presented in Chapter 13, to inform causality determinations and uncertainty characterizations for these welfare outcomes.

We look forward to discussing these issues with the CASAC Particulate Matter Review Panel at our upcoming meeting. Should you have any questions regarding the draft PM ISA, please feel free to

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