Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Chartered Clean Air Scientific Advisory Committee (CASAC)
Public Meeting on Particulate Matter
December 12-13, 2018

Date and Time: Wednesday, December 12, 2018 – Thursday, December 13, 2018

Location: Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, Virginia 22202; telephone; and live video webcast.

Purpose: The Chartered CASAC will peer review EPA's *Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018).*

Participants: Chartered CASAC Members (also see roster[1])
Dr. Tony Cox, Chair
Dr. James Boylan
Dr. Mark Frampton
Dr. Sabine Lange
Dr. Timothy Lewis (participated by phone)
Dr. Corey Masuca
Dr. Steven Packham

Mr. Aaron Yeow, Designated Federal Officer (DFO)

Dr. Erika Sasser, EPA Office of Air Quality and Planning Standards (OAQPS)
Dr. John Vandenberg, EPA National Center for Environmental Assessment (NCEA)
Mr. Jason Sacks, EPA NCEA

Other Attendees (See Attachment A)

Convene Meeting, Welcome, and Review of Agenda

Mr. Aaron Yeow, DFO, opened the meeting. He noted that, as required under the Federal Advisory Committee Act (FACA), the CASAC's deliberations are held in public, with advanced notice given in the Federal Register,[2] and that the meeting minutes will be made publicly available after the meeting. He noted that there was a public comment period on the agenda for members of the public who had registered in advance with the SAB Staff Office to make oral comments. He stated there was also a clarifying public comment period noted on the agenda where members of the public could request an opportunity to make short clarifying comments providing new additional information to the CASAC. He noted that the CASAC had received written public comments, which were posted on the meeting webpage. He stated that the SAB Staff Office determined that there were no issues with conflict-of-interest nor any issues with an appearance of a loss of impartiality for any of the CASAC members. He noted that one CASAC member, Dr. Timothy Lewis was participating on the phone.

Mr. Thomas Brennan, Acting Director of the Science Advisory Board Staff Office, welcomed everyone and thanked the CASAC members for their hard work in preparing for the meeting and for their public

service. He also thanked EPA for their efforts in producing the review document and thanked the members of the public for their participation.

Dr. Tony Cox provided an overview of the Agenda.[3] He indicated that the CASAC's goal over the next two days was to reach useful consensus answers to the charge questions and to provide feedback on making the ISA as excellent as possible, which includes soundness, accuracy, objectivity, and being transparent and reproducible. In thinking about what kinds of advice would be most useful, his own thinking focuses on preventable harm – what harm to human health and welfare could be prevented by changes in the National Ambient Air Quality Standards (NAAQS). He asked members of the CASAC to listen carefully to public comments, and to build on the work they have already done, to address that question of quantitative measures of preventable harm. He noted that many members of the CASAC and the public had raised questions of process. He stated they were not the primary focus of the CASAC's work, but that they were important issues and the CASAC's final advice might include advice about process. He then asked the EPA to begin their presentation.

EPA Presentation on the Draft ISA

Dr. John Vandenberg, EPA NCEA, began the EPA presentation,[4] introducing the EPA speakers, and providing the Outline for Presentation. Dr. Erika Sasser, EPA OAQPS, covered the Introduction and Statutory Requirements, Statutory Requirements: CASAC, Overview of Current PM NAAQS, Initiation of Expedited Review (May 2018 Memo), and Timeline and CASAC Role in the Current Review. She noted that the next time the CASAC would meet would be to review the Policy Assessment (PA) which would be accompanied by risk and exposure analyses. Regarding Dr. Cox's comments about quantifying preventable harm, she stated that the way the NAAQS review structure was set up was that typically the EPA would conduct those quantitative analyses as part of the risk and exposure analysis. It would be in the next set of documents that they would attempt to quantify various indicators of risk and potential preventable harm in the context of this review. Dr. Vandenberg continued with the Weight-of-Evidence Approach for Causality Determinations for Health and Welfare Effects, Evaluation of the Scientific Evidence, and the Framework for Causality Determinations in the ISA. Mr. Jason Sacks, EPA NCEA, continued with Contents of the Draft PM ISA, Scope of the PM ISA, Executive Summary and Chapter 1, PM Concentrations and Trends (Chapter 2), Exposure to PM (Chapter 3), Dosimetry of PM (Chapter 4), Draft PM ISA Health Effects: Causality Determinations, Example: Potential Biological Pathways Figure, Respiratory Effects (Chapter 5), Cardiovascular Effects (Chapter 6), Nervous System Effects (Chapter 8), Cancer (Chapter 10), Mortality – Short-term PM2.5 Exposure (Chapter 11), Mortality – Long-term PM2.5 Exposure (Chapter 11), Other Causality Determinations (Chapters 5-10), Policy-Relevant Considerations (Chapter 1), Populations Potentially at Increased Risk of a PM-related Health Effect (Chapter 12), Draft PM ISA Welfare Effects: Causality Determinations, Welfare Effects (Chapter 13), and acknowledging the PM ISA Team.

Dr. Cox thanked the EPA for an outstanding, clear, well-organized, well-presented presentation. He had several questions regarding the five categories of causal determinations. The first question was whether the categories were intended to be mutually exclusive. Dr. Vandenberg responded that as they develop their weight-of-evidence evaluation, they are determining which of the causal determination categories maps best against the multiple lines of evidence. Dr. Cox asked whether, if they were uncertain which category to map it to, the EPA would tend to round up or round down. Dr. Vandenberg responded that they would tend to ask the CASAC.

Dr. Cox asked if they determined there were a causal relationship between an exposure and a response, does that mean it is a direct causal relationship or could it be an indirect causal relationship, a total

causal relationship, or a mediated causal relationship. In epidemiological terms, which kinds of causality are being asserted? Dr. Vandenberg responded that they were making a causality determination, not a causality analysis. Mr. Sacks stated that they were evaluating a collective body of evidence, not just focusing on epidemiology, and forming a weight-of-evidence determination for the entire body of evidence, not just that one line of evidence.

Dr. Cox stated that when a concentration-response association is seen, very often in reality, that association will be partly due to confounding or modeling choices, maybe partly due to direct effects, and partly due to indirect effects. Does determining that a relationship is "causal" imply that the entire observed relationship is causal, or just that some of it is causal? Dr. Vandenberg responded that they were evaluating the body of evidence against the causal determination categories, not analyzing individual studies, and not doing percentages.

Dr. Cox asked what was meant by the term "independent health effect" in the context of $PM_{2.5}$, given what is known about its interactions with other factors. Mr. Sacks responded that, in the context of a NAAQS review, they were focusing on individual pollutants, so their job is to assess the scientific evidence and determine whether or not there is evidence that PM on its own can cause a health effect. Through experimental evidence and trying to use epidemiological approaches that are available, they seek to tease that out and figure out if there is evidence that PM is causing some effect. That is based on the different levels of the causal framework and how confident they are that the scientific evidence is reducing chance, confounding and other biases to allow concluding a specific causality determination. Dr. Cox asked whether, if there were an interaction between poverty and PM on a particular health outcome, EPA was not trying to apportion the effect partly to poverty and partly to PM, but was just trying to answer the qualitative question of whether PM by itself, in the absence of poverty, also caused an effect. Mr. Sacks indicated that that was correct.

Dr. Cox questioned the EPA's assertion in Chapter 3 that exposure errors tended to produce underestimation of health effects (for short-term exposures). For the sake of time, it was agreed to postpone the discussion until the CASAC deliberation on Chapter 3. Regarding the EPA's assertion of consistent positive associations for cardiovascular mortality (slide 22 of the EPA's Presentation), Dr. Cox asked about the Health Effects Institute (HEI) accountability studies which have shown inconsistent associations for cardiovascular mortality. He asked why the EPA did not discuss studies of the Irish coal burning ban. Mr. Sacks indicated that those studies looked at PM_{10} and sulfate, which was outside of the scope of the ISA, which focused on coarse and fine particles (per the advice of CASAC on the previous ISA).

Public Comments

Mr. Yeow indicated that public commenters would speak in the order presented in the List of Registered Speakers[5] and would be limited to 5 minutes each.

Gretchen Goldman, Union of Concerned Scientists, made an oral statement.[6] She stated that the expedited time frame and planned merging of documents, combined with gaps in expertise on the CASAC and the lack of the PM review panel and public input opportunities, are likely to undermine the ability of the EPA to set a science-based standard for particulate matter, protective of public health with an adequate margin of safety, as required by the Clean Air Act.

Chris Frey, North Carolina State University provided an oral statement[7] that focused on changes to the CASAC and the NAAQS review process harming the quality, credibility, and integrity of the NAAQS science review. He referenced written comments[8] from 15 former members of the disbanded CASAC PM panel, which has 8 major finding and 44 recommendations for restoring the quality, credibility, and integrity of the science review process.

Ted Steichen, American Petroleum Institute, made an oral statement[9] that focused on several overarching issues in the ISA that undermine its conclusions, including lack of a sufficiently detailed systematic review protocol, not sufficiently addressing study quality, not explicitly stating study relevance criteria, and the causal framework not being adequate.

Julie Goodman, Gradient, provided an oral statement[10] on behalf of Gradient, but noted that the American Petroleum Institute had provide funding for preparing comments and attending the meeting. She stated that the CASAC should recommend that the EPA address three overarching issues in the ISA that undermine its evaluations of health effects. Specifically, the CASAC should recommend that the ISA include a sufficiently detailed systematic review protocol, sufficiently address study quality by providing detailed study quality criteria, explicitly state study relevance criteria, and update the causal framework so that it is not biased towards a causal conclusion. She referred to her written comments for further detail,[11] but presented a table to show how study quality can be addressed in a systematic fashion.

Giffe Johnson, National Council for Air and Stream Improvement (NCASI), made an oral statement[12] focused on the EPA's causal framework lacking the most critical features of systematic review, leaving the ISA vulnerable to introducing the risk of bias and impairing the reliability of its conclusions. He referred to NCASI's written comments[13] for further details.

Douglas Dockery, Harvard T.H. Chan School of Public Health, presented an oral statement.[14] He wanted to demonstrate that epidemiology could be intuitive, sound, and easily understood. He presented results from the Harvard Six Cities Adult Mortality Study, which found that people in dirty cities (high particle concentrations) had less survival (greater mortality) than those in cleaner cities (lower particle concentrations). He stated that the study was validated using a different cohort by the American Cancer Society (ACS) - Cancer Prevention Study II. He said that, since then, many independent cohort studies have replicated and validated the Six Cities and ACS studies. He stated that, in a new study just published using a cohort of nearly 61 million Medicare beneficiaries, there is substantial evidence that below 12 $\mu g/m^3$ there are opportunities for continued improvements in public health, that is, preventable harm, with additional reductions in $PM_{2.5}$ concentrations.

Lianne Sheppard, University of Washington, made an oral statement,[15] focused on causality and the CASAC and NAAQS review process being broken. She stated that inferences using causal tools in epidemiologic studies can closely approximate causal conclusions, that there is a distinction between causal inference tools in a single study and the weight of evidence causal determinations made by the EPA, and that causal inference methods for application to air pollution are in their infancy and not ready to be required for use in regulatory policy. She stated that the changes to the CASAC and NAAQS review process were done without consultation with the CASAC and are arbitrary and capricious.

George Allen presented an oral statement,[16] noting that his comments did not necessarily represent the views of his employer, Northeast States for Coordinated Air Use Management (NESCAUM), although he referred the CASAC to NESCAUM's written comments.[17] He was concerned about the many changes to the CASAC and NAAQS review process, but focused his comments on concerns about the

accelerated schedule for the PM NAAQS review. He recommended that the CASAC reject the EPA's accelerated review schedule in favor of one that allows sufficient time for a staggered sequence of first draft documents.

Peter Adams withdrew his request to speak.

Jack Harkema, Michigan State University, was on the phone and made an oral statement[18] focused on the need for the CASAC to have more deliberation among experts from multiple disciplines to properly assess the data and conclusions made by the EPA. He gave an example regarding the causality determination for nervous system effects and long-term PM exposure needing toxicologists, epidemiologists, aerosol scientists, neuroscientists, and comparative animal biologists. He urged the CASAC to recommend reinstating the PM panel composed of recognized experts with different perspectives to ensure the best review.

John Balmes, University of California at San Francisco, was on the phone and presented an oral statement[19] that focused on the need for a proper and thorough scientific review of the PM ISA. He stated that the Chartered CASAC lacks the appropriate scientific expertise, particularly epidemiology and neuroscience, to review the massive and complex ISA. He strongly recommended that the PM panel be reconstituted.

Dan Greenbaum, Health Effects Institute (HEI), made an oral statement and also referred to written comments from HEI.[20] His comments were focused on the causality determinations in the ISA and the status of several key HEI-funded studies of low levels of exposure to PM and ozone currently undergoing detailed HEI peer review. HEI had specific comments on, and did not agree with, the causality determinations for long-term $PM_{2.5}$ exposure and lung cancer, long-term $PM_{2.5}$ exposure and nervous system effects, and long-term ultrafine (UFP) PM and nervous system effects. He noted that several HEI-funded studies cited in the ISA were currently undergoing peer review by HEI and would be published in an upcoming HEI Research Report, scheduled to be completed in December 2019. He requested that the CASAC recommend that the EPA consider including the HEI Research Report in the final ISA.

John Bachmann, Vision Air Consulting, LLC, was on the phone and presented an oral statement[21] on behalf of the Environmental Protection Network (EPN). His comments focused on EPN's concern that the changes made to the NAAQS review process will undermine its quality and credibility, and could lead ultimately to ill-informed decisions that might adversely affect public health. He also expressed support for the EPA's continued use of the core elements of the formal causal framework, which was developed with strong support of past CASAC panels over the last decade.

Anne Smith, NERA Economic Consulting, made an oral statement[22] on behalf of the Utility Air Regulatory Group, focused on the question of the shape of the concentration-response function. She stated that estimates of concentration-response shape are subject both to statistical uncertainty and to model uncertainty. She noted that there are more shape estimates now than in prior PM NAAQS reviews, but that they were highly varied and their confidence intervals erode any ability to discern what shape applies at any $PM_{2.5}$ level. She stated that smoothing methods need closer evaluation and development and that methods are needed for synthesizing model uncertainty and statistical uncertainty on the slope at varying $PM_{2.5}$ exposure levels. Both of these are needed before concentration-response shape evidence can be considered robust and reliable as a primary basis for policy judgements.

Albert Rizzo, American Lung Association, was on the phone and provided an oral statement.[23] He stated that the EPA should set air quality standards to provide protection against effects not only determined to be causal, but also for effects found to be "suggestive of a causal relationship." He called on the EPA to reinstate the PM panel and for a second draft of the ISA. He supported the EPA's approach to determine causality, that no threshold exists for harm from PM, and agreed with the causal determination for premature deaths for both short-term and long-term exposure to PM. However, he also supported a causal determination for both short-term and long-term exposures of PM on respiratory effects. He urged the EPA to strengthen the standards to protect public health.

Corwin Zigler, The University of Texas at Austin, was on the phone and made an oral statement[24]focused on causal inference methods. He stated that the current "weight of evidence" determinations of causality in the ISA are useful for judging the causal consequences of an anticipated change in PM concentrations. Individual studies contributing to these determinations should be interrogated and weighed according to their design, data structure, statistical analysis, and plausibility of underlying assumptions, not simply based on whether the methods used are nominally described as "causal." A variety of study designs and analysis approaches have the potential to produce reliable causal inferences, and no single method should be viewed as "automatically" capturing causal relationships. To the extent that formal causal inference methods are available in air pollution studies, their usefulness should be viewed in light of a mature literature in fields that focus on population-based observational studies.

Jia Coco Liu, Electric Power Research Institute, presented an oral statement.[25] She stated that although current studies estimate the association between ambient PM and human health, association is not causation. Characterizing the causal effect of PM on human health is critical for informing policy-making on ambient PM. She also stated that there is the potential presence of unmeasured confounding in long-term air pollution epidemiology studies, despite the fact that most studies strive to control for potential confounders.

Stewart Holm, American Forest & Paper Association, made an oral statement.[26] He stated that a recent paper by Pun et al., which was not cited in the ISA, demonstrated that the long-term relationship between $PM_{2.5}$ and mortality is confounded by some other, unmeasured long-term trend. He stated that the Pun study reveals confounding bias and illuminates the complexity and uncertainty in the studies at the heart of the $PM_{2.5}$ debate. Until this uncertainty is addressed, it is possible that a substantial portion of the conclusions reached by the ISA regarding adverse health effects may be unreliable. Accordingly, he urged the CASAC to recommend accepting the Pun study and maintaining the existing standard.

Sonja Sax, Ramboll, presented an oral statement[27] on behalf of the American Wood Council, Aluminum Association, and American Iron and Steel Institute, which focused on how the ISA process could be greatly improved with the implementation of a more rigorous and transparent systematic process. She stated that although the causal framework included some features of systematic review, it was lacking critical aspects including a systematic, documented approach for the selection of studies, clear criteria for the evaluation of study quality, and ranking and weighing of the evidence within a scientific line of evidence, as well as across all scientific studies. The focus of her comments were on the evaluation of study quality within a scientific line of evidence.

Jonathan Samet, University of Colorado School of Public Health, made an oral statement. He noted his experience as a prior Chair of CASAC and stated that the nature of the reviews has necessitated the augmentation of the Chartered CASAC with additional panelists to ensure the reviews were sufficiently broad and had depth in expertise. The approach used by the agency in its causal determinations reflects

the state of practice used by others, such as the Centers for Disease Control and Prevention, in evaluating the evidence on smoking and health. He stated that the Chartered CASAC does not have all the expertise that is needed for this review.

Fernando Garcia Menendez, North Carolina State University, represented over 200 scientists, engineers, public health experts who signed a letter to the EPA[28] expressing their concern with the recent dismissal of the PM panel. He stated that without sufficient expertise by qualified, independent scientists, the end result may be standards insufficient to protect public health. He strongly urged that the PM panel be reinstated to provide the CASAC with the best possible scientific understanding.

George Wolff, Air Improvement Resource, Inc., was on the phone and made an oral statement[29] on behalf of The Alliance of Automobile manufacturers. He shared historical perspective on the 1996/1997 PM NAAQS review by the CASAC, which he Chaired. It was the first PM NAAQS that weighed epidemiology more than toxicology or human exposure, but the EPA acknowledged many uncertainties that needed to be addressed before the next review. After two decades of research, significant uncertainties remain. He noted that the current PM ISA has deficiencies in dosimetry, toxicology, and epidemiology. He concluded by referring the CASAC to recent studies that had different conclusions than the conclusions made by the EPA in the Draft ISA.

Daniel Costa was on the phone and made an oral statement.[30] He stood in solidarity with previous statements made about the shortcomings on the decision to restructure the Chartered CASAC and to disband the PM Panel. His comments focused on three storylines nested within his 40-year career in science which demonstrated the history of credible science and policy reviews via a well-established process over the last 40 years. His professional and personal experiences have led him to believe that a decision to diminish the NAAQS review process and to press on with an agenda to weaken regulatory policy, if not deregulate all together, is without merit, and worse, is one without moral conscience.

Kevin Cromar, New York University, presented an oral statement in his role as vice-chair of the Environmental Health Policy Committee of the American Thoracic Society. He wanted to publicly recognize the quality and rigor of the PM ISA. The document is a good representation of the scientific evidence concerning health effects of particle pollution and the scientific conclusions and causal determinations are supported by a well-constructed framework. He stated that they had a high level of confidence that the causal conclusions reported in the ISA cannot be explained away by unmeasured confounders or other unidentified biases.

Kurt Blase, Blase Group LLC, made an oral statement on behalf of the Coarse PM Coalition. He made reference to written comments submitted to the CASAC on December 5, 2018,[31] and December 11, 2018.[32] He called attention to two issues raised in those comments, the upgraded coarse PM causality findings and the composition of the coarse PM in the coarse PM health studies. His slides[33] showed a table of how EPA addressed the aspects to aid in judging causality for cardiovascular effects from long-term coarse PM exposure. They did not find the EPA's analyses to be adequate and did not justify the upgrading of causal determinations for coarse PM. Regarding composition, he indicated that the composition of coarse PM in the health studies were mainly road dust, which differs from the coarse PM composition that their industries produce, which are mainly crustal.

Roger O. McClellan, a past Chair of CASAC, was on the phone and made an oral statement. He provided some highlights from his written comments.[34] He admonished the CASAC to recognize that its role was to review the science that will inform the Administrator's judgements in revision or reaffirmation of the NAAQS and that it was not a standard-setting committee. The Draft ISA is a good

first draft, but was encyclopedic in nature and had serious deficiencies that needed to be addressed. The ISA lacks contextual material essential for making policy judgements, lacks a conceptual basis, erroneously assumes that statistical associations are evidence of causality, does not adequately relate that the health outcomes of concern are uniquely caused by PM, and does not provide a succinct Executive Summary.

Anthony Maciorowski provided an oral statement focused on the historical role of the CASAC and the impact of eliminating the PM Panel. He asked the CASAC to consider whether they were adequately qualified to conduct the PM review, whether their advice would achieve the same scientific caliber and integrity of earlier CASAC reviews, and whether their recommendations would prove to be authoritative and compelling to the broader scientific community and the public at large.

Dr. Cox thanked all the public speakers and asked the CASAC members if they had any clarifying questions for the public speakers. Dr. Packham expressed thanks to the public speakers and indicated that he could only speak as a scientist in one discipline and that was clearly not sufficient.

With no further questions from the CASAC for the public speakers, Dr. Frampton asked the EPA if they could respond to a few questions. He noted the many public comments raising questions about the process changes that have been implemented, particularly about the decision to disband the PM Panel. He asked the EPA if they could provide any additional clarifying information about what the intended benefit was to disbanding the PM Panel. Dr. Vandenberg indicated that he was not involved with that decision and had no further information. Dr. Sasser stated that there was a desire, in the spirit of making the reviews more efficient, to return to the core statutory obligations of the CASAC and to reaffirm the committee as the principle advisor to the agency on the NAAQS. She noted, however, that this decision was not made at the staff level.

Dr. Lange echoed some of the concerns raised by the public commenters and asked the EPA where data quality and study quality was taken into account in the ISA. Dr. Vandenberg indicated that it comes in throughout the process but that essentially they throw out a wide net to identify potentially relevant studies, then narrow down focusing, as described in the Preamble. He indicated that they do systematic review, but have not used the same terminology about it that has been used in other venues. He stated that they do an evaluation of the science, identify the most policy-relevant studies, review those studies very carefully, and characterize them in the tables in the ISA. They do not do a point-by-point evaluation that sometimes is done in the systematic review of some of the Integrated Risk Information System (IRIS) assessments.

Discussion of ISA Charge Questions

After a lunch break, the CASAC members each introduced themselves. Dr. Cox then reviewed the charge questions from the EPA.[35] For the charge question pertaining to Chapters 5-11, he indicated that evaluation includes systematic review, evaluation included study quality criteria, and characterization included uncertainty. He stated that opinions, judgements, unverified assumptions are not scientific evidence. He asked the CASAC to focus on data and verified assumptions. When talking about evidence, he asked the CASAC to be specific about evidence of how changing PM affects risks to human health and welfare. Regarding application of evidence to causality determinations, he asked the CASAC to comment on whether the causal conclusions follow from the evidence and whether changes in causal conclusions follow from changes in evidence. Lastly, he asked the CASAC to consider whether uncertainty has been adequately characterized.

Dr. Cox indicated that a few weeks prior to the meeting, he asked the CASAC to consider additional supplemental questions[36] pertaining to treatment of exposure estimation errors, adequacy of lags and of modeling for lagged effects, control for latent variables, modeling of interactions and dependencies among explanatory variables and between explanatory and risk variables, treatment of manipulative causality, clear definition and quantification of direct, mediated, and total causal effects for causal concentration-response functions, treatment of inter-individual variability and heterogeneity in causal concentration-response functions, and uncertainty characterization.

Dr. Frampton indicated that process issues may have to be discussed before diving into responses to the charge questions because he has a major concern that they do not have the expertise on the Chartered CASAC to adequately review the ISA. Dr. Cox asked to hold the process discussion until later. He stated that he agreed that there are substantial advantages to being able to draw from a larger pool of expertise. Dr. Frampton thought that was fine, but getting the CASAC's thought on the process issues could have a major impact on the CASAC's discussion of the chapters. Dr. Cox instructed the CASAC to flag areas where additional expertise was needed as they discussed the chapters.

Discussion of Response to ISA Charge Questions

Chapter 2 - Sources, Chemistry and Measurement and Modeling of Ambient Concentrations of PM

Regarding sources of PM, Dr. Masuca noted that crustal matter dominated coarse PM in the US and fugitive dust was identified as the largest source of measured PM_{10}. He stated that there was no discussion in Chapter 2 of whether there was any potential for secondary coarse PM formation, speciation of $PM_{2.5}$ and PM_{10}, and no discussion of natural background concentrations or anthropogenic transport between cities/states/regions, etc. Regarding monitoring of PM, he noted that there have been huge reductions in $PM_{2.5}$ – from 2000-2017, there has been a 41% annual average reduction. With regards to measurement, there are new methods for more accurately measuring coarse matter, as opposed to the subtraction methods. There are limitations with the use of satellite remote sensing to accurately measure PM concentrations. He noted that there were limitations of three- to six-day sample collection using the Federal Reference Method (FRM), and that there was no discussion of limitations and/or uncertainties of chemistry-transport models. He noted that it was important for epidemiological studies to consider confounding from temperature and/or relative humidity. The ISA is missing a discussion of regional (state-to-state) transport.

Dr. Boylan thought that, overall, Chapter 2 was well-written. A discussion of capture fraction and transportable fraction should be included to help place the importance of dust emissions into proper perspective. The document should recognize that many states are now switching to the Federal Equivalency Method (FEM) and therefore more hourly monitoring data should be available. The design values for 2015-2017 are now available and should be used rather than data that is two or three years old. He also noted some potential errors in Figures 2-14 and 2-15.

Chapter 3 – Exposure to Ambient PM

Dr. Boylan indicated that, in general, Chapter 3 does a good job of describing the latest scientific information on exposure to ambient PM and implications for epidemiologic studies, methodological considerations for exposure measurement and modeling, and the influence of exposure error on effect estimates in epidemiologic studies. He noted that before using personal sampling data to estimate exposure, a detailed evaluation of the sampler performance compared to FRMs/FEMs should be performed. He noted that when dispersion models are being used to support health studies, spatial and temporal accuracy is much

more important compared with compliance assessments. Therefore, dispersion modeling results need to be evaluated against observations paired in time and space. He was in general agreement with the conclusions in Chapter 3: Exposure error tends to produce underestimations of health effects in epidemiologic studies of PM exposure, although bias in either direction can occur; New developments in PM exposure assessment methods have reduced bias and uncertainty in health effect estimates; High correlations of $PM_{2.5}$ with some gaseous copollutants necessitate evaluation of the impact of confounding on health effect estimates; There is typically more uncertainty for health effect estimates for exposure to $PM_{10–2.5}$ and UFP.

Dr. Lange thought there should be the addition of the Avery et al. (2010) papers, which provide meta-analyses of the relationships between personal and ambient PM exposures and demonstrate a lot of variability, which adds to exposure measurement error. Regarding copollutant confounding, the EPA notes that in Section 3.4.3, different pollutants can have different exposure measurement error, but that if $PM_{2.5}$ is measured with less error than copollutants, it is likely that the effect will be attributed to $PM_{2.5}$. This means that no matter which pollutant is causally related, the one that is measured with least error tends to be the one that has the risk attributed to it. She noted that this is an important point that needs to get captured when discussing exposure measurement error and carried through in the assessment of the studies.

Dr. Cox asked the EPA to address whether exposure measurement error tends to lead to understatements of health effects. Dr. Jennifer Richmond-Bryant, EPA NCEA, wanted to make clear that the scope of the chapter is ambient concentrations of PM. So when they look at personal exposures, they are looking at personal exposure to ambient PM. They are not stating that personal exposures are a surrogate for total PM because that has non-ambient influences (such as cooking, fireplace use, etc.). She indicated that a single concentration-response relationship is not useful to suggest causality by itself. But it is useful to consider how individual study concentration-response relationships might be impacted by exposure errors since the bulk of evidence is used together to contribute to the causal determination. To address Dr. Cox's comment that exposure error causes the response to be underestimated at high concentrations and overestimated at low concentrations, this assumes a non-zero threshold. However, she said that there are no identified studies that demonstrate a non-zero threshold.

Chapter 4 – Dosimetry

Dr. Lange stated that one of the ways that dosimetry could be made more interpretable in the health effects chapters would be to include exposure concentrations when discussing the study results. The EPA should note that, while several percent of extremely small particles may translocate into the peripheral circulation in rodent studies with exposure by lung installation, there is no evidence that this much translocation occurs with exposure to even very small particles (4-5 nm) in humans. When discussing results showing fetal translocation of particles, the EPA should state that this was using oral or IV particle administration.

Chapters 5 – 11- Health Effects of Exposure to PM

For Chapter 5 and 6 on respiratory and cardiovascular effects, Dr. Frampton did not find that the Draft ISA adequately explained the potential that cardio-pulmonary interactions could have in the health effects of PM. Pulmonary vascular effects are a likely pathway, in addition to inflammation and translocation, for both acute and long-term PM effects. For Chapter 7 on metabolic effects, a better distinction needs to be made between the potential metabolic effects of PM, and metabolic abnormalities as markers of susceptibility to cardiovascular effects of PM. The section on metabolic disease mortality needs to be rewritten for clarity because people do not die from metabolic disease, but metabolic conditions can increase risk for mortality from other causes.

Dr. Lange discussed biological plausibility and stated that most of the pathways start with respiratory inflammation, oxidative stress, and injury, which start a cascade of effects. The animal and human studies provide the most direct evidence of PM effects, particularly the controlled human exposure studies. However, there is not a lot of evidence of respiratory inflammation, oxidative stress, and injury, even at higher concentrations of PM than normal ambient concentrations. This makes it difficult to translate down biological pathways when demonstrations of upstream effects are not consistent. The experimental evidence is not demonstrating a good, solid biological plausibility pathway.

Dr. Cox indicated that Dr. Lewis needed to leave soon and wanted to provide him an opportunity to present his comments on Chapter 13 before he left, then they would come back to Dr. Lange's comments on Chapters 5-12.

Chapter 13 - Non-ecological Welfare Effects

Dr. Lewis indicated that there should be more discussion of whether there were specific quality criteria set as targets for inclusion or exclusion of welfare effects studies. There is little discussion of how study findings that consist of different PM concentrations, different mixtures, different experimental design questions, and different ambient conditions apply directly to non-ecological welfare effects in the United States. Comparing perceived visibility impairment of urban versus more "bucolic" settings may have inherent biases. The document does a good job more firmly establishing a causal relationship between PM and visibility, but it will be challenging for the agency to tease out the complex nature of PM across the country. The distinction between anthropogenic PM impairment versus natural PM impairment needs to be more clearly separated and explained. Uncertainty in the effects of complex aerosol composition on climate need to be better resolved. The climate effects of PM on ecosystems should be discussed in this document.

Due to the time, Dr. Cox proceeded with public clarifying comments and indicated that the discussion of the responses to the charge questions would resume after that.

Public Clarifying Comments on ISA

Mr. Yeow indicated that there were five members of the public who had registered to provide additional clarifying comments.[37]

Chris Frey, North Carolina State University, indicated that the CASAC's credibility depended on process issues and asserted that the CASAC lacked credibility to take on the weight-of-evidence causality framework due to the lack of expertise in epidemiology and the lack of diversity of perspectives. He urged the CASAC to recommend the reinstatement of the PM Panel and call for the formation of an Ozone Review Panel.

George Allen commented on the ability of the current $PM_{2.5}$ monitoring network to measure low annual average concentrations. He indicated that Clint Woods, Deputy Assistant Administrator for the EPA's Office of Air and Radiation, stated that a standard of 5$\mu g/m^3$ was well below what the current monitors can measure. Mr. Allen noted that the standard is an annual average and current monitors can measure annual average PM concentrations of 5 $\mu g/m^3$ with reasonable or useful quality in terms of comparison to the NAAQS.

Douglas Dockery, Harvard T.H. Chan School of Public Health, indicated that he had a lot of comments on substantive issues, but was most concerned about process. Although he respected the CASAC

members, he said that, with only the legally required minimum number of members with limited experience and expertise, they were set up with an undoable task.

Lianne Sheppard, University of Washington, stated that the CASAC process is broken, and that the sweeping changes made are arbitrary and capricious. She asserted that the day's deliberations made clear that seven individuals are not sufficiently qualified to conduct the PM ISA review. She noted the high number of public commenters who were not representing a funded agenda (industry, trade group, non-government organization, or an advocacy group). Today was different and many independent scientists felt compelled to speak up because of their commitment to quality, integrity, and public health. The CASAC and the EPA should put considerable weight on the concerns of these independent commenters.

Julie Goodman, Gradient, made a clarifying comment[38] about study quality versus relevance. She stated that the EPA indicated that they addressed study quality in the HERO database, but the winnowing down of studies in the HERO database is based on the relevance of study topics for the ISA, and is not based on quality. The EPA also discussed some specific aspects of study quality that they had considered. However, they did not discuss any criteria for addressing quality and specific criteria are not presented in the ISA or in the Preamble. It was mentioned that the EPA considered study quality while reviewing studies, but she said this was not done in a transparent, systematic, or reproducible manner, based on clear criteria.

Discussion of Response to ISA Charge Questions (cont'd.)

Chapters 5 – 11- Health Effects of Exposure to PM (cont'd.)

Dr. Lange reiterated that copollutants are not the only confounders of issue. For example, for asthma, allergens would be a big concern, as well as temperature. Confounders that are not copollutants need to be considered in all of these sections. There is more than one reason that there could be an association between a pollutant and a health effect. It could be due to a causal relationship or it could be due to bias, chance, or confounding. There was not much discussion about chance and the document is missing consideration of statistical significance. There should also be more discussion of how conflicting evidence is dealt with. When health effects are discussed, the concentrations of PM also need to be discussed to help compare across studies. When assessing coherence across studies, effects need to be looked at with similar concentrations, taking into account dosimetry differences (e.g., between animals and humans).

Dr. Cox indicated that discussion of the response to the charge questions on Chapter 12, Executive Summary, and Chapter 1, as well as process issues would continue the next day. Dr. Boylan also asked that the CASAC weigh in on whether they agreed with the causality determinations.

Mr. Yeow indicated that the meeting would be recessed until 8:30 am, December 13, 2018.

<u>Thursday, December 13, 2018</u>

Discussion of Response to ISA Charge Questions (cont'd.)

Dr. Cox wanted to discuss process issues before the discussion of charge questions. He noted that many public commenters discussed the need for additional expertise for the review and he agreed that the

CASAC should recommend that it be given access to whatever expertise it needs to provide the best review possible. The second process issue had to do with the agency's NAAQS schedule and their plan for only one draft of the ISA. The other CASAC members agreed that additional expertise would be helpful and that a second draft of the ISA should be brought back for CASAC review. Dr. Boylan added that not only should there be breadth of expertise added, but also depth of expertise added, for more than one expert per discipline. He also was in favor of having a Risk and Exposure Assessment Planning Document as well as a separate Risk and Exposure Assessment Document. Drs. Frampton and Lewis both agreed on the need for additional expertise and suggested reinstating the previous CASAC PM panel.

Dr. Cox had put together slides of the charge questions[39] with emphases added to aid in the discussions. Mr. Yeow clarified that the CASAC's main job was to develop consensus responses to the charge questions. The CASAC's advice to the EPA will take the form of a letter to the Administrator, which will highlight the major comments and recommendations, followed by more detailed consensus responses and then individual comments. The CASAC agreed to continue deliberating on the responses to the charge questions and not to develop bullet responses, but would try to verbally summarize the consensus responses.

Chapter 12 - Populations and Lifestages Potentially at Increased Risk for Health Effects Related to PM Exposure

Dr. Packham found that Chapter 12 lacked definition of terms (such as what is an adverse effect and causality) and lacked a discussion of causality. Dr. Cox stated that the fundamental gap with the causality framework is that its concept of causality is not equivalent to the concept of prevention, which is what most people mean when they refer to causality, and causality is not well defined in the framework. Dr. Packham asked Dr. Frampton for his thoughts on terms, causation, definition of adverse effect, etc. Dr. Frampton agreed that they are foundational issues, and noted that the American Thoracic Society put out a document on what it means for something to be an adverse effect of air pollution. He indicated that these issues were not resolved and probably never would be resolved and that he did not find a problem with it not being resolved in the Draft ISA. He did not find any problems with the causality framework that the EPA has used in the Draft ISA. Dr. Packham did not find any issues with clarity in Chapter 12, but did find issues with key information missing from Chapter 12.

Executive Summary and Chapter 1

Dr. Cox's presented slides[40] on his comments on the Executive Summary and Chapter 1. He found the Executive Summary to be generally well written and that it fairly represents the rest of the Draft ISA. However, the key information and conclusions being summarized are themselves unclear in several respects. Many terms are undefined or used inconsistently, and there is conflation of estimated and true exposures as well as conflation of different types of causes, effects, and concentration-responses. He said there is ambiguity in the 5 causal determination categories and resolution and clarity need to be added to the causality framework. He stated that the reasons and criteria for study inclusion or exclusion are not always clear. How conflicting evidence is reconciled is also not very clear. He provided additional detail on clarity about effects, definitional ambiguity of causality of the exposure-risk association, and clarity about causes. Information should be added on whether reducing PM exposures would reduce adverse human health effects. Other things to fix/address in the Executive Summary include: systematic review, explicit individual study quality criteria, an assumption of linear no threshold model is not evidence of a linear no threshold relationship, measurement error does not necessarily usually lead to underestimates of health effects, model uncertainty should be characterized,

measurement/estimation errors should be characterized and accounted for, estimated and true exposures should be distinguished, and conclusions on mortality, lung cancer, cardiovascular, and neurological health effects should be revisited.

For Chapter 1, Dr. Cox found the summary to be effective, but the information being summarized has a lot of controversial material in it. The other chapters need to be fixed, then the same process used to distill them. Regarding the usefulness and effectiveness of the summary presentation, he provided a specific example of statements regarding the causality determination for total mortality and PM2.5 exposure. He had questions regarding the accuracy and confidence in those statements. He provided examples of several studies that were excluded from the Draft ISA that call into question the accuracy of those causal determination statements. He recommended the following information to be added to the ISA: accountability studies, causal mediation studies and analyses, natural experiments and quasi-experiments, inflammation toxicology for lung and cardiovascular, socioeconomic drivers and trends, co-morbidity and co-pollutant drivers and trends, study selection criteria, individual study quality evaluation criteria, synthesis and conflict resolution criteria, and systematic review results.

Dr. Frampton indicated that he did not equate causality with preventability. He defined it as one thing leads to another. The pathways may not be known and it is very hard for epidemiology studies alone to prove causality. He viewed causality and whether reductions in exposures would lead to reductions in health effects as two separate matters. Accountability studies are very difficult to do. He did not find that the causal definitions introduced by Dr. Cox to be helpful in understanding what is going on and felt they just obfuscate and would lead to confusion if included in the ISA. Dr. Cox stated that decision makers need to know about manipulative causation because they are in charge of manipulation. They need to know how different choices will affect probabilities of health outcomes. Dr. Cox suggested that the recommendation be for greater clarity and to recommend reaching out to experts in accountability studies (such as Dan Greenbaum with HEI, who made public comments regarding accountability studies in progress). Dr. Frampton was supportive of the recommendation to strengthen the accountability aspect of the ISA and to get additional expert input on strengthening the accountability evidence.

After a break, Dr. Sasser, EPA OAQPS, requested to provide clarification to the overarching charge questions and indicated that some of those questions pertained to assessments and decisions that will come further down the review cycle. They are not questions that could be fully and adequately addressed at this stage of the review process and are not intended to be answered for each of the review documents along the way.

Summary of Consensus Responses to Charge Questions

Dr. Masuca indicated that Chapter 2 accurately conveys and appropriately characterizes information regarding sources, chemistry, and measurement and modeling of ambient concentrations of PM. He noted that the chapter did not discuss intercontinental and regional transport of PM. Chapter 2 does a sufficient job of describing the spatial and temporal trends of ambient PM concentrations at various scales. Dr. Boylan indicated that, for dust emissions, there needs to be a discussion of capture fraction, there needs to be a discussion of the new trends of the FEMs that are being deployed across the country, and the errors in figures need to be addressed.

Dr. Boylan indicated that Chapter 3 does a good job describing the methods for exposure measurement and modeling. Some additional clarifications and references should be added. In general, the chapter adequately discusses exposure assessment and the influence of exposure error on effect estimates in epidemiologic studies, however, one of the main conclusions was that exposure errors tend to produce

underestimates of health effects. However, this is only true with certain caveats (e.g. assumption of a linear non-threshold model) and these caveats need to be added to the document. Dr. Lange indicated that there needs to be more discussion of the relationship between ambient and personal exposures. Dr. Boylan indicated that additional expertise in modeling, risk assessment modeling, and photochemical modeling would be helpful as well as expertise in assessing how exposure errors would impact epidemiologic studies.

Dr. Lange indicated that, for the most part, Chapter 4 clearly conveys the dosimetry of inhaled PM and the process of deposition, clearance, retention, and translocation. In terms of clarity, it would benefit from editing and some streamlining. Additional information should be added about the concentrations at which the dosimetry exposures were conducted, the impacts of the concentrations on the effects that are observed, and whether the observed effects are expected at lower concentrations. The current discussion on translocation of insoluble versus soluble components is good, but additional information on the contribution of soluble particles to the total particles would be useful. There needs to be a more accurate discussion of the uncertainty of the data for translocation of particles to the brain in humans. Most of the data is from animals or human autopsy studies and it is not clear how to interpret those studies. Additional expertise in comparing animal physiology to human physiology would be helpful.

For Chapter 13, Dr. Lewis indicated that additional expertise on the impact of PM on visibility impairment, climate and materials would be helpful. It would be good to have a table showing all the instrumentation used for measuring visibility. A discussion of the direct effect of PM or other pollutants on visual acuity should be included. Societal differences could affect perceived visibility. Analyses for different size fractions to determine effects on visibility, climate, and materials are needed. Regarding materials, it was difficult to determine from the chapter what level of damage to materials was unacceptable and how that relates back to PM concentration, size and mixture.

For Chapter 12, Dr. Packham indicated that he would need considerable help as he did not have the expertise to answer the question. He asked Mr. Yeow to what extent he could consult with outside expertise in writing the response. Mr. Yeow indicated that Drs. Frampton and Lange were also lead discussants for the chapter and urged them to deliberate on the issues during the meeting. If after deliberation they felt they needed to ask specific scientific questions from outside experts, he asked them to work through him, as the DFO, to ensure that the requirements of FACA are met. He indicated that these would need to be specific questions on a general scientific topic, not asking other experts about their thoughts on the chapter and then adopting that advice as their own. But he urged the lead discussants to deliberate on the chapter.

Dr. Lange indicated that it would be helpful to differentiate susceptibility, vulnerability, intrinsic factors, and extrinsic factors. Are they at risk because of increased exposure or innate vulnerabilities? Better integration of the information presented in the chapter is needed, beyond listing study results. Conclusions between chapters should be integrated. Dr. Frampton indicated that he did not adequately review this chapter, agreed with all the points already made, but said that he would likely have additional comments later. They asked Mr. Yeow if that was permissible or if everything needed to be deliberated now. Mr. Yeow indicated that although it was highly desirable for all items to be deliberated now, FACA allows workgroups to develop draft products that will be deliberated by the full committee in public. The lead discussants (workgroup) could add items during the development of their draft consensus response (draft product) as those would be deliberated by the full committee in public at the future teleconference.

Dr. Cox stated that the Executive Summary did a good job summarizing key information from the ISA, but that information itself is unclear (as discussed earlier). Key information on whether reducing PM exposures would reduce adverse health effects need to be added. Other topics to address include systematic review, linearized nonthreshold models, measurement error, model uncertainty and its characterization, importance of measurement and estimation errors, distinction between estimated and true exposures, as well as whatever is discussed in the responses to Chapters 5-11 charge questions should make its way into the response to the Executive Summary response.

For Chapter 1, Dr. Cox indicated that the summary was effective, but had issues with the information being summarized. Information about accountability studies should be added to Chapter 1. Dan Greenbaum, HEI, in his public comments the previous day, asked that accountability studies in progress be considered. Dr. Cox indicated that would be desirable. Additional discussion of the independent effect of $PM_{2.5}$ needs to be provided. Information to add includes: study selection criteria, individual study quality evaluation criteria, synthesis and conflict resolution criteria, and systematic review results. Dr. Frampton indicated that regarding study quality, the Preamble to the ISA presented a lengthy description of the criteria EPA uses to select studies. However, there is nothing that discusses how the study quality determination information is used in the process and this should be explained up front. There needs to be an explicit description of how study quality is used.

After a lunch break, the CASAC continued with the summary of the consensus responses for Chapters 5-11. Dr. Frampton indicated that the Draft ISA needs to better treat the interactions between heart and lung consequences of PM exposure. This specifically has to do with pulmonary circulation, pulmonary hypertension, potential effects on right ventricular function, the effects right ventricular failure can have on left ventricular function, and pulmonary effects including presenting to the emergency department. The EPA needs to revisit the consistency of their statements on the characterization of the evidence and to revisit the accuracy of the interpretation of the studies. Regarding the strengthening of the causal determination for neurological effects from long-term exposure to UFP, this was based primarily on animal toxicology studies and not epidemiologic studies. There needs to be caution in overinterpreting causality without the additional lines of evidence to support it.

Dr. Lange indicated that the Draft ISA needs more integration of different types of evidence with the expected direction of effect and how pathways are expected to be activated/deactivated. There needs to be a discussion of biologic coherence. Chance, bias, and confounding need to be adequately considered in all of the epidemiology studies. Heterogeneity of results needs to be addressed. For the causality determination for long-term $PM_{2.5}$ exposure and neurological effects, it is not clear why this was strengthened to "likely to be causal." The epidemiologic studies largely show null, inconsistent results. This determination should be reconsidered. There needs to be additional expertise in neurobiology and neuropathology, as well as epidemiology. The causal determination for lung cancer and PM exposure should also be revisited. Statistical significance, heterogeneity, and discordance of evidence need to be considered when evaluating results from the evidence.

The CASAC members all agreed that they would like to review a Second Draft ISA. They also agreed that they would like access to additional expertise.

Summary and Action Items

Dr. Tony Cox discussed action items, schedule, deadlines and the drafting of the report. The draft report will be discussed on a future teleconference.

The meeting was adjourned by Mr. Yeow at 2:45 pm.

Respectfully Submitted:	Certified as Accurate:
/s/	/s/
Mr. Aaron Yeow Designated Federal Officer EPA SAB Staff Office	Dr. Louis Anthony Cox, Jr. Chair CASAC

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by Committee members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect consensus advice from the Committee members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters or reports prepared and transmitted to the EPA Administrator following the public meetings.

Materials Cited

The following meeting materials are available on the CASAC website: https://yosemite.epa.gov/sab/sabproduct.nsf//MeetingCalCASAC/33BB9FC41F61A40085258328005B3EF6?OpenDocument

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[1] Chartered CASAC Roster
[2] Federal Register Notice Announcing the Meeting
[3] Agenda
[4] EPA Presentation - Review of the Integrated Science Assessment for Particulate Matter (External Review Draft)
[5] List of Registered Public Speakers
[6] Written Comments from Gretchen Goldman, Union of Concerned Scientists
[7] Oral Statement from H. Christopher Frey, North Carolina State University
[8] Written Comments from 15 Former Members of the CASAC PM Review Panel that was Disbanded on October 11, 2018
[9] Oral Statement from Ted Steichen, American Petroleum Institute (API)
[10] Oral Statement from Julie Goodman, Gradient
[11] Written Comments from Julie Goodman, Gradient
[12] Oral Statement from Giffe Johnson, National Council for Air and Stream Improvement (NCASI)
[13] Written Comments from the National Council for Air and Stream Improvement (NCASI)
[14] Oral Statement from Douglas Dockery, Harvard T.H. Chan School of Public Health
[15] Oral Statement from Lianne Sheppard, University of Washington
[16] Oral Statement from George Allen
[17] Written Comments from the Northeast States for Coordinated Air Use Management (NESCAUM)
[18] Oral Statement from Jack Harkema, Michigan State University
[19] Oral Statement from John Balmes, University of California at San Francisco
[20] Written Comments from the Health Effects Institute (HEI)
[21] Oral Statement from John Bachmann, Vision Air Consulting, LLC, on behalf of the Environmental Protection Network
[22] Oral Statement from Anne E. Smith, NERA Economic Consulting, on behalf of the Utility Air Regulatory Group
[23] Oral Statement from Albert Rizzo, American Lung Association
[24] Oral Statement from Corwin Zigler, The University of Texas at Austin
[25] Oral Statement from Jia Coco Liu, Electric Power Research Institute
[26] Oral Statement from Stewart E. Holm, American Forest & Paper Association
[27] Oral Statement from Sonja Sax, Ramboll, on behalf of the American Wood Council, Aluminum Association, and American Iron and Steel Institute
[28] Written Comments from 206 scientists and engineers with expertise in air quality, environmental sciences, and public health
[29] Oral Statement from George Wolff, Air Improvement Resource, Inc., on behalf of the Alliance of Automobile Manufacturers
[30] Oral Statement from Daniel L. Costa
[31] Written Comments from the Coarse PM Coalition-12-05-18
[32] Written Comments from the Coarse PM Coalition-12-11-18
[33] Slides for Oral Statement from Kurt Blase, Blase Group LLC, on behalf of the Coarse PM Coalition
[34] Written Comments from Roger McClellan
[35] Charge for Particulate Matter Integrated Science Assessment (External Review Draft)
[36] CASAC Chair Memo to Chartered CASAC
[37] List of Registered Public Speakers - Clarifying Public Comments
[38] 12-12-18 Clarifying Public Comment from Julie Goodman, Gradient
[39] Charge Questions for Bullet Point Responses
[40] Charge Question for Response Bullet Points: Executive Summary and Chapter 1

ATTACHMENT A – Other Attendees

Name	Affiliation	12/12/18	12/13/18
Allen, George	NESCAUM	x	x
Allen, Jill	APPA	x	
Axelrad, Daniel*	EPA		
Bachmann, John*	EPN		
Bahadori, Tina	EPA	x	x
Balmes, John*	University of California at San Francisco		
Billings, Paul	American Lung Association	x	
Blake, Uni	API	x	
Blase, Kurt	Blase Group LLC	x	
Buckley, Barbara	EPA	x	x
Chan, Elizabeth	EPA	x	
Cohen, Benjamin*	NYISO		
Copley, Bruce*	ExxonMobil Biomedical Sciences, Inc.		
Cory-Slechta, Deborah*	University of Rochester		
Costa, Dan*			
Cromar, Kevin	NYU	x	
Cullen, Alison*	University of Washington		
Curtis, Holly*	NESCAUM		
Cybulski, Walt	EPA	x	
Damico, Louis	EPA	x	
Daniels, Rebecca*	EPA		
Dockery, Doug	Harvard T. H. Chan School of Public Health	x	
Downs, Tom*	Maine DEP		
Dutton, Steven	EPA	x	x
Fann, Neal*	EPA		
Fekete, Gabrielle*	EPA		
Fenner-Crisp, P.A.*			
Frey, Chris	NC State University	x	x
Fritz, Patricia*	NYS DOH		
Gale, Kat	AF & PA	x	
Gledhill, Jonathan	Policy Navigation Group	x	
Glenn, Barbara*	EPA		
Goldman, Gretchen	UCS	x	
Goodman, Julie	Gradient	x	
Graham, John*	Clean Air Task Force		
Greaver, Tara	EPA	x	x
Greenbaum, Daniel	HEI	x	
Hale, Zack	S&P Global	x	

Name	Affiliation	12/12/18	12/13/18
Harkema, Jack*	Michigan State University		
Hart, Mary-Thomas*	NCBA		
Hauser, Theresa*	TCEQ		
Hemming, Brooke*	EPA		
Hockstad, Leif*	EPA		
Hodson, Elke*	OIRA		
Holm, Stewart	AF & PA	x	
Honeycutt, Michael*	TCEQ		
Hong, Shara*	Health Canada		
Hotchkiss, Andrew*	EPA		
Hoyer, Marion	EPA	x	
Igoe, Sheila	OGC	x	
Irby, Sebastian	EPN	x	
Jarabek, Annie*	EPA		
Jenkins, Scott	EPA	x	x
Johnson, Giffe	NCASI	x	
Johnston, Khanna	EPA	x	
Jones, Samantha	EPA	x	x
Kalisz, Cath*	API		
Katz, Stacey	EPA	x	
Kelly, Jim*	EPA		
Kirrane, Ellen	EPA	x	x
Lamichhane, Archana*	EPA		
Lamson, Amy	EPA	x	x
Langworthy, Cindy	Hunton Andrews Kurth	x	x
Lassiter, Meredith	EPA	x	x
Lavoie, Emma	EPA	x	
Lefohn, Allen*	A.S.L. & Associates		
Levine, Jesse*	U.S. Tire Manufacturers Association		
Liu, Jia Coco	EPRI	x	
Luben, Tom*	EPA		
Lyrette, Ninon*			
Mabson, Michelle*	Earthjustice		
Maciorowski, Tony		x	
McClellan, Roger O.*			
McDow, Steve	EPA	x	x
Menendez, Fernando Garcia	NC State University	x	
Miles, Kenyatta	Shell	x	x
Mongoven, Karen	NACAA	x	x
Moutinho, Jennifer	ExxonMobil	x	
Nestlerode, Jamie*	MECA		

Name	Affiliation	12/12/18	12/13/18
Nichols, Jennifer	EPA	x	x
Oates, Tom		x	x
OKeefe, Ron	HEI	x	
Ollison, Will*	API		
Paciga, Andrea*	Phillips 66		
Palasits, Sara	US House of Representatives	x	
Papadogeorgou, Georgia*	Duke University		
Parker, Stuart*	IWP News		
Patel, Molini	Department of State	x	
Pavlich, Dave	Phillips 66	x	x
Peffers, Mel*	EPA		
Pekar, Zachary*	EPA		
Peltier, Rick*	Umass		
Perlmutt, Lars	EPA	x	x
Perlmutt, Lars	EPA		x
Pinto, Joe	UNC		x
Popovech, Marusia	ExxonMobil Biomedical Sciences, Inc.	x	x
Rauch, Molly	Moms Clean Air Force	x	
Reilly, Sean	E & E News	x	
Reyes, Jeanette*	EPA		
Rizzo, Albert*	American Lung Association		
Robarge, Gail	EPA	x	
Rohr, Annette*	EPRI		
Ross, Mary	EPA	x	x
Sacks, Jason	EPA	x	x
Saiyid, Amena	Bloomberg Environment	x	x
Salas, Paola	UCS	x	
Samet, Jonathan*	Colorado School of Public Health		
Sasser, Erika	EPA	x	x
Sauerhage, Maggie	EPA	x	
Sax, Sonja	Ramboll	x	
Schwab, Margo*	OMB		
Sheppard, Lianne	University of Washington	x	x
Shirley, Stephanie*	TCEQ		
Silverman, Steve	EDF	x	
Smith, Anne	NERA	x	
Song, Jamie*	MECA		
Soto, Vicki*	EPA		
Steichen, Ted	API	x	x
Thomas, Ed	TFI		x
Vandenberg, John	EPA	x	x

Name	Affiliation	12/12/18	12/13/18
Warner, Mandy	EDF	x	
Wayland, Bob	EPA	x	
Webster, Martha*	Maine DEP		
Wesson, Karen	EPA	x	x
Weyer, Erica*	EPA		
White, Kathleen*			
Wilson, Linda*	New York State Office of the Attorney General		
Wolff, George*	Air Improvement Resource, Inc.		
Wulf, Brian	ExxonMobil Biomedical Sciences, Inc.	x	x
Zarba, Chris		x	
Zigler, Corwin*	UT Austin		

*Participated via teleconference/webcast