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What’s Next for the U.S. Ambient Air Quality Standards?

*Perspectives of Scientists and the Regulated Community*

by Susan S.G. Wieman

Following on from the focus of the September issue, this month’s *EM* continues the discussion of updates to the U.S. Clean Air Act (CAA) National Ambient Air Quality Standards (NAAQS) program, and considers what’s next for NAAQS.

Columns

**EPA Research Highlights:** Studies by ACE

Centers Show Populations Impacted by Air Pollution

by Michaela Burns

Recent findings from EPA’s Air, Climate, and Energy (ACE) research centers.

**PM File: It’s About Time**

by David Elam

The first of several columns designed to help members of the environment, health, and safety community better understand the financial aspects of consulting firm operations and management.

Departments

**Message from the President:** Looking Forward to an Exciting 2019

by Chris Nelson

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In my office, early December is a very busy time. By late December, many people either take vacation time or take advantage of all the vacations to catch up on work without many distractions. This year, A&WMA is also very active in early December with online and in-person programming. Then there will be a short break and we will hit the ground running in January with our winter Intercouncil and Board meetings in Quebec City.

2018 was a solid year for A&WMA. The quality of our technical programs and publications remained high. Many of our members and colleagues found them useful for their professional development. From a budget standpoint, some of those same programs did not perform as well as we had hoped. Our Board continues to review these setbacks and adjust our future strategy to ensure our investments of staff and volunteer time are aligned with our members and the marketplace. Early in the year, I outlined several areas for Association evolution: mentoring, modern media, and an “academy approach” to content delivery. There was conceptual support for these ideas but we were not able to make demonstrable progress on them. I am proud of the work our volunteers and staff completed in 2018 and wish we had a few more months to move some key projects forward.

Luckily, we will continue to drive our priorities in 2019. Michele Gehringer will take over as A&WMA President in January. I am excited to support her as a Board member and see where she wants to take our Association in her year as President. 2019 already has some great programs on the calendar. Our Measurement and Modeling programs justifiably attract experts in those fields and members who are seeking to learn the latest technology and techniques. I am particularly excited about the Measurements program. With the increase in capability and decrease in cost of small-scale sensors, we will all need to better understand those technologies and their applicability in our communities. The 2019 Annual Conference & Exhibition in Quebec City will be an exciting event and a great opportunity to compare regulatory notes with our members and colleagues in Canada.

The new year will bring a transition on our Board of Directors as well. I will leave it to Michele to welcome our new Board members. I really want to recognize our current colleagues on the Board. Past-President Scott Freeburn, Directors Chris Frey and Leah Blinn, and Council Chairs Lee Lundberg, Greg Johnson, and Jen Cowman Moore will rotate off the Board at the end of 2018. Each has made strong contributions to our Association, both as members and through their roles on the Board. I will still get to see Jen around the office, but I will be sad to only see everyone else each year at the Annual Conference. Thanks to all for their service to A&WMA.

I appreciate all our members’ contributions to A&WMA throughout 2018. Let’s continue to work together to create programs that build strong relationships, enhance our knowledge of environmental issues, and lead to better environmental decisions.
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The U.S. Environmental Protection Agency (EPA) recently revised its process for reviewing U.S. National Ambient Air Quality Standards (NAAQS). This article offers background and context for the subsequent articles in this issue, which present related perspectives of some scientists and representatives of the regulated community, describe scientific research underlying the NAAQS, suggest how EPA might make the review process more efficient, and stress the importance of a science-based process. These articles complement the September 2018 issue of EM, which presented the perspectives of representatives of EPA and state air quality agencies.
The U.S. Clean Air Act (CAA) requires EPA to consider every five years whether new scientific information indicates a NAAQS should be modified. Each NAAQS has four key characteristics—the indicator pollutant, the level, the averaging time, and the form—and each characteristic influences the stringency of the standard. A fifth, very important part of adopting a NAAQS is specifying the monitoring method. Also key to enforcement of the standard is EPA’s “implementation guidance,” specifying how a state can demonstrate it meets (i.e., “attains”) the standard and how EPA will interpret related provisions of the CAA. Guidance addresses issues such as interstate transport, background air pollution, and exceptional air pollution events. EPA’s goal is to issue implementation guidance at the same time a standard is adopted.

An important source of scientific analysis contributing to EPA’s decisions about NAAQS has been the Health Effects Institute (HEI), which is sponsored by both government and industry. The first article in this issue, “Air Quality and Human Health: The Role of Health Science in Setting National Ambient Air Quality Standards,” was prepared by Daniel S. Greenbaum and Rashid Shaikh of HEI. As President of HEI, Greenbaum leads the institute’s efforts to provide public and private decision-makers with high-quality, impartial, relevant, and credible science about the health effects of air pollution. Dr. Shaikh, HEI’s Director of Science, oversees HEI’s multidisciplinary research program on air pollution and health. The article by Greenbaum and Shaikh describes the types of health effects studies that EPA considers when setting a NAAQS and how scientists consider whether a causal relationship exists between exposures and effects. EPA’s decisions on primary NAAQS can be controversial, and the authors note, “…the determination from the health science literature of what levels are ‘requisite’ to protect public health with ‘an adequate margin of safety’ [is] at the very center of the debate for the setting of each NAAQS.” Greenbaum and Shaikh emphasize aspects of the NAAQS review process that ensure high-quality decisions, and they highlight research demonstrating improvements in public health resulting from implementation of NAAQS.

The second article, “The New NAAQS Review Process Begins to Take Shape,” includes a concise review of recent actions by President Trump and EPA that set the stage for upcoming decisions on NAAQS. The authors, Aaron M. Flynn and Lucinda Minton Langworthy, are from the law firm Hunton Andrews Kurth in Washington, DC. Flynn has represented companies in major environmental litigation and regulatory matters, including those pertaining to the CAA. Langworthy has advised clients for over 30 years in complex administrative proceedings to set and implement U.S. air quality standards, and in related litigation in federal courts. Their article suggests ways to streamline the process of reviewing NAAQS and notes that comments from stakeholders on issues such as how to treat background ozone and international emissions and how to distinguish between scientific and policy issues may be important to forthcoming NAAQS proposals.

The CAA directs EPA to obtain advice from the EPA-appointed Clean Air Science Advisory Committee (CASAC) on the scientific basis for the NAAQS. The third article in this issue, “Back to Basics: A Rush to Judgment,” by H. Christopher Frey of North Carolina State University, describes the important role of CASAC and expresses concern about EPA’s recent revisions to the advisory process. As a former Chair of CASAC, Dr. Frey’s perspective is informed by his leadership and widely recognized expertise in reviewing the basis for NAAQS. CASAC has seven members, with at least one member of the National Academy of Sciences, one physician, and one person representing state air pollution control agencies. Until EPA recently announced it was discontinuing the practice, additional experts were appointed as members of CASAC panels and subcommittees to help CASAC address specific requests for advice.

As Dr. Frey describes, EPA previously revised the NAAQS review process in 2006 after discussions with CASAC and public review, and the revisions helped to separate technical information from policy choices. Thus, EPA prepares several documents during the NAAQS review process, requesting CASAC advice on a plan for how to conduct the review, an assessment of recent scientific information, an estimate of risks of adverse health and/or welfare impacts, and an assessment of policy choices. Figure 1 in Greenbaum and Shaikh’s article illustrates the relationship between these documents, CASAC’s review, and EPA’s decision.

EPA typically has not completed NAAQS reviews within five years, but in recent years, EPA has come closer to meeting the CAA-required schedule. Figure 1 in this article illustrates the estimated timing of the review processes.

Recent activity at EPA with respect to the NAAQS up to the time this article was prepared includes the following:

- EPA has followed two recent CASAC recommendations to not revise existing NAAQS. After consulting with
CASAC and a public review process, EPA published its decision to retain the current nitrogen dioxide (NO₂) primary NAAQS on April 6, 2018.

- In April 2018, CASAC advised EPA concerning EPA’s Risk and Exposure Assessment and Policy Assessment (REA and PA) for the sulfur dioxide (SO₂) primary NAAQS. EPA issued the final REA and PA in May 2018 and on June 8, 2018, proposed to retain the current NAAQS. EPA is under a court order to sign a final rule by January 28, 2019.

- In September 2017, CASAC advised EPA concerning EPA’s Integrated Science Assessment (ISA) for oxides of nitrogen, oxides of sulfur, and particulate matter—ecological criteria. EPA responded in December 2017 that it expects to issue a revised ISA in 2018.

- EPA initiated review of the NAAQS for particulate matter (PM) in December 2014. In April 2016, EPA requested advice on a draft Integrated Review Plan (IRP), CASAC provided advice in August 2016, and EPA finalized the IRP in December 2016. In October 2018, EPA published the public review draft of the ISA, disbanded the expert panel formed to provide advice to CASAC about the PM NAAQS, and replaced several CASAC members. A decision about a revised PM standard had been scheduled for 2022, but EPA has indicated it expects to decide whether to revise the PM NAAQS by December 2020.

- In July 2018, EPA requested nominations of experts for a panel to review an IRP for the NAAQS for ozone; however, in October 2018, EPA decided it would no longer use expert panels to assist CASAC. EPA has indicated it expects to decide whether to revise the ozone NAAQS by October 2020.

The EPA Administrator’s decision to set a NAAQS is informed by science, but is not a purely scientific decision. John Bachmann’s 2007 Annual A&WMA Critical Review provides a valuable history of the NAAQS; he explains that the administrator must weigh potential health and welfare effects and judge what is acceptable:

“Congress was aware in 1977 and 1990 that NAAQS do not provide an absolute level of safety, and continued to place the decision in the hands of a politically responsible decision-maker, not a panel of scientists. This does not mean that the decision is unfettered. The scientific review and policy assessments place limits on the range of supportable alternatives. The judicial review, although typically giving great deference to the administrator’s decisions, is a check against wholly unreasonable..."
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Congress's requirement for EPA to evaluate each NAAQS every five years may not be practical, but it is an effective incentive that allows public and judicial pressure to be brought to bear on EPA to consider new scientific developments. The NAAQS have become more stringent over the years under both Republican and Democratic Presidents as science has expanded our understanding of the relationship between exposure and effects. Congress's requirement for EPA to evaluate each NAAQS every five years may not be practical, but it is an effective incentive that allows public and judicial pressure to be brought to bear on EPA to consider new scientific developments. The various perspectives expressed in articles in this issue and the September 2018 issue indicate that stakeholders will continue to play important roles in providing oversight as the process continues to evolve.  

Susan S.G. Wierman is a member of EM’s Editorial Advisory Committee and an A&WMA Fellow. She served as Executive Director of the Mid-Atlantic Regional Air Management Association from 1996 through 2017 and is currently a part-time instructor in the Johns Hopkins University’s online Engineering for Professionals Program. She thanks Leiran Biton of the U.S. Environmental Protection Agency for his help in soliciting articles for this issue. Any opinions expressed in this article are her own personal opinions.

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7. U.S. Environmental Protection Agency decisions on the NO2 and SO2 NAAQS can be found online at https://www.epa.gov/no2-pollution/primary-national-ambient-air-quality-standards-naaqs-nitrogen-dioxide; and https://www.epa.gov/naaqs/sulfur-dioxide-so2-primary-air-quality-standards.
An overview of the use of health science in evaluating the CAA and air pollution standards, including the different types of science that contribute and the process for determining whether a particular pollutant causes a particular effect.
For nearly 50 years, the United States has been implementing the U.S. Clean Air Act (CAA) to identify key air pollutants of concern and take action to reduce exposure to those pollutants, with substantial success. At the core of this success has been the creation of an extensive body of scientific literature on the health effects of air pollution, the critical evaluation of that literature by the U.S. Environmental Protection Agency (EPA), the application of that literature to setting National Ambient Air Quality Standards (NAAQS), and identification and targeting control of pollutant emissions.

The creation and evaluation of this science has been a central strength of the CAA, and at the same time a source of continued controversy, especially as standards and requirements for pollution control have become more and more stringent. Given that, we seek here to review the basis in the CAA for the use of this health science, the different types of science that contribute, and the process for assessing whether the accumulated science enables the EPA and its science advisors to determine that a particular pollutant causes a particular effect. This scientific process has by most measures worked well over many years, but there have been continuing questions and new developments; we seek to assess these as well.

The Clean Air Act and the Setting of Air Quality Standards

Beginning with the 1970 Amendments of the CAA, Title I of the Act has set specific requirements for the review of exposure and health science on the major air pollutants found in the United States, commonly known as “criteria pollutants.” For each of these pollutants—currently ozone, particulate matter, sulfur oxides, nitrogen oxides, carbon monoxide, and lead—Section 108 of the CAA requires EPA to establish air quality criteria that “shall 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 such pollutant in the ambient air.”

Section 109 of the CAA then calls upon the EPA Administrator to set national primary and secondary ambient air quality standards “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.” (emphasis added) It is these primary NAAQS which have set the basis for the great majority of air pollution control actions, with the determination from the health science literature of what levels are “requisite” to protect public health with “an adequate margin of safety” at the very center of the debate for the setting of each NAAQS.

The exact steps of the process to develop this science and make NAAQS decisions have evolved over the years. As illustrated in the figure on the opening page of this article, it today involves three major technical steps: (1) an Integrated Science Assessment (ISA) of all of the latest air pollution exposures and health science; (2) a Risk/Exposure Assessment (REA) that applies that science to estimate public health implications at current and potentially new levels of the NAAQS; and (3) a Policy Assessment (PA) that recommends whether the current NAAQS protects public health with an adequate margin of safety, and recommends changes to the NAAQS if appropriate. To ensure that the science is assessed independent of its policy implications, the ISA is prepared by EPA’s Office of Research and Development (ORD) and the REA and PA are prepared separately by the EPA Office of Air and Radiation (OAR).

At each of these stages, the documents are subjected to detailed and public review by the seven-member Clean Air Scientific Advisory Committee (CASAC) created by Section 109 of the CAA. CASAC is required to “complete a review of the criteria published under section 108 of this title and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards.” The Act also requires that every five years, the EPA administrator will review and revise the NAAQS, as appropriate, in view of evolving science and other information.

How Does Health Science Contribute?

Several different types of air pollution health studies are considered in each ISA, typically involving critical review and evaluation of thousands of individual peer-reviewed scientific papers. Chief among these are:

- **Animal and Toxicology Studies** (i.e., studies exposing cells and laboratory animals to air pollutants and pollutant mixtures). These can contribute to the understanding of potential biological mechanisms of how air pollutants can cause effects, although the issues of relevance to actual human effects must always be examined.

- **Human Epidemiology Studies** (i.e., studies of human population to determine whether, even when attempting to control for other factors that might cause health effects, such as smoking, obesity, and other “confounders,” there is a robust association of air pollution exposure with specific health effects). These can take many forms, from small “panel” studies of carefully selected subjects to large population studies of selected population cohorts ranging to very large administrative data sets (e.g., Medicare recipients). These studies, if well designed, can help determine “concentration-response relationships” that can be important to determining the lowest levels at which effects are observed—and thus the potential level at which to set a NAAQS. At the same time, challenges in exposure assessment, control for all possible
confounders, and differing statistical techniques can introduce uncertainty in the results.

• **Controlled Human Exposure Studies** (i.e., studies of exposure of informed human volunteers to specific pollutants and levels in carefully controlled chambers). These studies also have limitations; they do not represent exposure to pollution mixtures which are most common, and ethical considerations preclude the ability to test those who may have the highest susceptibility. However, they do provide direct evidence of whether there are effects in humans from specific pollutants, and can do so at levels relevant to actual ambient levels.

**Assessing Causality**

The complex process of synthesis and integration of evidence, reaching scientific conclusions, and determining causality. That is, are the associations observed in various studies real or artefactual and, if real, to what extent are they influenced by coincidental factors (confounders)? Epidemiology—representing real-world conditions—is particularly susceptible to such problems, while other kinds of studies have their own limitations in terms of representativeness of the population, species or dose studied. The ISA integrates the various lines of evidence, taking into account the strengths and limitations of each line of evidence.

Bradford Hill in 1965 laid out a framework for ascertaining various aspects of causality in epidemiology and public health, and this framework has been adapted, with many modifications, by EPA and other organizations. The ISA uses a five-level hierarchy that classifies the weight of evidence in terms of causality. In such determinations, EPA systematically assesses and integrates evidence from the various kinds of health studies described above and with different endpoints, and with short- and long-term exposures at levels relevant to current conditions. In addition, EPA also evaluates the quantitative relationship between exposure to the pollutant and health response.

In recent years, formal, statistical tests for determining causality have been developed. Although these may be valuable, it is difficult to foresee how a single statistical test could readily supplant EPA’s comprehensive approach to evaluate the overall strength and weight of evidence. Refinements to the current ISA framework, including possibly more formal methods for causality determination, may serve to enhance the current process; such changes are topics of discussion and debate.

**Recent Developments**

The process of reviewing and drawing conclusions from the relevant health science has evolved substantially since 1970, with an explosion of new studies, development of new techniques for systematically identifying and evaluating the scientific evidence, and calls for more rigorous assessments of the weight of causal evidence from CASAC and others. This has included the development of the Health and Environmental Research Online (HERO) database by EPA, the most comprehensive, regularly updated database on environmental and health research available worldwide today. It also has included more cogent summaries of the evidence contained in the ISAs, and the development and implementation of the much more systematic assessment of causality described above, which was first applied in the review of evidence of nitrogen oxides in 2008.

Most recently, there have been two major efforts to revise the process.

The first, issued on April 30, 2018, was a Notice of Proposed Rule Making for “Transparency in Regulatory Science,” which proposed to restrict the use of science for which all data was not available in “a manner suitable to allow for independent validation” and proposed additional requirements for the evaluation of “dose–response” relationships. This proposal has been the subject of extensive comments from a diverse set of parties and is currently under review. While there are many reasons for enhancing access to underlying data, and many organizations have been advocating this in recent years (including our organization the Health Effects Institute, which
has had a data access policy for over two decades), many of the studies relevant to NAAQS considerations are older and relied on subject confidentiality agreements that cannot be readily altered, leading to the prospect that such a rule—should it be finalized—could preclude the use of otherwise high-quality studies in the NAAQS review process.

Second, on May 9, 2018, the then-EPA Administrator Pruitt issued his “back-to-basics” memo for the NAAQS process. This memo called for several key steps:

1. Completing review of the NAAQS for particulate matter and ozone by 2020, closer to or meeting the statutorily required five-year deadline (which has often not been met).
2. Asking CASAC to consider all of the CAA provisions for their review and advice, especially noting that they had not in the past been asked to “advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards,” as noted in Section 109 of the CAA.
3. Directing a streamlining of the NAAQS review process (i.e., by combining the development and review of the ISA, REA, and PA), while at the same time calling for differentiation between the science and policy judgments in the process.

This latter memo has also sparked controversy, extensive work to move ahead in the near term to streamline the process, and attempts to reconcile the somewhat contradictory requests to on one hand combine the science evaluation and policy-setting steps, while at the same time calling for stronger differentiation between science and policy considerations. The directive to more actively consider the CAA provisions seeking CASAC advice on, among other things, the “social, economic, or energy effects” has also sparked considerable controversy as the CAA has routinely been interpreted by the courts to not allow the explicit consideration of costs and other economic factors in the setting of the NAAQS.

Ensuring Public Health is at the Center of NAAQS Decisions

Through nearly 50 years, the process of developing and applying health science to inform air quality and public health decisions has worked well to distill the best evidence and contribute to substantial improvements in public health. Those improvements are now being documented in accountability, or intervention, studies of actual health benefits.

At the same time, the process has not been static: it now conducts much more systematic reviews of the literature and applies a rigorous framework for assessing causality based on a diverse literature. And the entire process is conducted in public view, with ample opportunity for public review and comment, and independent scientific peer review from CASAC. In the global work on control of air pollution, the U.S. approach is unique and much admired.

There are always opportunities to improve any such process, and the newest developments should be taken as an opportunity to make further improvements. But it is critical, in further enhancing the process, to not undermine the high-quality scientific process that it is in place, and its significant success.

References


Daniel S. Greenbaum is President, and Rashid Shaikh is Director of Science, both with the Health Effects Institute, Boston, MA. E-mail: dggreenbaum@healtheffects.org.
The New NAAQS Process Begins to Take Shape

Assessing the near- and long-term impacts of recent changes to the NAAQS review process.
The U.S. National Ambient Air Quality Standards (NAAQS) are the centerpiece of the U.S. Clean Air Act (CAA) and establish allowable concentration levels for six “criteria air pollutants”: ozone, particulate matter, lead, carbon monoxide, nitrogen dioxide, and sulfur dioxide. The CAA requires the U.S. Environmental Protection Agency (EPA) to review and, as appropriate, revise the NAAQS at least every five years, and EPA has, since 1970, regularly adopted increasingly stringent standards. Whether those revisions have gone far enough or too far has become a predictably contentious issue, with each review involving debates over science, the role of EPAs Clean Air Science Advisory Committee (CASAC), the discretion of the EPA Administrator, and the format of the review process itself, among many other issues.

**Presidential Memo**

Changes to the NAAQS review process have been an apparent priority for the Trump administration’s EPA. The first definitive statement on the administration’s plans came from the White House in an April 12, 2018, Presidential Memorandum for the Administrator of the Environmental Protection Agency. Much of the Presidential Memo is concerned with ensuring timely EPA action in processing state implementation plans, permit applications, and other agency activities, like approvals of exceptional event demonstrations. Other provisions venture further into policies that are likely to be controversial.

Perhaps most significant, the Presidential Memo, in a section titled “Future NAAQS Reviews,” addresses several issues that have been key points of contention in past reviews. First, it directs the Administrator to evaluate whether EPA is complying with the CAA provisions governing “the scope and characterization of advice provided by its Clean Air Act Scientific Advisory Committee [CASAC], including requirements that the Committee advise the Administrator regarding background concentrations and adverse public health or other effects that may result from implementation of revised air quality standards.” The role of CASAC, the type of advice it should and should not provide to EPA, and under what circumstances EPA can depart from CASAC advice are all issues that have been litigated and will likely be litigated again. Also significant, the Presidential Memo directs EPA to examine the current NAAQS review process, to develop criteria to ensure transparency in the review of relevant science, and to prepare guidance for distinguishing between science and policy considerations.

**Back-to-Basics Memo**

A number of the Presidential Memo’s general directives received further attention in Administrator E. Scott Pruitt’s May 9, 2018 memorandum titled “Back-to-Basics Process for Reviewing National Ambient Air Quality Standards.” The Basics Memo is described in detail in the September issue of EM in “EPA’s ‘Back-to-Basics’ Process for Review of the National Air Quality Standards” by Alexander Dominguez and Clint Woods. A few key points are relevant here.

First, in seeking to further the goal of meeting statutory deadlines, the Basics Memo calls for expediting the NAAQS review process, including the manner in which CASAC provides advice to the agency. In particular, it calls for combining CASAC’s review of the key NAAQS review documents—the Integrated Science Assessment (ISA), the Risk and Exposure Assessment, and the Policy Assessment—into a single round of comment.

Similarly, in its call for the streamlining and standardization of the review process, the Basics Memo suggests identifying the policy-relevant considerations for each review earlier in the process to more effectively contain the scope of each review. To that end, it calls for a more concise ISA that focuses on the key studies most likely to influence a NAAQS review, and for eliminating the production of more than one draft of each review document.

Another key principle discussed in the Basics Memo is expansion of the types of information considered by the agency. The Basics Memo calls for ensuring that CASAC provides advice on all of the categories of information described in section 109(d)(2) of the CAA, a role that CASAC has not consistently performed. That includes providing information on the role of natural and international emissions and “any adverse public health, welfare, social, economic, or
energy effects which may result from various strategies for attainment and maintenance of a NAAQS. The Basics Memo also calls on EPA and CASAC to distinguish between scientific and policy concerns more clearly, perhaps in an effort to more consistently identify and be cognizant of areas that fall exclusively within the judgment of the administrator.

Finally, the Basics Memo calls for more timely issuance of NAAQS implementation regulations and guidance, and where possible the publication of those materials concurrently with the issuance of the revised NAAQS. The lack of timely implementation rules has hindered efforts by state regulators to comply with the standards. Further, the public’s inability to fully perceive how a revised NAAQS will be implemented at the time a revision is under consideration has been a shortcoming of the process in the eyes of many stakeholders.

**First Test: Ozone NAAQS**

We are likely to see these policies in fully put into action first, and to get a sense of their real scope and ambition, in the recently-initiated review of the ozone NAAQS. EPA has committed to completing that review by the statutorily prescribed deadline of October 2020. In an August 1, 2018, status report filed in the D.C. Circuit litigation concerning the 2015 ozone NAAQS, EPA stated that it had begun a new ozone NAAQS review using the administration’s newly devised process and that EPA would specifically address whether background ozone concentrations should be considered when deciding whether to revise a NAAQS.

Completing the ozone review on this schedule will be a challenge, so how might EPA streamline the process to achieve its goal? A new or updated ISA, perhaps more concise than we have seen in recent reviews, would be required under section 108(d)(1) of the CAA, and EPA would have to submit that ISA to CASAC for review. But, as noted in the Basics Memo, multiple drafts are not required.

Although the Basics Memo does not suggest their elimination, EPA is under no legal obligation to prepare either a Risk and Exposure Assessment or a Policy Assessment as part of a NAAQS review. EPA could dispense with both documents to speed up the review process. Such a decision would be most defensible if EPA determined that the most recent science could not support any NAAQS revision. For example, in the review resulting in EPA’s recent decision to retain the existing primary nitrogen dioxide NAAQS, EPA did not prepare a separate Risk and Exposure Assessment.

Notice-and-comment rulemaking, an important step in completing a NAAQS review, requires publication of a proposed rule in the Federal Register and a “reasonable time” for public comment, which is almost certain to be at least 30 days. A proposed rule on revising the ozone NAAQS could be released at the same time EPA released its final ISA, which might also speed up the typical review process.

A final rule, according to the CAA, should be published within 90 days of publication of the proposed rule. EPA has
not been able to keep to that schedule, given its obligation
to review and respond to public comments on the proposal,
and any modification to the process could result in legal risks
for a resulting standard. Nevertheless, EPA could conceivably
reduce the time between the closing of the record on the
proposed rule and publication of a final rule to hit its 2020
target for completing the ozone NAAQS review.

Review Process under Scrutiny
As to the substance of the ozone NAAQS review and future
reviews for other criteria pollutants, the administration’s public
statements suggest that certain issues will particularly resonate
with the agency and be the focus of EPA action. Public
comment on these issues is likely to be unusually impactful.

For instance, EPA’s renewed commitment to examine back-
ground emissions and how to address them suggests that
comments addressing legal and policy justifications for taking
background into account, and how to do so, could be partic-
ularly helpful to the agency. Likewise, comments addressing
the proper definition of background and the role of interna-
tional emissions could also affect significant change in EPA
policy. Similarly, factors to consider in determining what
constitutes an adverse effect and how to distinguish between
scientific issues and policy issues could result in considerable
changes from past EPA practice and have a meaningful im-

EPA’s goals for reforming the NAAQS review process could
result in significant changes to the program. Completing
reviews in compliance with the statutory schedule will be a
target. May be enough legal flexibility in the statute
to make that possible, however, under the right circum-
stances. The bigger questions are how much substantive
change these procedural modifications will bring and how
long the reforms will last. Whether or not EPA seeks to make
significant changes to the NAAQS themselves, the new
review process will be under intense scrutiny.

References
1. Presidential Memorandum for the Administrator of the Environmental Protection Agency – Land & Agriculture, April 12, 2018;
2. “Back-to-Basics Process for Reviewing National Ambient Air Quality Standards.” Memorandum from E. Scott Pruitt, EPA Administrator, to EPA Assistant
5. CAA § 109(a)(1)(B).

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On May 9, 2018, then-EPA Administrator Scott Pruitt issued a memorandum, titled “Back-to-Basics Process for Reviewing National Ambient Air Quality Standards”. This article provides context for NAAQS review and an analysis of the memorandum.
Section 109 of the U.S. Clean Air Act (CAA) requires the U.S. Environmental Protection Agency (EPA) Administrator to “complete a thorough review” of the National Ambient Air Quality Standards (NAAQS) at five-year intervals. The CAA further requires the Administrator to “appoint an independent scientific review committee” that “shall complete a review” of existing NAAQS and that “shall recommend to the Administrator any new” NAAQS and “revisions of existing criteria and standards as may be appropriate.” CAA Section 108 states that the standards “shall 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 such pollutant in the ambient air.” The EPA Clean Air Scientific Advisory Committee (CASAC) is chartered under this mandate.

The Five-Year Requirement

EPA has generally failed to meet the CAA requirement for a five-year review cycle for the NAAQS. For the most recent reviews of the primary NAAQS that focus on public health, including carbon monoxide, lead, nitrogen dioxide, ozone, and particulate matter, the review cycle took between 4.0 years to 7.1 years from the initial call for information for the integrated scientific assessment (ISA) to the publication of the final rule, with an average of 5.9 years. The current review for sulfur oxides is past the proposed rule stage, but not yet finalized, at just over 5 years. However, EPA is generally completing the review process in a timelier manner than in the past.

Based on the time from the consultation on the integrated review plan (IRP) to its final advice on the policy assessment (PA), the duration of CASAC’s role in the most recent six NAAQS reviews focused on public health has been 2.2 years to 4.7 years, with an average of 3.2 years. The scientific aspects of these review cycles have been thorough and of high quality, and have resulted in CASAC advice based on the “latest scientific knowledge” required under the CAA. The separation between the ISA, risk and exposure assessment (REA), and PA facilitates separation of science and policy advice by CASAC. CASAC has also been careful to distinguish policy advice from scientific advice.13,14

The most recent review of the carbon monoxide NAAQS was started more than 13 years from the prior review completed in 1994, and it is now over 7 years since the last revision of the carbon monoxide standard in 2011. For the other five criteria pollutants, the amount of time that elapsed from the end of the prior review cycle to the start of the next ranged from 0.5 years to 2.9 years, with an average of 1.6 years. For the five most recent completed primary NAAQS reviews, it has taken EPA between 1.1 to 3.4 years to finalize a rule, with an average of 1.9 years, after CASAC completed its final advice on the most recent policy assessment.

The May 2018 memorandum quotes from CASAC letters from ca. 2006–2008 regarding putative problems with the current review process that are implied to justify speeding up the process.1 Those letters addressed concerns with the review process prior to its modification in 2006 or during the

Recent History and Components of the NAAQS Review Process

The process for NAAQS review was revised in 2006 based on consultations within EPA, including the Office of Air and Radiation (OAR) and the Office of Research and Development (ORD), with current and former members of CASAC, and with other stakeholders.2 The revised process included four major components: planning; integrated science assessment (ISA); risk and exposure assessment (REA); and policy assessment (PA). Separation between these review steps enables differentiation and transparency regarding scientific issues, which are the main focus of the ISA and a major focus of the REA, and policy issues, which is the main focus of the PA.

The ISA reviews, synthesize, and evaluates policy-relevant science to establish key scientific findings. Such findings include, for example, characterization of physical and chemical processes that lead to ambient air pollutant concentrations, evaluation of air quality monitoring and modeling methods, spatial and temporal variability in ambient concentrations, quantification of background concentrations, quantification of human exposure, dosimetry and mode of action, identification of adverse effects, causal determination between exposure and adverse effects, characterization of populations potentially at increased risk, environmental and ecosystem effects, and interactions with climate change.3,4

The REA is a quantitative analysis of exposure and risk based upon scientific evidence established in the ISA. The REA builds upon the findings of the ISA, such as regarding key adverse effects and populations at increased risk, to provide details regarding input data and modeling methods and results for assessment of exposure and risk.5,6 The PA was initially in the form of an advanced notice of proposed rulemaking (ANPR). An April 2007 memorandum modified the process to enable CASAC to review a second draft of the REA and for the REA to be finalized before an ANPR was issued.7 In May 2009, then-Administrator Lisa Jackson deleted the ANPR and replaced it with a policy assessment (PA).8 The ANPR is a regulatory document that involves input from politically-appointed leadership, whereas the PA is a staff evaluation of the policy implications of the scientific and technical information in the ISA and REA. The PA includes assessment by EPA staff of whether the current standard is adequate and, if not, options for the indicator (pollutant), level, averaging time, and form of possible alternative standards.9,10

Taking into consideration the PA, CASAC formulates its advice regarding whether an existing NAAQS should be retained or revised, and whether a new NAAQS is recommended. CASAC logically provides this advice before EPA formulates a proposed rule.

Planning has typically included an integrated review plan (IRP) for the review cycle, and a scope and methods plan (SMP) or similar planning document for the REA.11,12 The scientific basis of the review is logically established in the ISA before the REA can be completed. The methodology, input data, and results of the REA have been scientifically reviewed before the PA is finalized.
Brief Primer on CASAC

CASAC is comprised of seven members appointed by the EPA Administrator, referred to as the “chartered CASAC”. For each NAAQS review, CASAC has been augmented with additional experts and has been since the 1970s. The augmented panels include multiple experts in each of the many scientific disciplines that pertain to the ISA, REA, and PA. In addition to its mandate under the CAA, CASAC is subject to the Federal Advisory Committee Act (FACA). CASAC meetings must be announced in the Federal Register; the public must be allowed to attend, and CASAC must allow for public comments. Public comments provide an opportunity for stakeholder input to the review process.

For a full review cycle, there is an initial teleconference to convey individual member comments on the IRP; followed by four face-to-face meetings that typically take two days each and focus on: (1) first draft of the ISA and draft of the REA scope and methods plan; (2) second draft of the ISA and first draft of the REA; (3) second draft of the REA and first draft of the PA; and (4) second draft of the PA. Panelists receive a draft document (often hundreds of pages, sometimes over a thousand pages in length) and charge questions from EPA approximately 30 to 60 days prior to a meeting, and submit individual written comments before the meeting.

During the public meeting, the review panel is asked to develop consensus responses to charge questions provided by EPA, but may also provide other advice it deems to be appropriate. After the public meeting, panelists develop a written draft of the responses to charge questions, and may update their individual comments. Although consensus is sought, and often achieved, panelists are always able to convey their individual comments. The panel chair develops a draft letter to the Administrator that conveys the key aspects of CASAC’s advice. The draft letter and responses to charge questions are reviewed and deliberated at a teleconference open to the public. The chartered CASAC completes a public “quality review” of each draft report before it is transmitted to the Administrator.

The duration from receipt of a draft EPA report by panelists to the delivery of advice from CASAC to the Administrator is typically 3 to 5 months. EPA staff usually have a good idea of the main points of CASAC’s advice at the conclusion of the first public meeting on a particular document, which is typically within 2 months of panel members receiving a draft.

example, CASAC panels for each criteria pollutant deliberated regarding EPA staff proposals for an updated framework for determination of causality of adverse effects from exposure to air pollutants, leading to improved formulation and clarity of the framework and improved consistency and transparency of its application over time. Thus, the issues raised based on the cited letters from a decade ago are of limited current relevance.

Wait, and Then Hurry Up!
The May 2018 memorandum states that the NAAQS review will be completed by October 2020 for ozone and by December 2020 for particulate matter. Administrator Pruitt took office on February 17, 2017. EPA did not announce the start of the current ozone review until June 26, 2018. Although the current particulate matter review has nominally been underway for more than two years, EPA did not release the first draft of the ISA until October 2018. There are approximately two years from now to the deadlines indicated in the May 2018 memorandum. EPA has never completed a NAAQS review cycle in such a short time.

Can the Review Process be Shortened?
The ISA is critically important to establishing the scientific findings regarding the determination of causality of short- and long-term exposures with regard to adverse effects, and the data and methods relevant to later steps of the review. For each primary NAAQS, two drafts of the ISA were reviewed by CASAC. However, in the case of lead and ozone, a third draft of the ISA was required because CASAC found that the second draft did not adequately address CASAC’s prior comments. CASAC has recognized that the ISA, as well as the REA and PA, do not have to be perfect, but must be adequate for their intended purpose, taking into account the CAA mandate that NAAQS be based on “a thorough review” and the “latest scientific knowledge.”

The ISA may appropriately contain more information than is later used directly in rulemaking, including scientific questions for which the answer was a null finding. For example, in the previous particulate matter review, a scientific assessment was made that there was insufficient health effects evidence to justify developing a new standard for ultrafine particulate matter (UFP). EPA and CASAC considered UFP in deciding, at that time, not to recommend a standard for UFP. Identification of key uncertainties is also critical to CASAC’s mandate to advise the administrator of areas where new science is needed that may be relevant in the next review cycle.

In cases for which there has been limited new information since the last review, the REA either has been omitted, relying instead on the REA from the prior review cycle, had minor updates, or been combined into the PA. CASAC has been amenable to these adjustments to the review process, when appropriate. However, the duration of the review process does not appear to be highly correlated with whether a separate REA is produced. For example, from the initial call for information for the ISA to the publication of the proposed rule, the reviews for which there was not a separate REA took
58 to 66 months. The review for sulfur oxides, with only a single draft of the REA, took 61 months. In contrast, the reviews for carbon monoxide, ozone, and particulate matter, for which there were two drafts of the REA, took 41, 75, and 60 months, respectively.

**Combining Multiple Steps into One Step**

The May 2018 memo states that EPA “shall consider combining” the ISA, REA, and PA into a single review.”¹ One of the benefits of sequencing these documents is to avoid a problem with an initial draft of one document, such as the ISA, from propagating to later steps in the REA and PA.³ Combining these documents into one review could lead to an inadequately developed scientific basis, a premature risk and exposure assessment, and a poorly supported policy assessment. Furthermore, the sequence of these documents increases transparency regarding science and policy issues.

A single review step would imply that EPA staff working on the REA and PA are presuming the outcome of the ISA before the content of the ISA has stabilized based on CASAC review. Combining these steps would presume that the policy outcome is known before the scientific assessment has been finalized. A rushed combined process would be inherently less transparent.

One of the key reasons why EPA discontinued the use of an advanced notice of proposed rulemaking (ANPR) and replaced it with a policy assessment was because the former was “vulnerable to the introduction of policy options that are not supported by the relevant scientific information,” whereas the PA “presents a transparent staff analysis of policy options…to be considered by the relevant scientific information,” where CASAC panel could easily digest a combined ISA–REA–PA reviews into a much shorter timeframe. It is debatable whether a CASAC panel could easily digest a combined ISA–REA–PA and deliberate on its advice without additional review and meeting time, while maintaining the level of quality consistent with current practice and the mandate of the CAA.

**Sudden Death: Eliminating the PM and Ozone Review Panels**

On October 11, 2018, members of the CASAC PM (particulate matter) Review Panel received an email from EPA stating that “your service on the panel has concluded.” The PM Review Panel was appointed in 2015 and originally had 26 members. Also on October 11, 2018, candidates for the CASAC Ozone Review Panel were informed that “the Agency will not form a CASAC Ozone Panel.” The ozone review panel for the review cycle completed in 2015 had 20 members. There was no prior consultation with members of the PM Review Panel, nor any public indication that elimination of the panels was being considered, nor any public process for providing input related to this issue.

In an October 10, 2018, press release, EPA announced that the chartered seven-member CASAC would conduct the reviews of both the ozone and PM NAAQS simultaneously. Thus, instead of having approximately 20 or more experts chosen for relevant expertise review separate planning, ISA, REA, and PA documents over a period of typically three years, a committee of only seven members will conduct a review in a period that would have to be only about one year, taking into account time for EPA to develop and publish proposed and final rules.

Furthermore, rather than have two mostly non-overlapping groups of experts conduct the reviews, subject to approval by the chartered CASAC, the same group of seven will review these two NAAQS concurrently. For PM in particular, there has been a tremendous amount of new research since the last review, as indicated by the 1,800+ page length of the first draft ISA released just days after the PM Review Panel was disbanded.¹⁵ EPA has argued that the CAA does not require that CASAC be augmented with additional experts. However, it has been clear for the last four decades that a seven-member group does not have the breadth and depth of scientific expertise needed for these reviews, and CASAC’s charter allows for the formation of panels.

**Transforming CASAC from a Scientific to a Stakeholder Committee**

Over the decades, CASAC members have been appointed based on their scientific expertise. In contrast, on October 31, 2017, memo from Administrator Scott Pruitt requires that members of EPA federal advisory committees should “reflect prominent participation from state, tribal, and local governments,” and that priority should be given to “geographic diversity.”¹⁶ There is no mention of the importance of having experts of high stature that represent the wide range of scientific disciplines, and the depth of knowledge and experience, necessary to the work of committees such as CASAC or the EPA Scientific Advisory Board (SAB).

On October 10, 2018, EPA announced that Acting Administrator Wheeler appointed five new members to the seven-member chartered CASAC. The current CASAC is comprised of representatives from four state agencies, one federal agency, a consulting firm, and one academic researcher. For the most part, these members were selected for their geographic location or affiliation, rather than primarily based on depth of expertise.

The memorandum states that “no member of an EPA federal advisory committee currently receive EPA grants,” but that this “principle should not apply to state, tribal, or local government agency recipients of EPA grants.”¹⁷ This is illogical for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not...
another class of persons. The second is the longstanding recognition that receipt of a peer-reviewed scientific research grant, for which the agency does not manage the work nor control the output, is not a conflict of interest. Per the Office of Management and Budget (OMB): “When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no government research grant through an investigator-initiated, research is limited. As such, when a scientist is awarded a

awards through a competitive process that includes manage ment and Budget (OMB): “When an agency

acknowledges that there are benefits of continuity and knowledge provided by having some previous members up for deliberation. Fourth, the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have a conflict of interest.

The October 31, 2017, memo calls for greater turnover in membership of EPA advisory committees, but fails to acknowledge that there are benefits of continuity and knowledge provided by having some previous members continue to serve. Under this new policy, well-qualified scientists have been “rotated” off of the CASAC, in favor of new members selected for their affiliation or geographic location.

CASAC Advice on Implementation of NAAQS

The CAA states that CASAC shall advise the EPA Administrator regarding “any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance” of NAAQS. However, past administrations have typically not asked CASAC for this advice, nor have EPA staff prepared scientific assessment documents for CASAC review that would be relevant to developing such advice. The May 2018 memorandum indicates that EPA will include a charge question to CASAC seeking such advice.

In a June 26, 2014, letter to the EPA Administrator, CASAC outlined how such advice would need to be developed, taking into account that it is illegal to consider cost or technological feasibility when setting a NAAQS. CASAC stated that it did not want to commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS. CASAC noted that not all implementation effects are adverse; therefore, “any comprehensive assessment would include both adverse and beneficial effects.” For example, there are economic benefits from avoided morbidity and premature mortality.

CASAC further advised that “the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct such a review.” The expertise to address social, economic, and energy effects differs from that needed to address other aspects of CASAC’s mandate. Review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards. Furthermore, EPA should recognize that as a scientific advisory committee, it would be CASAC’s responsibility to take a scientific approach to providing advice regarding implementation effects based on valid methods and data, and that such advice cannot be based merely on anecdotes or stakeholder opinions.

CASAC historically relies on EPA staff to prepare draft documents and does not have the resources to commission its own studies. The May 2018 memorandum indirectly acknowledges that CASAC needs to be provided with relevant documents. To clearly separate its advice on implementation versus advice on the standards themselves, an appropriately formulated separate CASAC NAAQS implementation review panel should be provided with a separate draft implementation assessment document. It is likely that there will be a significant learning curve for the both the agency and CASAC in dealing with assessment of implementation issues, which should be recognized in setting schedules. The timing of CASAC advice regarding implementation logically would not be the same as that regarding whether to revise a standard, to avoid conflating implementation issues with the development of advice regarding the setting of NAAQS.

Lack of Transparency about Transparency

The story is not complete without mentioning the proposed rule regarding “transparency” in regulatory science. This proposed rule could have the effect of banning some scientific studies that have been influential in prior NAAQS reviews. As the SAB has pointed out, this proposed rule was not developed based on a transparent process. For example, there was no consultation with the SAB or CASAC, nor were EPA staff scientists or external scientists consulted or offered the opportunity for input. Policies regarding how science is conducted at EPA are usually developed as guidance documents, not as regulations. Although increased transparency is a broadly shared goal in the scientific community, there are legitimate scientific studies for which the underlying data are based on confidential human subject data.

A Way Forward

EPA is a science-based agency with a science-based mission to protect the public health, as mandated by the laws under which EPA must operate. The combined effect of multiple rushed and poorly founded ad hoc initiatives, including the October 31, 2017, and May 8, 2018, memoranda, a proposed rule to ban the use of particular types of scientific studies, the conversion of CASAC to a stakeholder committee, and the summary dismissal of an existing review panel, undermines the application and evaluation of science in the NAAQS review process.

A one-year time frame for NAAQS review by a reconstituted CASAC, for which a highly qualified augmented review panel was dismissed for one pollutant and not formed for another, will create problems that could call into question the quality and adequacy of the review. Although EPA is required to complete
NAAQS reviews in five years, EPA clearly has “gotten away” with longer review cycles. In some cases, EPA has been sued and courts have supervised the timing of the review process. Court approved or ordered completion schedules have taken into account the need for adequate scientific review time. For example, under consent decrees for the recent nitrogen dioxide and sulfur oxides reviews, EPA followed an appropriate process that preserved the integrity of the scientific review. In the current cases for PM and ozone, EPA has wasted a lot of time in getting the reviews underway.

EPA could shorten the length of the review process by reducing the time between the conclusion of the prior review and the start of the next review, and possibly by reducing the time to the final rulemaking after receiving final CASAC advice. EPA could also potentially reduce review time if it is able to commit staff resources to the ISA, REA, and PA to shorten the calendar time, but not the scope and quality, of the development effort for each draft report submitted to CASAC. To maintain the credibility of the process, CASAC should continue to review separate ISA, REA, and PA documents, and complete its advice on the PA prior to EPA formulating a proposed rule. EPA should abandon the arbitrary constraints imposed on CASAC membership. CASAC should continue to engage additional experts as has been the case for approximately three decades, should reinstate the PM Review Panel, and should form an ozone review panel.

EPA staff in the Office of Research and Development (ORD) and Office of Air and Radiation (OAR) should be lauded for their good faith efforts over the years to shorten the review time for NAAQS, as illustrated by the development and implementation of new processes since 2006. CASAC has generally tried to honor EPAs schedule needs by recognizing that assessment documents must be adequate for their intended purpose but do not need to be perfect. The May 2018 memorandum was not developed based on an open and transparent process. For example, there was no consultation with CASAC. If EPA wants to revise the NAAQS review process, it should do so via an open and transparent process similar to that undertaken in 2006. Such a process would lead to a more accurate understanding of the key needs and challenges of a NAAQS review and perhaps effective ideas for more timely reviews.

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15. Integrated Science Assessment for Particulate Matter (External Review Draft); EPA/600/R-18/179; U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018.
The Coordinating Research Council (CRC) and the Truck and Engine Manufacturers Association (EMA) co-sponsored the 2018 Southern California Ozone Research Symposium (SCORES), June 6 and 7, held at the University of California, Riverside. The symposium brought together leading experts from academia, government, and industry to review and discuss the capabilities and limitations of air quality models to simulate air quality trends as observed in the past years and to predict future concentrations. After several background presentations and research updates, participants brainstormed and prioritized a list of five high-priority research-needs, summarized below, to address the knowledge gaps identified in the discussions. The discussions also acknowledged that the identified research needs from SCORES are applicable to other locations and pollutant species.
Emission controls have been leading to reductions in **ozone** throughout the United States. Southern California, which suffers from the worst ozone pollution in the nation, shows steady progress in ambient ozone levels (see Figures 1 and 2), yet it still requires substantial further emissions reductions (see Figure 3) to attain ozone and fine particulate matter standards. Chemical transport models play a pivotal role in assisting air regulators to develop strategies to improve air quality. Regulatory use of such models relies on relative reduction factors (RRF), which assumes models are better capable of predicting relative responses to emission changes rather than the absolute concentrations. While the RRF approach is a practical tool to predict future concentration, it does not reflect evolution of weather conditions or changes in land use due to the expansion of urban areas or climate change. In addition, uncertainties in meteorology (e.g., temperature, mixing height, vertical profiles of wind speeds), emissions inventory (e.g., magnitude of emissions, unidentified sources, temporal and spatial trends), and chemical mechanism (e.g., proper speciation, granularity of chemical speciation) limit the ability of models to simulate ambient ozone levels accurately.

An accurate characterization of the observed trends by models is needed to further validate control strategies. High ozone episodes such as those observed in 2016 and 2017 in South Coast Air Basin underscore the year-to-year variability inherent in air quality measurements. These short-term fluctuations do not necessarily compromise longer term improvements in air quality, yet it is important to understand their causes and reflect improved science in the models. These concerns suggest further research is needed to better understand the mechanisms for ozone formation and how they are captured in the models. The resultant improvements in knowledge and models will also be beneficial to ozone and particulate matter strategies at locations beyond Southern California.

The 2018 SCORES symposium gathered together the leading experts in the relevant fields of atmospheric chemistry, ozone science, emissions inventory, and air quality modeling to discuss research needs regarding the core assumptions about the formation, mitigation, and modeling of ground-level ozone.

Eighty invited technical experts on air quality simulations attended the symposium. To help identify the most critical air quality modeling research needs that could lead to improvements in the accuracy of model outputs, the symposium began with invited presentations, followed by a series of brainstorming sessions. The presentation topics were: Ozone, Particulate Matter, and Precursor Trends in the South Coast; Modeling in the South Coast; Model Evaluation and Diagnostic Studies; Emissions and Background Ozone; Chemistry, and Physical Processes; Meteorological Inputs; and Perspectives from Other Stakeholders.

After the presentations, participants separated into three groups to brainstorm “big-picture” ideas regarding issues related to emissions inventory, chemistry, and air quality modeling. After the brainstorming session, each group convened to clarify and consolidate their ideas and voted on their group’s top five priorities. The next day, the three groups developed...
a list of research needs based on their big-picture ideas, and voted on the top five research needs. Last, the participants reconvened to discuss the groups’ priorities and voted to identify the overall top-five priority research projects. The overall top five priorities are presented below.

**Top Five Overall Research Needs**

**Observational Response of Ozone to Changes in NOx and VOCs (Chemistry Topic)**

Additional data and analyses may help further characterize the real-world relationships between oxides of nitrogen (NOx) and volatile organic compound (VOC) emissions leading to elevated ozone concentrations, and can take the form of analysis of historical data and/or additional experimental analyses. In terms of historical data analysis, appropriate research could involve developing observationally-based models linking changes in ozone and ozone sensitivities to emissions changes, both at individual locations and regionally (e.g., the regional ozone design value). Such an analysis can be compared to air quality modeling responses. An outcome of such an analysis would be to show how ozone has responded to past changes and to estimate how ozone will respond to future, planned emissions changes.

Examples of experimental approaches are projects such as in-situ, dual/triple-chamber smog chamber observations and/or experimentation at several ground sites, and aircraft measurements could be used to understand spatial (horizontal and vertical) patterns. The dual/triple chamber analyses would involve using ambient air in one chamber and adding either VOC or NOx to the other chamber(s) to follow the ozone response. Aircraft experiments and satellite observations may also provide information on the response of ozone to NOx and VOC emissions. Some aircraft data are available that could be analyzed further, such as data from the California Air Resources Board’s CalNex program. New aircraft observations of precursor concentration information is needed to provide information on the current ozone air quality regime and how that may relate to future responses to emissions changes.

**Short-, Medium-, and Long-Term Relationships and Evaluation of Ozone with Meteorology (Modeling Topic)**

More accurate characterization of the meteorological parameters would allow scientists to better capture their influence on air quality variability over daily to decadal time-scales. Errors in meteorological fields used to drive air pollution models can influence the model’s ability to accurately estimate air quality trends, thus affecting researchers’ ability to make accurate inferences on plausible factors dictating discrepancies between model and observed trends.

For instance, systematic low bias in early morning surface wind speeds could artificially overestimate model NOx, which may over-attribute errors in mobile emissions. Similarly biases in temperature, radiation, ventilation, and air–surface exchange can influence biases in predicted air pollutant concentrations. These relationships must be characterized more accurately over short, medium, and long-time scales, so that more robust inferences on model-predicted changes in air quality can be made.

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Mobile Source Emissions (Emissions Topic)
More research is needed to identify data gaps to accurately characterize variability in heavy-duty vehicle (HDV) emissions and how to temporally and spatially allocate these emissions. Data are needed to better understand how HDVs equipped with selective catalytic reduction deteriorate based on maintenance intervals. Satellite trend data could be used for gathering the emissions information.

Biogenic Vegetation (Emissions Topic)
Biogenic emissions contribute a significant fraction of the overall emissions inventory, and this contribution is expected to grow over time as regulatory efforts reduce anthropogenic emissions. In addition, ozone formation in most urban areas in Southern California is limited by VOC availability. However, information on urban biogenic emissions is limited, which may be critical for the ability of air quality models to characterize ozone formation in urban regions. Uncertainties in biogenic emissions stem from limited characterization of vegetation species, lack of information on the location and spatial extent of vegetated areas, or limited data on emission factors and how these are affected by stress conditions, such as exposure to high levels of air pollution, strong winds, and anomalous temperatures. Further research to improve the understanding of urban biogenic emission is necessary to accurately simulate photochemistry. Rapidly changing urban land use and adaptation of vegetation to temperature and climate changes need to be addressed appropriately as well.

Dynamical Model Evaluation in Southern California (Modeling Topic)
Chemical transport models are used to assess control effectiveness and demonstrate future attainment. Multi-decadal periods witnessing significant technological and emission changes could be analyzed to determine the trends in the ozone decline, plateau, and uptick. Trends in precursor species and other secondary pollutants should be analyzed, along with trends in background ozone and long-range transport contributions. Efforts should be devoted toward developing historical emission inventories that consistently represent the changes in emissions of various precursor species over the multi-decadal period based on changing activity data and speciation profiles reflective of control technologies and fuel formulation changes.

Conclusion
This list of prioritized research needs resulting from the 2018 SCORES symposium can serve as a guide for future funding and conducting near-term air quality research. By identifying this short list of priority research needs, the symposium participants hope to better focus limited resources toward improving the models used in air quality planning efforts. The proposed research projects would help enhance air quality modeling, and would help inform the policy decisions that utilize and rely on air quality modeling results.

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In Next Month’s Issue...

Air Toxics
Emissions of toxic air contaminants can result from a wide variety of industrial and commercial activities. Air toxics are those compounds that are known to cause cancer or result in other negative health effects. The January issue will evaluate the release and impact of toxic air contaminants.
Studies by ACE Centers Show Populations Impacted by Air Pollution

by Michaela Burns

In 2016, the U.S. Environmental Protection Agency (EPA) announced funding, through the Science to Achieve Results (STAR) grant program, for three Air, Climate and Energy (ACE) Centers. The research at these multi-project centers is designed to improve understanding of the health impacts from exposure to air pollutants from multiple sources; determine what regional differences in air pollution may exist; and explore the effects of a changing climate and human activity on local air quality and human health. The ACE Centers include research scientists at universities across the country and are already producing important studies. Three major findings from 2017 are highlighted here.
Racial Disparities Found in Air Pollution Exposure

CACES researchers from the University of Washington and the University of Minnesota examined pollution levels over time and found that race makes a difference when it comes to exposure to nitrogen dioxide (NO₂), a transportation-related air pollutant. This study estimated the exposure of outdoor NO₂ by race-ethnicity, socioeconomic status, and location across the United States in 2000 and 2010. Consistent with several previous studies, researchers found that the disparities in exposure were larger by race-ethnicity than other socioeconomic categories.

“We saw disparities by race at every level of income. You look at lower income, middle income, and higher income, and there is still a difference by race. This relative disparity in pollution exposure is largely unchanged over a decade,” says Julian Marshall, one of the authors of the study and a professor of Civil and Environmental Engineering at the University of Washington.

Marshall and his colleagues examined changes over time, and found that average exposure to NO₂ for all races and income levels decreased from 2000 to 2010. However, relative disparities persisted: non-whites were exposed to 40-percent higher concentrations of NO₂ than whites in 2000, and 37-percent higher concentrations in 2010. Further, though none of the populations were exposed to levels that exceeded the National Ambient Air Quality Standard (NAAQS) for NO₂ in 2010, non-whites were 2.5 times more likely to live in areas where the average NO₂ concentrations exceeded the World Health Organization’s guideline.

“One really important aspect of our study is that we observed disparities in exposure to air pollution throughout the country and how it varies by city and by state. Our findings point to a national pattern of race being a more important determinant of exposure to air pollution than other factors such as income, age or education,” says Marshall.

Additional work is needed to further investigate potential underlying causes.

Women, the Elderly, and Low-Income People Are Vulnerable

An article by ACE Center researchers from Harvard University reported health impacts of fine particulate matter (PM₂.₅) and ozone (O₃) at levels below the current NAAQS.

Researchers examined the association between long-term exposure to PM₂.₅ and time to death for the entire Medicare population in the continental United States from 2000 to 2012 and determined that short-term exposure to PM₂.₅ and warm-season ozone, even at levels lower than the
current NAAQS standards, were significantly associated with an increased risk of death. Unique to this study was the inclusion of individuals living in smaller cities, towns, and rural areas that were not included in previous research studies.

The study also assessed the association of mortality with PM$_{2.5}$ for low-income individuals, people of color, women, and the elderly (age 70 or older). Researchers found that these groups had higher risks of mortality associated with exposure to levels of PM$_{2.5}$ below the NAAQS compared to the rest of the Medicare population. Researchers saw the largest effect for individuals that were part of multiple vulnerable subgroups such as women who were non-white, elderly, and had a lower income.

“One advantage of studying a large population is that we were able to more fully explore the effects of short-term PM$_{2.5}$ on vulnerable groups,” says Francesca Dominici, one of the authors of the study, and a professor of biostatistics at Harvard T.H. Chan School of Public Health.

Coarse Particle Pollution Impacts Children’s Health
A study by SEARCH ACE Center researchers from Johns Hopkins University found that children exposed to airborne coarse particulate matter (PM$_{10-2.5}$) are more likely to develop asthma and need emergency room or hospital treatment than other children. This research finding is significant because while previous human health studies have established an association between exposure to PM$_{2.5}$ and the development of asthma and other respiratory diseases, coarse PM, which can come from grinding and roadway-derived particles such as brake wear, was thought to be less dangerous to health. While PM$_{2.5}$ can penetrate the lungs and go into the bloodstream, the larger particles of coarse PM can deposit in the upper airways and can lead to obstructive lung diseases such as asthma.

SEARCH researchers examined asthma prevalence and disease in a dataset of nearly 8 million children between 5 to 20 years of age enrolled in Medicaid in 34 states between 2009 and 2010. They found that coarse PM was associated with increased asthma diagnosis, hospitalizations, and emergency room visits in children. Children aged 11 and younger were found to be more susceptible to health effects from coarse PM. Researchers hypothesized that this is because younger children traditionally spend more time outdoors and are in a critical window of lung development.

“I think this study along with other studies suggest that we should be paying more attention to this fraction of particulate matter,” says Dr. Corinne Keet, Associate Professor of Pediatrics at the Johns Hopkins University School of Medicine and lead author of the study.

The research conducted by the ACE Centers could help answer important questions about which air pollutants pose the greatest threat to human health and the environment, how they can harm health and how we might reduce that risk.
It’s About Time

by David Elam

Many A&WMA members are employed by consulting firms; others are employed by industry or regulatory agencies and may hire consultants or transition into careers in consulting. Given the importance of consulting in the environment, health, and safety (EH&S) project management field, it is appropriate to address issues that are unique to project managers in the consulting field. The goal of my next several columns is to help members of the EH&S community better understand the financial aspects of consulting firm operations and management. Accordingly, these columns will provide information that helps professionals advance their careers if they are in consulting, better manage their projects if they hire consultants, and equip those who are considering consulting careers with insights that will improve their prospects for success should they make a transition to consulting.
Consultants sell solutions by allocating professional and technical time to the investigation, understanding, and resolution of a client’s specific problem or need. Although there are several different compensation models, consulting firms generate their revenue by charging for the time that is spent developing solutions. There are 52 40-hour work weeks in a calendar year, resulting in 2,080 available work hours if overtime, vacation, and holidays are not considered. In the course of a work week, consultants will divide their time between project and non-project work. Non-project work includes, but is not limited to, management of the firm and staff, administrative tasks, performance reviews, career planning, training, and business development. Effort spent on project work is typically referred to as “direct labor” and effort spent on non-project work is typically referred to as “indirect labor.” Direct labor generates revenue for the firm. Indirect labor does not generate revenue for the firm, but is expected to produce value for the firm in other ways.

As we’ll examine in more detail in the next column, the management of direct and indirect labor is critically important to a consulting firm and one of the primary metrics the firm will use to track performance. Thus, individual consulting firm employees will have direct labor goals that vary with their roles. Technical professionals actively involved in project work may have very high direct labor goals. On the other hand, individuals involved in the management of the firm or business development may have minimal or no direct labor goals.

Consulting firms can establish direct labor goals for employees in different ways. Some firms may simply assign a direct labor goal in hours (e.g., 36 hours per week or 1,872 hours per year). Other firms may assign a chargeability, billability, or utilization goal. These goals, in their simplest form and expressed in percentages, are calculated by dividing the direct labor hours by the total hours worked and multiplying the result by 100. In the case of employees working 36 direct hours in a 40-hour work week, their chargeability, billability, or utilization would be 90 percent. Consulting firms typically monitor direct labor weekly, which can often be a source of stress for employees and their managers, particularly if there is a lull in project work.

The value of direct labor is easy to understand. It represents a client’s financial investment in a solution to a problem or an effort to satisfy a need. With respect to the consulting firm, direct labor produces the revenue that sustains the firm. Direct labor is good. But a firm cannot survive on direct labor alone.

The value of indirect labor is a bit more difficult to understand, perhaps in part, due to its association with “utilization.” Over the years, many colleagues have indicated that they feel “utilization” is synonymous with “value” or “productivity.” When employees do not meet their utilization goals, some may feel they are viewed as valueless or nonproductive. However, this perception is far from the case. Managed correctly, indirect labor is an investment in the firm. Thus, indirect labor represents the firm’s highest level of investment. Accordingly, employees should charge indirect labor hours to the firm with the same spirit and dedication that they would when they post direct labor hours to project work. Success of both the firm and employee are achieved when indirect labor is invested in staff development, thought leadership, productivity improvement, and business development. Employees who understand the consulting revenue model and the value of indirect labor will work closely with their supervisors to ensure that their indirect labor is aligned with the growth objectives of the firm.

Employees who do not have direct labor goals or who have reduced direct labor goals are evaluated in other ways. Management is responsible for the financial performance of the firm, administrative staff is responsible for the proper and timely completion of administrative duties, and business development staff is responsible for selling work. Successful firms will use indirect labor to create, sustain, and advance an environment that enables employees with elevated direct labor goals to achieve them. Thus, a firm will build a team of employees with varying direct labor goals to work synergistically to create a viable and sustainable business.

Consulting firms incur costs beyond employee salaries. Costs that are allocable to projects such as car rental, airline tickets, meals, or field supplies, are direct costs. Costs that are not allocable to projects such as rent, utilities, benefits, or marketing, are indirect costs. Consulting firms track and manage direct and indirect costs closely for the same reasons that they track and manage direct and indirect labor.

Direct and indirect labor and expenses are both critical components of the business model for a successful EH&S consulting firm. In the next column, we’ll explore how direct and indirect labor and expenses work together to establish the firm’s billing rate for its employees.

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