UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 21 2009

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Process for Reviewing National Ambient Air Quality Standards

TO: Elizabeth Craig
Acting Assistant Administrator
for Air and Radiation

Lek Kadeli
Acting Assistant Administrator
for Research and Development

The national ambient air quality standards play a central role in enabling the U.S. Environmental Protection Agency to fulfill its mission to protect the nation's public health and the environment. Therefore, the NAAQS need to be built on a strong scientific foundation which is developed through a transparent and credible process, consistent with the core values highlighted in President's Obama's memorandum of March 9, 2009, on scientific integrity. Recognizing the importance of the NAAQS and the President's commitment to transparency and scientific integrity, I have reexamined the process that your offices use to review and update these standards to take into account the latest peer-reviewed science.

The NAAQS development process has evolved over time. The latest changes in the process were announced in a series of memoranda from the former Deputy Administrator (December 2006; April 2007; September 2008). In reviewing these changes, I have considered the Agency's experience in implementing these changes, as well as the insights of the statutorily mandated independent Clean Air Scientific Advisory Committee. While many changes have contributed significantly to the scientific integrity and transparency of the process, one change has not proven consistent with those goals and must be revisited.

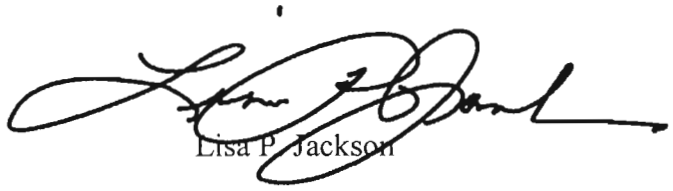
On the positive side, changes which contribute to ensuring the timeliness, scientific integrity and transparency of the review process should be preserved and enhanced. For example, I support the addition of a public workshop early in the planning phase and the development of one integrated review plan that highlights key policy-relevant issues that will frame the review for both of your offices. I also welcome restructuring of the science assessment and risk and exposure assessment documents to be more concise, more focused on policy-relevant information, and better coordinated across offices. Further, I encourage the ongoing

development and implementation by the Office of Research and Development of an electronic database of scientific studies.

As a further improvement, I am directing that the review process include consultation with experts in other federal agencies with responsibility for protection of health and the environment and expertise in the assessment of health and environmental data. I believe our NAAQS reviews will benefit from the expertise in these agencies and their input will help ensure the use of the best available science in our reviews.

One change announced in the former Deputy Administrator's memoranda that has raised strong concerns is the replacement of the policy assessment document, generally referred to as a Staff Paper, with an advance notice of proposed rulemaking issued after completion of the Agency's scientific and risk/exposure assessments. I believe this step has complicated and delayed the NAAQS development process and made it vulnerable to the introduction of policy options that are not supported by the relevant scientific information. We must address these concerns by reinstating the use of a policy assessment document which presents a transparent staff analysis of policy options for senior Agency management to consider prior to rulemaking. Although the ANPR would be discontinued, there will remain ample opportunities for public comment both during the scientific assessment stages of the process and the rulemaking itself.

Attached to this memorandum is a fuller description of the major elements of the NAAQS review process that incorporate these changes. I believe this process incorporates important improvements that have been recommended by Agency staff, the public, and CASAC. Recognizing that your offices are under court-ordered deadlines for the reviews of the nitrogen dioxide and sulfur dioxide primary standards, the nitrogen dioxide/sulfur dioxide secondary standards, and the carbon monoxide standards, I ask that your offices apply this new process to ongoing NAAQS reviews to the extent possible. The implementation of this process should help the Agency and CASAC meet the NAAQS review requirements in the Clean Air Act, in a manner that ensures scientific integrity through an open and transparent process.



Lisa P. Jackson

Attachment

ATTACHMENT

Major Elements of the Process for Reviewing National Ambient Air Quality Standards

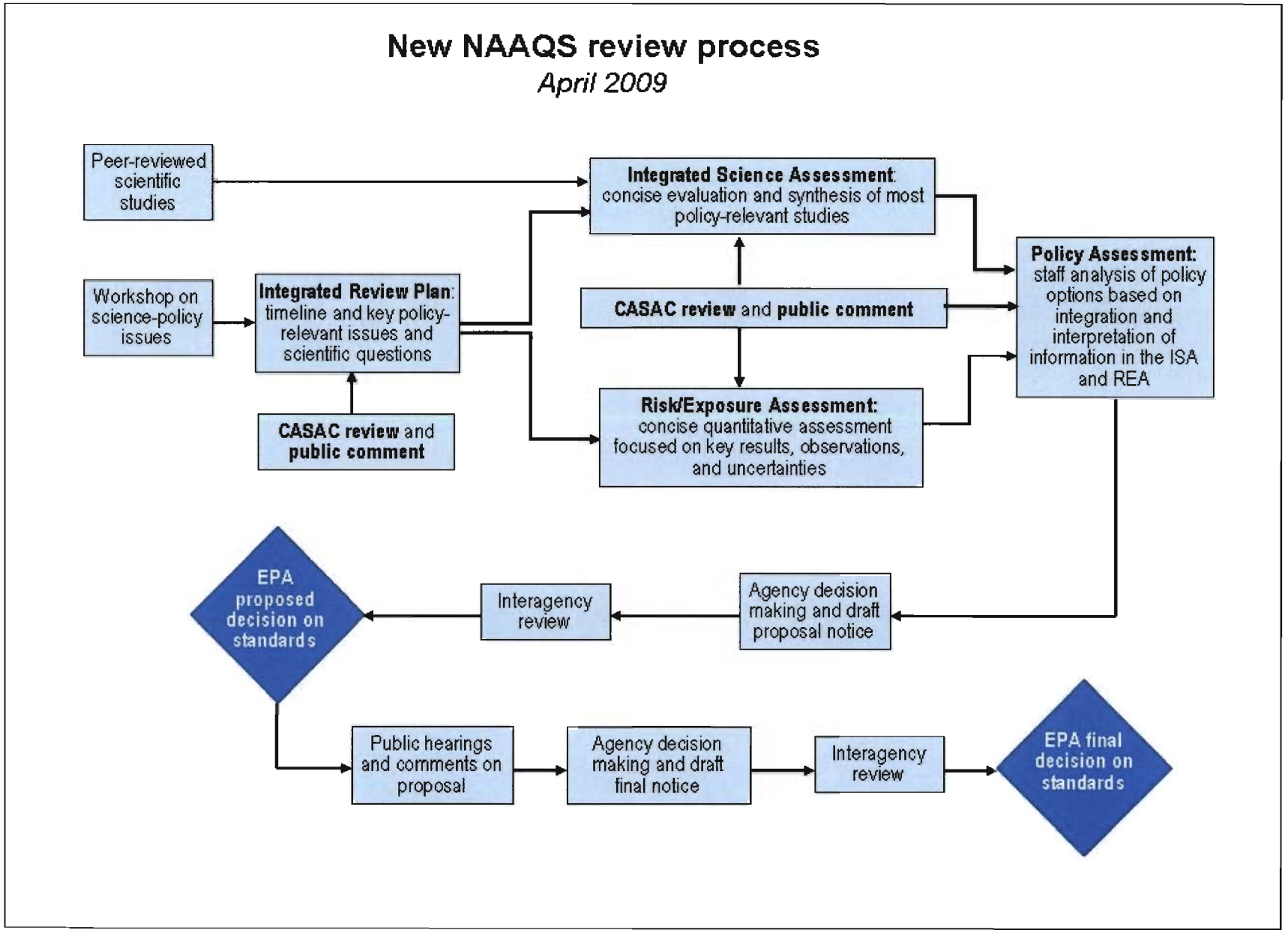
- *Planning:* The review process begins with the preparation of an integrated review plan that includes the science-policy questions that will frame the review, an outline of the process and schedule that the review will follow, and more complete descriptions of the purpose, contents, and approach for developing each of the key documents in the review. The Agency will hold a "kick-off" workshop early in the planning phase to get input from Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency-contracted outside scientists, and the public regarding policy-relevant questions from the prior review and any new policy-relevant science issues that have emerged since the last review. This workshop, together with early guidance from Agency management, should help inform the preparation of a draft IRP to be released for consultation with CASAC and public comment prior to issuance of a final IRP.

- *Integrated Science Assessment:* The science assessment document will provide a concise evaluation and integration of the policy-relevant science, including key science judgments that are an important aspect of the risk and exposure assessments. First and second drafts of the ISA will be released for CASAC review and public comment. In addition, special outreach will be made to experts in other Federal agencies whose missions include assessment of health and environmental scientific information to solicit their input and comment on the science assessment. More specifically, experts in the National Institutes of Health (e.g,, the National Institute for Environmental Health Sciences), the Centers for Disease Control and Prevention, the Agency for Toxic Substances and Disease Registry, the National Institute for Occupational Safety and Health, and the National Park Service, as well as in other Federal health and environmental agencies, are to be included in this outreach, as appropriate. Also, the ongoing development and implementation of an electronic database, Health and Environmental Research Online, that facilitates a more continuous process to identify, characterize, and prioritize new scientific studies should be an integral part of the EPA's Office of Research and Development's ongoing scientific assessment activities.

- *Risk/Exposure Assessment:* Risk and exposure assessments, focused on human health or welfare-related impacts, will provide a concise presentation of methods, key results, observations, and related uncertainties. A planning document that discusses the scope and methods planned for use in conducting the assessment will be prepared in concert with the first draft ISA; the first draft REA should be linked to the second draft ISA; and the second draft REA should be linked to the development of the final ISA. As with the ISA, in addition to CASAC review and public comment, special outreach will be made as appropriate to experts in other Federal agencies as noted above whose missions include assessment of health and environmental risk to solicit their input and comment on the risk/exposure assessment.

- *Policy Assessment:* The preparation of a policy assessment document that provides a transparent staff analysis of the scientific basis for alternative policy options for consideration by senior Agency management prior to rulemaking, will be reinstated, and the use of an ANPR is discontinued. This policy assessment document should integrate and interpret information from the ISA and the REA to frame policy options for consideration by the Administrator. As it did in the past, this document is intended to help "bridge the gap" between the Agency's scientific assessments, presented in the ISA and REA, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the standards. This document will be released in draft form for CASAC review and public comment. This document is intended to facilitate CASAC's advice to the Agency and recommendations to the Administrator on any new standards or revisions to existing standards as may be appropriate, as provided for in the Clean Air Act.

- *Rulemaking:* As required by the Clean Air Act, the Agency will issue a proposed rule for public comment. Taking public comments into consideration, a final rule will be issued to complete the rulemaking.


New NAAQS review process
April 2009
Peer-reviewed scientific studies
Integrated Science Assessment: concise evaluation and synthesis of most policy-relevant studies
Workshop on science-policy issues
Integrated Review Plan: timeline and key policy-relevant issues and scientific questions
CASAC review and public comment
Policy Assessment: staff analysis of policy options based on integration and interpretation of information in the ISA and REA
CASAC review and public comment
Risk/Exposure Assessment: concise quantitative assessment focused on key results, observations, and uncertainties
EPA proposed decision on standards
Interagency review
Agency decision making and draft proposal notice
Public hearings and comments on proposal
Agency decision making and draft final notice
Interagency review
EPA final decision on standards