



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees

Report No. 13-P-0387

September 11, 2013



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Abbreviations

CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CFR	Code of Federal Regulations
Council	Advisory Council on Clean Air Compliance Analysis
DAEO	Designated Agency Ethics Official
DEO	Deputy Ethics Official
DFO	Designated Federal Officer
EPA	U.S. Environmental Protection Agency
FAC	Federal Advisory Committee
FACA	Federal Advisory Committee Act
FY	Fiscal Year
GAO	U.S. Government Accountability Office
GSA	U.S. General Services Administration
ISA	Integrated Science Assessment
ISI	Influential Scientific Information
NAAQS	National Ambient Air Quality Standards
NCEA	National Center for Environmental Assessment
NO ₂	Nitrogen Dioxide
OAQPS	Office of Air Quality Planning and Standards
OFACMO	Office of Federal Advisory Committee Management and Outreach
OIG	Office of Inspector General
OMB	Office of Management and Budget
ORD	Office of Research and Development
PM	Particulate Matter
PPM	Parts Per Million
SAB	Science Advisory Board
SGE	Special Government Employee
SO ₂	Sulfur Dioxide

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At a Glance

Why We Did This Review

The U.S. Environmental Protection Agency Office of Inspector General conducted this review in response to a congressional request about the EPA's management of the Clean Air Scientific Advisory Committee and the Advisory Council on Clean Air Compliance Analysis. We sought to determine whether the EPA has managed the CASAC and Council in accordance with applicable laws, regulations and guidance pertaining to (1) potential conflicts of interest, (2) appearances of a lack of impartiality, (3) rotation of members (i.e., term limits), (4) balance of committee viewpoints and perspectives and (5) peer review. The EPA's Science Advisory Board Staff Office manages the CASAC and Council, which provide advice to the EPA on setting air quality standards and in developing cost-benefit analyses of the Clean Air Act.

This report addresses the following EPA Goals or Cross-Cutting Strategies:

- *Taking action on climate and improving air quality.*
- *Advancing science, research, and technological innovation.*

For further information, contact our Office of Congressional and Public Affairs at (202) 566-2391.

The full report is at:
www.epa.gov/oig/reports/2013/20130911-13-P-0387.pdf

EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees

What We Found

In general, the EPA managed the CASAC and Council in accordance with applicable statutes and regulations. These regulations allow agencies discretion in choosing federal advisory committee members and achieving balance.

We reviewed 47 CASAC and Council member appointments, including all ozone panel appointments for the last two ozone standard reviews. We found that the EPA has adequate procedures for identifying potential ethics concerns, including financial conflicts of interest, independence issues and appearances of a lack of impartiality. However, the EPA can better document its decisions on selecting members with independence and partiality concerns. This would allow for better transparency, thus giving assurance that CASAC and the Council provide independent and objective advice to the Administrator on such important decisions as setting ambient air standards. We also identified one instance where agency procedures involving a potential conflict of interest were not followed.

We also reviewed the peer review process for three EPA-developed analyses included in scientific assessments peer reviewed by the CASAC. Peer review is one method for enhancing the quality and credibility of the government's scientific information. One of these analyses was not peer reviewed in accordance with Office of Management and Budget and agency guidance. The EPA's National Center for Environmental Assessment did not have a formal process for determining whether such analyses were subject to OMB requirements and the EPA's peer review guidance before public dissemination.

Recommendations and Planned Corrective Actions

We recommend that the EPA instruct staff on the proper process for addressing potential conflicts of interest, develop procedures to document decisions and mitigating actions regarding independence and partiality concerns, and implement a process to determine whether its scientific work products are influential scientific information that require peer review in accordance with OMB and the EPA's guidance. The agency completed corrective action for one recommendation and that recommendation is closed. The agency agreed with three other recommendations and provided corrective action plans that we accepted. The agency disagreed with one recommendation but proposed an alternative action that we accepted. Thus, four recommendations are resolved but open pending completion of the corrective actions.

Noteworthy Achievements

Although not required, the EPA applies many Federal Advisory Committee Act guidelines and procedures to managing subcommittees and panels.



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

THE INSPECTOR GENERAL

September 11, 2013

MEMORANDUM

SUBJECT: EPA Can Better Document Resolution of Ethics and Partiality Concerns in
Managing Clean Air Federal Advisory Committees
Report No. 13-P-0387

FROM: Arthur A. Elkins Jr

A handwritten signature in black ink, appearing to read "Arthur A. Elkins Jr", is written over the printed name.

TO: Lek Kadeli, Principal Deputy Assistant Administrator
Office of Research and Development

Avi Garbow, General Counsel
Office of General Counsel

Christopher Zarba, Director
Science Advisory Board Staff Office

This is our final report on the management of Clean Air Act federal advisory committees conducted by the Office of Inspector General of the U.S. Environmental Protection Agency. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report presents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

Action Required

The agency agreed with recommendation 1 and provided evidence of corrective action taken. This recommendation is closed and no further action is required. The agency agreed with recommendations 2, 3 and 5 and provided planned corrective actions and completion dates that meet the intent of these recommendations. The agency disagreed with recommendation 4 but provided an alternative action that we accepted. Therefore, the agency is not required to provide a written response for these four recommendations, which remain open with corrective actions ongoing. For these recommendations, please update the EPA's Management Audit Tracking System as you complete the planned corrective actions. Please notify my staff if there is a significant change in the agreed-to corrective actions. We will post this report to our website at <http://www.epa.gov/oig>.

If you or your staff have any questions regarding this report, please contact Assistant Inspector General for Program Evaluation Carolyn Copper at (202) 566-0829 or copper.carolyn@epa.gov, or Director for Air Evaluations Rick Beusse at (919) 541-5747 or beusse.rick@epa.gov.

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Chapter 1

Introduction

Purpose

In response to a congressional request, our objective was to determine whether the U.S. Environmental Protection Agency has managed the Clean Air Scientific Advisory Committee and the Advisory Council on Clean Air Compliance Analysis in accordance with applicable laws, regulations and guidance pertaining to:

- Potential conflicts of interest.
- The appearances of a lack of impartiality.
- The rotation (i.e., term limits) of members.
- A balance of committee viewpoints and perspectives.
- Peer review.

Background

Advisory committees have provided advice to the federal government since its inception. Congress enacted the Federal Advisory Committee Act in 1972 to address the use of federal advisory committees that had developed over the years. Congress had two major concerns with FACs before 1972. First was a public perception that many commissions were duplicative, inefficient, and lacked adequate controls or oversight. Second was a widespread belief that FACs did not adequately represent the public interest and that meetings were often closed to the public.

FACA addressed these concerns by creating a process for establishing, operating, overseeing and terminating FACs. FACA requires that no FAC can meet or take any action until a charter has been filed with the head of the agency to whom the FAC reports and with the appropriate standing committees of the Senate and House of Representatives. FAC members appointed as Special Government Employees are subject to federal financial conflict of interest laws with some exceptions. FACA requires each agency sponsoring a FAC to appoint a committee management officer to oversee the administration of FACA's requirements. Further, a designated federal officer must be assigned to each FAC to ensure compliance with FACA.

FACA also required the administrator of the U.S. General Services Administration to prescribe administrative guidelines and management controls for FACs. Each federal agency head must establish administrative guidelines and management controls for FACs formed by its agency, consistent with the directives issued by GSA.

Federal Advisory Committee Rule

GSA's rule¹ on FAC management provides administrative and interpretative guidelines and management controls for federal agencies to implement FACA. The rule provides requirements for many aspects of managing a FAC. For example, the rule establishes requirements for FAC charters, recordkeeping and public notification. However, the rule allows for agency discretion in managing certain aspects of a FAC. For example, unless otherwise provided by statute or presidential directive, the length of FAC memberships is at the sole discretion of the appointing authority.

The rule restates the FACA requirement that FACs be fairly balanced with respect to the points of view represented and function to be performed. However, the rule does not prescribe specific procedures for achieving balance. Instead, the rule provides factors for an agency to consider in developing a fairly balanced FAC.

GSA's rule does not prescribe procedures for addressing appearances of a lack of impartiality or peer review. However, the EPA has established procedures governing these and for balancing FAC member viewpoints, potential conflicts of interest, and rotation of members.

The EPA's FACA Management Process

The EPA's Office of Federal Advisory Committee Management and Outreach is the national program manager for the EPA's committee management program. OFACMO provides policy, coordination, oversight, consultation, advice and technical assistance to FAC managers and the EPA's senior officials. OFACMO has issued a handbook² which provides the EPA's administrative guidelines and management controls for FACs.

The EPA's key personnel for establishing and managing an FAC include the Administrator, the Deputy Administrator, the relevant program office's assistant administrator, the committee management officer, and the designated federal officer. Table 1 shows FAC responsibilities of key agency officials.

¹ GSA Final Rule on Federal Advisory Committee Management, 41 CFR Parts 101-6 and 102-3.

² EPA Federal Advisory Committee Handbook, March 2012. The previous EPA Handbook was issued in October 2003.

Table 1: FAC Responsibilities of key EPA officials

EPA official	Summary of FAC responsibilities
Administrator	Responsible for the establishment, management and termination of the EPA's FACs. The Administrator has delegated most of these responsibilities to other agency personnel but remains fully accountable for ensuring compliance with the statutory and regulatory requirements of the FACs. The Administrator also appoints FAC members and FAC subcommittee members.
Deputy Administrator	Approves membership packages for FACs (authority delegated to the Deputy Administrator by the Administrator). Approves establishment and renewal charters for FACs.
Assistant Administrator	Responsible for the request and justification of the establishment of proposed FACs. The assistant administrator ensures that the FAC is balanced by points of view for the function to be performed, appoints a DFO for each FAC, and ensures that the FAC's advice and recommendations are the result of the FAC's independent judgment.
Committee Management Officer	Provides oversight for the establishment and operation of the EPA's FACs. The committee management officer also serves as a resource for DFOs and ensures proper recordkeeping for FACs (appointed by the director of OFACMO).
Designated Federal Officer	Responsible for the day-to-day operations and management of the FAC. The DFO works closely with the committee management officer to ensure full compliance with FACA requirements.

Source: Office of Inspector General-developed based on information in the EPA's Federal Advisory Committee Handbook (2012).

Clean Air Scientific Advisory Committee Created to Provide Advice on Ambient Air Quality Standards

The Clean Air Act required the EPA to establish an independent scientific review committee to provide advice to the Administrator in developing criteria and standards for national ambient air quality. Thus, the EPA established the CASAC. The CASAC has seven members who provide advice on criteria and standards for six air pollutants. These pollutants are carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter and sulfur dioxide.

The CAA requires the EPA, with the assistance of CASAC, to review the criteria for the National Ambient Air Quality Standards every 5 years. The EPA augments CASAC with panels of expert consultants to help review the six pollutants. The review panels we examined generally included 16 consultants plus the seven CASAC members.

Each panel reviews and comments on the supporting documentation for its specific pollutant. Prior to 2007, the two primary documents the panels reviewed were the criteria document and the staff white paper. The EPA's Office of Research and Development prepared the criteria document. This document was a comprehensive and integrative assessment of relevant scientific studies related to the pollutant. The EPA's Office of Air Quality Planning and Standards prepared the staff white paper. The staff used the information in ORD's criteria document and the results of the EPA's OAQPS risk and exposure assessments to develop

and support their conclusions and recommendations for an air quality standard. The OAQPS staff paper also included various ranges of standards for the Administrator to consider.

The EPA revised its process for developing NAAQS in December 2006. The EPA replaced the criteria document and the staff white paper with an integrated science assessment, a risk/exposure assessment, and a policy assessment. The EPA also decided it would publish the policy assessment in the Federal Register as an Advanced Notice of Proposed Rulemaking. The revised process also called for CASAC to be more involved in the initial planning for conducting the NAAQS review. In May 2009, the EPA ended the requirement to publish the policy assessment in an Advanced Notice of Proposed Rulemaking. Instead, the EPA releases a draft of the policy assessment to CASAC and for public comment. This policy assessment includes the air quality staff's conclusions and recommendations for a range of standards for senior agency management to consider.

Advisory Council on Clean Air Compliance Analysis Created to Provide Advice on Cost-Benefit Analyses

The Advisory Council on Clean Air Compliance Analysis was established in 1991, pursuant to the CAA Amendments of 1990. The Council's purpose is to review the data, methodology and findings of a statutorily mandated agency report³ that assesses the costs and benefits of the CAA. The Council must include at least nine members. The Council is to include experts in the fields of the health and environmental effects of air pollution, economic analysis, and environmental sciences. Members can also be appointed from other fields that the Administrator determines to be appropriate.

As of July 2012, the Council included 15 members. The Council is supplemented with subcommittees and consultants as needed. The Council has commented on three CAA cost-benefit studies.⁴ In 2002, the agency requested the Council's assistance in planning a third study assessing the benefits and costs of the CAA for the period 1990 through 2020. From 2004 through 2011, the Council issued several reports providing advice to the agency with respect to the third study. This included advice on planning the study and selecting data, methods and models, and commenting on draft findings and conclusions. To review the study, the EPA augmented the Council with the Special Council Panel, the Air Quality Modeling Subcommittee, the Health Effects Subcommittee and the Ecological Effects Subcommittee.

³ This report was mandated by Section 812 of the CAA Amendments of 1990 but the requirement for the report to Congress was repealed by the Federal Reports Elimination and Sunset Act of 1995 (P.L. 104-66).

⁴ The Benefits and Costs of the Clean Air Act, 1970 to 1990, October 1997; The Benefits and Costs of the Clean Air Act, 1990 to 2010, November 1999, EPA-410-R99-001; and The Benefits and Costs of the Clean Air Act from 1990 to 2020, March 2011.

Science Advisory Board Staff Office Manages the CASAC and Council

The EPA's Science Advisory Board Staff Office manages the CASAC and the Council. The SAB Staff Office develops the required FAC documentation, including charters and membership packages. The SAB Staff Office also collects and reviews financial disclosure forms submitted by prospective SGEs. The SAB Staff Office director recommends members for the committees to the Administrator for approval. The SAB Staff Office director also has the authority to select expert consultants to assist the chartered FACs. These consultant appointments are not submitted to the Administrator for approval.

All CASAC and Council committee, subcommittee and panel members are appointed to serve as SGEs, or in rare cases as regular government employees. As government employees, they are covered by federal ethics and conflicts of interest statutes and regulations. The SAB Staff Office director is also the agency deputy ethics official for the office. The DEO is responsible for reviewing and resolving ethics and conflicts of interest concerns with respect to members of the CASAC, the Council, and their respective subcommittees and panels.

Prior Audit Reports

The OIG has not conducted any prior audits or evaluations of CASAC or Council activity, or of the EPA's management of FACs. We reported on the EPA's external peer review process in April 2009.⁵ Our 2009 report focused on contractor-developed peer review panels. In response to the report, the EPA developed an addendum to the Peer Review Handbook that provided additional guidance for identifying appearances of a lack of impartiality in any of the peer reviewers.

The U.S. Government Accountability Office reported on FAC independence and balance in 2004.⁶ GAO's report was based on a review of policies and practices at nine federal departments and agencies, including the EPA. According to the GAO report, GSA's guidance on FAC management did not address what types of information could be helpful to agencies in assessing the points of view of potential FAC members. Additionally, agency procedures did not identify the type of information that should be collected about potential members to make decisions about FAC balance. Thus, eight of the nine departments and agencies that GAO reviewed did not identify and systematically collect and evaluate information pertinent to determining the points of view of potential FAC members. Such information would include previous public positions or statements on matters being reviewed. The EPA was the only agency to routinely collect and evaluate this information.

⁵ EPA Can Improve Its Process for Establishing Peer Review Panels, EPA OIG Report No. 09-P-0147, April 29, 2009.

⁶ GAO-04-328, FEDERAL ADVISORY COMMITTEES: Additional Guidance Could Help Agencies Better Ensure Independence and Balance, April 2004.

Noteworthy Achievements

FACA regulations do not apply to subcommittees or working groups that provide advice to the parent FAC. Still, the EPA applies many of its FACA guidelines and procedures when assembling these subcommittees and panels. That includes:

- Requiring subcommittee and panel members designated as SGEs to complete financial disclosure forms.
- Reviewing and vetting these forms for financial conflicts of interest and appearances of a lack of impartiality.
- Preparing membership grids showing each proposed member's qualifications and background.

The EPA's revised Federal Advisory Committee Management Handbook incorporates new procedures and factors to consider in selecting FAC members. The Handbook now requires the EPA's DFOs to prepare an outreach plan. This plan describes how the DFO plans to publicize the proposed FAC and solicit members from various groups to achieve FAC diversity.

Scope and Methodology

Our evaluation assessed the EPA's management of the CASAC and Council during the period 2006 through 2011, although we did review older records as necessary. In particular, we focused on management of CASAC's ozone and PM panels, and the Council's Health Effects Subcommittee. We evaluated the procedures the EPA used to ensure compliance with FACA and applicable federal and agency guidance. We did not evaluate the quality of scientific advice the CASAC or Council provided to the EPA.

We performed our work at the EPA's OFACMO, SAB Staff Office, and Office of General Counsel in Washington, D.C. We also conducted work at the ORD's National Center for Environmental Assessment in Research Triangle Park, North Carolina. We interviewed the EPA staff and managers tasked with overseeing the EPA's compliance with FACA, and obtained data and documents as appropriate. We also interviewed staff and managers responsible for managing the CASAC and Council.

To assess the EPA's management of the CASAC and Council we selected a sample of FAC, subcommittee and panel member appointments for review. Our selection criteria were all members of the last two NAAQS ozone panels, any expert who served on both the 2006 and 2011 PM review panels, and any expert specifically cited in the requester's letters to the OIG. This represented 47 of 126 members appointed during the period of fiscal years 1998 through 2012. We reviewed the SAB Staff Office case files for these 47 members for evidence of independence, impartiality, or financial conflicts of interest concerns. Based on potential concerns we identified during our initial file review, we reviewed 27 of

these cases in depth. We also interviewed six CASAC members to obtain their views on membership balance.

We conducted our evaluation from April 2012 through May 2013. We conducted this evaluation in accordance with generally accepted government auditing standards. Those standards require that we obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our objectives.

Chapter 2

Financial Conflicts of Interest

The EPA has implemented a process to manage the CASAC and Council in accordance with applicable laws, regulations and guidance regarding financial conflicts of interest. The EPA requires prospective and active SGEs to complete financial disclosure forms. The SAB Staff Office reviews these forms for financial conflicts of interest. We identified one instance where agency procedures involving a potential conflict of interest were not followed.

SGEs Are Generally Subject to Federal Statutes and Regulations Governing Financial Interests

Rules governing conflicts of interest for federal employees can be found in the Code of Federal Regulations. Specifically, 5 CFR Part 2635 Subpart D provides in part that:

An employee is prohibited by criminal statute, 18 U.S.C. 208(a), from participating personally and substantially in an official capacity in any particular matter in which, to his knowledge, he or any person whose interests are imputed to him under this statute has a financial interest, if the particular matter will have a direct and predictable effect on that interest.

SGEs are generally subject to financial conflict of interest provisions with some exceptions. In certain circumstances, SGEs who serve on FACs, within the meaning of the FACA, are uniquely eligible for a particular waiver of the prohibition of Section 208(a). Under 18 U.S.C. 208(b)(3), an SGE serving on a FAC may be eligible for a waiver where the official responsible for his or her appointment certifies in writing that the need for the SGE's services outweighs the potential for a conflict of interest posed by the otherwise disqualifying financial interest involved. EPA Order 1000.28A states that only the designated agency ethics official or the alternate agency ethics official may issue such waivers. According to the EPA's OGC, this should occur only upon consultation with the U.S. Office of Government Ethics.

SGEs serving on FACs are also covered by certain exemptions from Section 208 that have been promulgated by the U.S. Office of Government Ethics, pursuant to 18 U.S.C. 208(b). The most significant of these is 5 CFR 2640.203(g), which pertains to certain financial interests arising from the SGE's outside employment. This exemption permits SGEs serving on FACs to participate in matters of general applicability where the disqualifying interest arises from the SGE's non-federal employment or prospective employment. This exemption is subject to the following limitations:

- The matter cannot have a special or distinct effect on either the SGE or the SGE's non-federal employer, other than as part of a class.
- The exemption does not cover interests arising from the ownership of stock in the employer or prospective employer.

Further, according to the EPA's OGC the non-federal employment must involve an actual employee/employer relationship, as opposed to an independent contractor relationship.

The EPA's Process for Identifying Conflicts of Interest

The EPA requires prospective charter FAC, panel and subcommittee members to complete the EPA's Form 3110-48.⁷ Active members must also update their forms annually as well as before any particular matter is considered by a given member. The form includes sections for listing employment and consulting work, paid expert testimony, research or project funding for the past 2 years, and assets. The form also includes a section for describing prior activities or statements that could affect, or appear to affect, an expert's ability to provide impartial advice.

The SAB Staff Office's ethics officer (assistant to the SAB Staff Office DEO) and the SAB Staff Office DEO review each active or prospective member's financial disclosure form for potential ethical issues, including financial and other conflicts, and possible lack of impartiality. Both reviewers sign and date the first page of the form to document their review. The forms may include the reviewer's handwritten notes if issues are noted.

If the review identifies potential issues, the SAB Staff Office informs the prospective or active member and asks for an explanation. The SAB Staff Office may also discuss any concerns with the member and require that the member take action to mitigate the concern. The SAB Staff Office director's personal practice was to not grant financial conflict of interest waivers. We did not identify any waivers for financial conflicts of interest for the 47 CASAC and Council charter, subcommittee and panel members we reviewed from FYs 2002 through 2012.

Receipt of Federal Grant Is Not a Financial Conflict of Interest

The EPA does not consider a prospective or current member's receipt of an agency or other federal research grant to create the basis for a financial conflict of interest. This is consistent with other federal guidance in this area. For example, OMB's Final Bulletin on Peer Review states that:

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

⁷ *Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency (EPA Form 3110-48).*

a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects.

The above guidance does not mean that a prospective or active member's work on a specific grant or research project could not potentially present an independence concern. A prospective or active member's research or grant is a potential area of concern if the FAC, panel, or subcommittee plans to address work performed under the research grant. Prospective and active EPA SGE members must report any research grants received during the past 2 years in Section 4 of the EPA's Form 3110-48. Our review of impartiality and independence is discussed in chapter 3.

Review of Financial Conflict of Interest Procedures

We reviewed 47 financial disclosure forms completed by prospective CASAC and Council committee, panel and subcommittee members from 2002 through 2012. We identified one instance where agency procedures regarding a potential conflict of interest were not followed.

Conclusions

The EPA has adequate procedures for identifying financial conflicts of interest. Nonetheless, we identified one instance where the agency's procedures for handling a potential conflict of interest were not followed. As such, we believe the agency should remind DEOs of the proper procedures for addressing potential conflicts of interest to prevent any future occurrences.

While receipt of grant funds from the EPA may not constitute a financial conflict of interest on the part of a FACA member, receipt of such funding could raise concerns of independence depending upon the nature of the research conducted under the grant and the issues addressed by the FAC.

Recommendation

We recommend that the EPA designated agency ethics official:

1. Instruct DEOs and assistant DEOs on the proper process for handling potential conflicts of interests for SGEs, including the process for implementing any applicable steps to remedy the conflicts of interest.

Agency Comments and OIG Evaluation

The agency agreed with our recommendation and responded that the DAEO will review already available reference material and guidance to determine whether

any additional guidance is warranted for SGEs. Further, the agency provided us with documentation that the DAEO has instructed DEOs on the proper process to follow in addressing conflicts of interest. Thus, this recommendation is closed and no further response is required from the agency.

Chapter 3

Independence and Impartiality

In general, the EPA has implemented an adequate process to identify independence and impartiality concerns. However, the EPA can improve its controls over this process by better documenting how it addressed concerns identified during the financial disclosure review process. We reviewed financial disclosure forms and associated SAB Staff Office files for 47 members from FYs 2002 through 2012. In nine instances, final determination on and steps taken to mitigate independence or partiality matters were either not adequately documented or, in our view, needed additional steps to sufficiently address potential independence or partiality concerns. Better documentation of ethics decisions will help ensure that the FAC process is transparent and that advice to the Administrator on important issues such as setting ambient air standards to protect public health and the environment is impartial and objective.

The EPA's Guidance Recommends Avoiding Experts Who Appear to Lack Impartiality

FACA requires that FACs provide independent advice free of inappropriate influence from the appointing authority or special interests. FACA does not establish requirements for reviewing the independence or impartiality of FAC members. However, SGEs are subject to federal ethics regulations and should avoid appearances of a lack of impartiality in performing their work. Title 5 CFR Part 2635.502(a) in large part addresses impartiality with respect to particular matters involving specific parties. Since the CASAC and Council address matters of general applicability this provision would not normally apply to CASAC and Council members. However, 5 CFR Part 2635.502(a)(2) addresses impartiality concerns that may arise under other circumstances. It states that:

An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter.

Based on 5 CFR 2635.502 (c) and (d), EPA Order 1000.28A authorizes DEOs to make determinations as to whether a reasonable person would be likely to question the employee's impartiality in a particular matter under 5 CFR Part 2635, Subpart E. In instances where impartiality is likely to be questioned, but would not violate 18 USC 208(a), the Order further authorizes DEOs to determine whether the employee should be allowed to participate in the matter, and if so, authorize participation in writing.

The EPA’s *Peer Review Handbook* provides guidance for how the EPA should address impartiality and independence concerns on peer review panels. The Handbook states that the EPA should make every effort to use reviewers who are independent and do not have an appearance of a lack of impartiality. The Handbook states, as a general rule, experts who have made public pronouncements on an issue or who have clearly “taken sides” may lack impartiality and should be avoided. The Handbook recognizes that these reviewers with appearances of a lack of impartiality may still serve on a panel to fill the need for experience or technical balance and representation. For example, if an SGE has an appearance of a lack of impartiality, it may still be possible to make a written determination that the SGE may serve on the FAC or to ensure that the SGE is recused from certain areas of a review. With respect to impartiality, the Handbook states:

. . . it is also important that any decision that is made concerning advisory committee members or peer reviewers be appropriately documented. . . .

The *Peer Review Handbook* defines an independent reviewer as an expert who was not associated with developing the work product, either directly by substantial contribution to its development or indirectly by significant consultation during its development.

The EPA’s Financial Disclosure Forms Include Questions to Identify Independence Concerns and Appearances of a Lack of Impartiality

As discussed in chapter 2, the EPA requires FAC committee, subcommittee and panel candidates who are designated as SGEs to complete EPA Form 3110-48. Once selected, members must also periodically update their form. The form includes a supplemental set of questions specifically designed to help the EPA identify any potential appearance of a lack of impartiality (table 2).

Table 2: Supplemental questions to identify concerns with independence and impartiality

No.	Questions asked
1	Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the panel/committee/subcommittee or any reason that your impartiality in the matter might be questioned?
2	Have you had any previous involvement with the review document(s) under consideration including authorship, collaboration with the authors, or previous peer review functions? If so, please identify and describe that involvement.
3	Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
4	Have you made any public statements (written or oral) on the issue that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

Source: OIG-developed table based on section 6 of EPA Form 3110-48.

The EPA Can Better Document Identification and Resolution of Independence and Impartiality Concerns

We reviewed the SAB Staff Office's files for 47 of the 126 SGE appointments to CASAC and the Council, including subcommittees and review panels, over the period of FYs 1998 through 2012. We reviewed 27 appointments in greater detail based on information in the case files that in our opinion indicated the SGE's appointment might raise ethical concerns with respect to the FAC's or panel's work. We also reviewed the meeting minutes for 14 Council meetings held between 2003 and 2010. We found:

- Four instances where recusals for independence concerns were not documented or came after the expert had participated in activities related to the concern.
- Three instances where, in our view, potential independence concerns were not identified or their resolution was not adequately documented.
- Two instances where, in our view, potential appearances of a lack of impartiality were not identified or adequately resolved.

The following sections discuss in more detail the results of our review.

Some Recusals Were Not Documented or Came After SGE Participation in Activities That Created an Independence Concern

The SAB Staff Office determined that four members of the chartered Council should recuse themselves from certain meetings where the charge questions were related to work these members had produced. SAB Staff Office procedures state that the DFO should start each meeting by stating for the record that all participating panel members are in compliance with ethics and conflict of interest rules. If not, the DFO should note any instances where a member will recuse him/herself from discussion on a particular aspect of the meeting. The EPA's FAC Handbook also recommends that meeting minutes document all recusals.

- In two instances, the EPA appointed experts as members to the chartered Council who had co-authored studies that the EPA used to support conclusions in the EPA's CAA Section 812 cost benefit analysis. These studies pertained to the monetized benefit of reducing ozone and PM mortality. The DFO told us they orally instructed members to recuse themselves from any meeting where charge questions related to the application of their work in the Section 812 study were discussed. However, the meeting minutes did not state whether these two members recused themselves from meetings where the charge questions related to their work.

- In one instance, a potential independence concern about a Council member was raised and discussed at a Council meeting. The concern was that the member was one of five experts selected to serve on a pilot expert elicitation study panel on PM mortality. The Council was asked to review the design of the pilot study. Because of the information discussed at this meeting, the DFO sent a written notice to the member instructing him to recuse himself from meetings where his prior work on the pilot elicitation study was to be discussed. Meeting minutes we reviewed indicate that this member recused himself from applicable meetings after receiving SAB's notice for a period of several years. The member later served as one of 12 participants in the full-scale expert elicitation study. According to the SAB Staff Office, when the Council met in 2008 to advise the agency on the potential use and presentation of expert elicitation study results, the member did not participate in the meeting. However, 6 years after the initial independence issue arose, this member attended a meeting as a member of the Council's Health Effects Subcommittee where the interpretation and presentation of the results of the elicitation study were discussed. Meeting minutes did not indicate whether this member recused himself from discussing the EPA's application of the results of the study he had worked on.
- In one instance, a Council member had contributed significantly to a product peer reviewed by the Council. Both the member and the SAB Staff Office identified this member's participation as an independence concern. The SAB Staff Office director noted that the member would be required to recuse himself from any discussion of that portion of the document. The meeting minutes for two Council subcommittee meetings did not indicate whether this member recused himself from any portion of the deliberations. A draft peer review report was prepared after these two meetings. Prior to a third meeting where this topic was discussed, the DFO sent the member a written recusal reminder notice. Meeting minutes we reviewed indicated the member recused himself from meetings after receiving the written recusal notice.

Some Potential Independence Concerns Were Not Identified

We identified three instances where the SAB Staff Office appointed experts to panels that reviewed work products that the experts had helped develop or incorporated extensive information from work products the experts had developed. In all three instances, the experts reported their involvement in these precursor work products on EPA Form 3110-48.

- In two instances, experts appointed to a CASAC review panel had participated substantially in preparing chapters included in ORD's ozone and PM criteria documents for the prior review period. These members were allowed to serve as reviewers for the next 5-year review's criteria

document. The SAB Staff Office director told us that these members were allowed to serve because they had not worked on producing the document under review by the CASAC. However, our review of the integrated science assessments (formerly known as criteria documents) found that these work products included conclusions and information from the chapters that had been written by the experts for the prior criteria documents. Further, the charge questions for the ISA reviews included commenting on the usefulness and completeness of the scientific information in chapters that included information from these experts' prior work. Thus, even though these experts did not develop the ISA documents, in our view, their service on the panels created a risk that they could potentially review their own work. Further, the agency should document in writing its determination that the expert's service will not create an independence concern and any steps needed to reduce the risk that this could occur.

- In one instance, an expert selected to serve on the Council's Health Effects Subcommittee was a member of the project team that developed the methodology for both the pilot and later full-scale expert elicitations. This member also interviewed experts for the elicitation study. This member's participation in the expert elicitation studies was noted at a Council meeting. Later, this member attended at least two meetings where the Health Effects Subcommittee charge included interpretation and presentation of the results of the pilot expert elicitation study for the section 812 cost-benefit analysis. The meeting minutes did not record any recusals from the member. We found no indication in the SAB case file that the SAB Staff Office identified this as a potential independence issue. In our view, this member indirectly participated in the work product being reviewed based on his significant consultation during its development. We concluded that such participation does not meet the definition of an independent reviewer as described in the EPA's *Peer Review Handbook*.

Appearances of a Lack of Impartiality Not Identified or Adequately Resolved

The *Peer Review Handbook* states that, as a general rule, “. . . experts who have made public pronouncements or have had a predominant influence on the position for a given organization on an issue, those who have clearly "taken sides," may have an appearance of a lack of impartiality.” We reviewed two instances where experts had expressed public viewpoints on NAAQS standards but were appointed to serve on the CASAC or one of its panels.

- The requester questioned the appointment of a CASAC member who had co-authored an article⁸ in 2006 opposing the EPA's PM standard and was later appointed chair of the PM review panel. This member's case file

⁸ William N. Rom and Jonathan M. Samet, "Small Particles with Big Effects," 173 Am. J. Resp. & Crit. Care Med. 365, 366 (2006).

included a bibliography of publications that included the article in question. However, the member did not list this article in section 6 of the disclosure forms we reviewed, and the EPA's notes to the file did not include any discussion regarding this article. The article made the following conclusion about the PM standard:

In the face of the extensive evidence on PM and health and the strong mandate of the Clean Air Act for public health protection, the PM NAAQS proposed by Administrator Johnson appear lax. Based on the same evidence, the American Thoracic Society and other health organizations have recommended 12 and 25 $\mu\text{g}/\text{m}^3$ for the average annual and 24-h $\text{PM}_{2.5}$ standards, respectively. The proposed, less stringent standard does not protect the nation's health, as required by the Clean Air Act.

In our view, the above statement presents an appearance of a lack of impartiality based on guidance in the *Peer Review Handbook*. This guidance states that, generally, experts who have made a public pronouncement on an issue should be avoided. This expert served as a consultant on the PM review panel that advised the Administrator on the 2006 proposed and final PM standard. This expert was later appointed to the CASAC and the next 5-year PM review panel in 2007. While public statements expressing an opinion would not automatically disqualify a member, we believe that the SAB Staff Office, if aware of this article, should have prepared a written determination justifying the selection.

We noted that the case file did include documentation of the SAB Staff Office's resolution of potential concerns with respect to an article the expert had co-authored in 2004. According to notes in the case file, the SAB Staff Office intended to remind the expert to list such articles in section 6 of his disclosure form.

- In the remaining instance, a nitrogen oxide/sulfur oxide review panel member reported on his disclosure form that he had made statements at scientific meetings and in classrooms that the body of epidemiological evidence warranted consideration of a lower nitrogen oxide standard. The SAB Staff Office initially flagged this as a potential appearance of a lack of impartiality. However, the Staff Office later noted in the case file that there was not an appearance of a lack of impartiality since the member stated that he had not made these statements while serving on the panel during the past year. Guidance in the EPA's *Peer Review Handbook* does not limit statements that could create the appearance of a lack of impartiality to those only made while serving on a panel. In our view, refraining from making public statements on a topic while on the panel does not mitigate any appearances created by making public statements prior to an expert's appointment to the panel.

SAB Staff Office Does Not Treat Viewpoints Expressed as Part of Committee Functions as Appearance of a Lack of Impartiality

The requester raised concerns about two letters from CASAC members to the EPA Administrator. These letters encouraged the EPA Administrator to set the NAAQS at the levels CASAC had recommended following its review of the supporting technical documents and proposed standards. Many of the members who signed these letters were later re-appointed to the CASAC review panels that convened for the next 5-year NAAQS review cycle. The requestor expressed concerns that these members had an appearance of a lack of impartiality based on their publicly expressed viewpoints.

The SAB Staff Office director told us that her office distinguishes between viewpoints expressed outside of the FAC's activities and those expressed as part of the FAC's chartered function to provide advice to the Administrator. She considered these letters to be a normal part of the FAC's advice function and did not consider the viewpoints expressed to be appearances of a lack of impartiality that would affect the member's future service. However, she noted that if a panel member were to express a personal viewpoint outside of the FAC process, this could potentially present the appearance of a lack of impartiality. For opinions voiced outside of the member's FAC duties, the director told us that an expert must advocate a specific NAAQS level for the SAB Staff Office to consider it a viewpoint that would present the appearance of a lack of impartiality. According to the agency's alternate agency ethics official, she would instruct the CASAC after they have made their final communications to the Administrator to make any further communications through the DFO.

Procedures for Addressing and Documenting Resolution of Concerns Raised During Disclosure Form Reviews Could be Strengthened

The SAB Staff Office procedures include documenting any relevant correspondence between the file reviewer and the active or potential member regarding ethics questions. Further, these procedures state that the DFO should start each meeting by stating for the record that all participating panel members are in compliance with ethics and conflict of interest rules. If not, the DFO should note any instances where a member will recuse him/herself from discussion on a particular aspect of the meeting.

SAB Staff Office procedures do not address making written determinations when members with ethical concerns are allowed to serve. The EPA's *Peer Review Handbook* states that written determination should be made when SGEs with the appearance of a lack of impartiality are allowed to serve on FACs. Further, EPA Order 1000.28.A, *Duties of EPA Ethics Officials*, states that DEOs are authorized to:

When informed by an employee of an impartiality issue under 5 CFR Part 2635, Subpart E, or when requested by the employee's supervisor or other person responsible for the employee's assignment, make determinations as to whether a reasonable person would be likely to question the employee's impartiality in a particular matter. If impartiality is likely to be questioned, determine whether the employee should be allowed to participate in the matter, and if so, authorize participation in writing [5 CFR § 2635.502(c) and (d)].

In general, the files we reviewed contained handwritten notes, typed notes to the file, emails, or other documentation pertaining to concerns that arose during the review. However, in some cases the files did not contain the SAB Staff Office's final determination explaining how potential issues they identified were resolved. We needed additional oral explanation from SAB staff to ascertain how the Staff Office resolved these cases and the reasoning behind those determinations. Further, the meeting minutes we reviewed did not contain a record of the DFO's statements on recusals when the SAB Staff Office had recommended recusals.

Conclusions

The SAB Staff Office has adequate procedures for identifying independence and impartiality concerns. However, SAB's final determinations and evidence that mitigating measures were implemented were not always documented in the files we reviewed. Such documentation will better ensure that the FAC process is transparent and the advice from FACs is impartial. When experts with independence or impartiality concerns are allowed to serve on FACs without sufficient written justification it can potentially undermine the credibility of: (1) the FAC's advice, (2) the agency's scientific and technical documents, and (3) the corresponding regulations issued by the agency.

Recommendations

We recommend that the director, Science Advisory Board Staff Office:

2. Develop procedures to adequately document the resolution of ethical concerns. This should include:
 - a. Preparing written determinations as to why members with independence concerns or the appearance of a lack of impartiality are allowed to serve on FACs, subcommittees and panels, including any steps recommended for mitigating these concerns or appearances.
 - b. Documenting that all recommended steps for mitigating independence concerns, such as recusals from certain meetings, are implemented.

We recommend that the EPA designated agency ethics official:

3. Periodically review the SAB Staff Office's resolution of independence concerns and appearances of a lack of impartiality, including the sufficiency of recordkeeping documentation, and recommend corrective actions to the SAB Staff Office as appropriate.

We recommend that the director, Science Advisory Board Staff Office:

4. Develop a framework to guide decisions regarding public pronouncements made by current or prospective FAC members related to topics under consideration by the FAC.

Agency Comments and OIG Evaluation

The agency agreed with recommendations 2 and 3, and provided a corrective action plan and milestones that meet the intent of these recommendations. The agency did not agree with recommendation 4 and offered an alternative corrective action. The agency responded that public pronouncements did not fall under the purview of federal ethics regulations since they were not "covered relationships" and that the SAB typically deals with matters of general applicability, not "specific party" matters. We interpreted 5 CFR Part 2635.502(a)(2), which addresses impartiality concerns that may arise under other circumstances not described in that section, as potentially applying to particular matters of general applicability. However, we believe the SAB Staff Office's proposal to develop a framework to guide decisions regarding public pronouncements by current or prospective FAC members will be an appropriate management control. As such, the agency's proposed alternative action meets the intent of the draft report's recommendation. Thus, we revised our recommendation to reflect the agency's proposed alternative corrective action. All three recommendations are resolved and open pending the agency's completion of the agreed-to corrective actions.

Chapter 4

Membership Tenure

The EPA's policy on tenure generally limits FAC members to 6 years of service, with any service over 6 years based on written justification from the program office and approval by the Administrator or Deputy Administrator. The EPA generally followed this policy in its management of the CASAC and Council. In three instances prior to 2010, EPA approved FAC chairs to serve more than 6 years based on written justification submitted to the Administrator. Beginning in FY 2010 under former Administrator Jackson's term (2009-2013), the EPA has more strictly limited the granting of extensions for service more than 6 years.

The EPA's policy on tenure does not apply to review panel or subcommittee memberships. From FYs 1998 through 2012, 36 percent of all CASAC members/consultants served more than 6 years as a charter CASAC member or review panel consultant. During the same period, 12 percent of all Council members/consultants served more than 6 years as a Council charter member, or review panel or subcommittee consultant. By not applying its membership policy to review panels and subcommittees, the EPA may be not be achieving the policy's intent of providing fresh perspectives to its FACs.

The EPA's Policy Limits Committee Terms to 6 Years

Title 41 CFR Section 102-3.130(a), regarding policies that apply to the appointment and compensation or reimbursement of advisory committee members, staff, experts and consultants, states that:

Unless otherwise provided by statute, Presidential directive, or other establishment authority, advisory committee members serve at the pleasure of the appointing or inviting authority. Membership terms are at the sole discretion of the appointing or inviting authority.

As noted in the EPA's 2003 Federal Advisory Committee Handbook membership terms should be no longer than 6 years to provide fresh perspectives on the FAC. The Handbook notes the deputy administrator may grant appointments beyond the 6-year limit if the program office provides adequate justification as to why the office cannot find an appropriate replacement. In the case of the CASAC and Council, appointments are made by the Administrator, who may grant (and has granted) appointments beyond the 6-year limit if the SAB Staff Office provides adequate justification for the extension.

According to the former SAB Staff Office director and staff in the EPA's OFACMO, since 2010 former Administrator Jackson more strictly limited FAC

service to no longer than 6 years. OFACMO noted that Administrator Jackson granted some extensions but only in exceptional circumstances based on a detailed written justification. The EPA's 2012 revised Handbook reiterated the 6-year limit and clarified that members should be appointed for no longer than a total of 6 years (typically in 2- or 3-year terms), with an extension limited to 1-year upon approval of a detailed written justification.

The EPA applies its term policy only to FAC charter members and not to SGEs who serve on panels or subcommittees that supplement the charter FAC. The SAB Staff Office director noted that the consultants on the CASAC review panel are not voting members. Further, these panels often meet over a period of several years. Thus, the time spent in service on one NAAQS review panel could last approximately 6 years. The director also noted that the Staff Office's practice is to replace about two-thirds of the members on subsequent panels. In their view, subsequent panels benefit from the experience and working knowledge provided by having some of the previous panel members serve on the next panel.

The EPA Followed Its Policy on Tenure

The EPA generally applied its policy of limiting terms of service. We reviewed the length of service for all CASAC and Council members who served from FYs 1998 through 2012. Only three members served more than 6 years (one CASAC and two Council committee members). In all three instances written justifications were provided for the members' extended service. These three FAC members' length of service ranged from 7 to 10 years. Figure 1 (see next page) shows the percentage of CASAC and Council charter members who served more than 6 years from FYs 1998 through 2012.

Many Members Served More than 6 Years If Service on Review Panels Were Considered

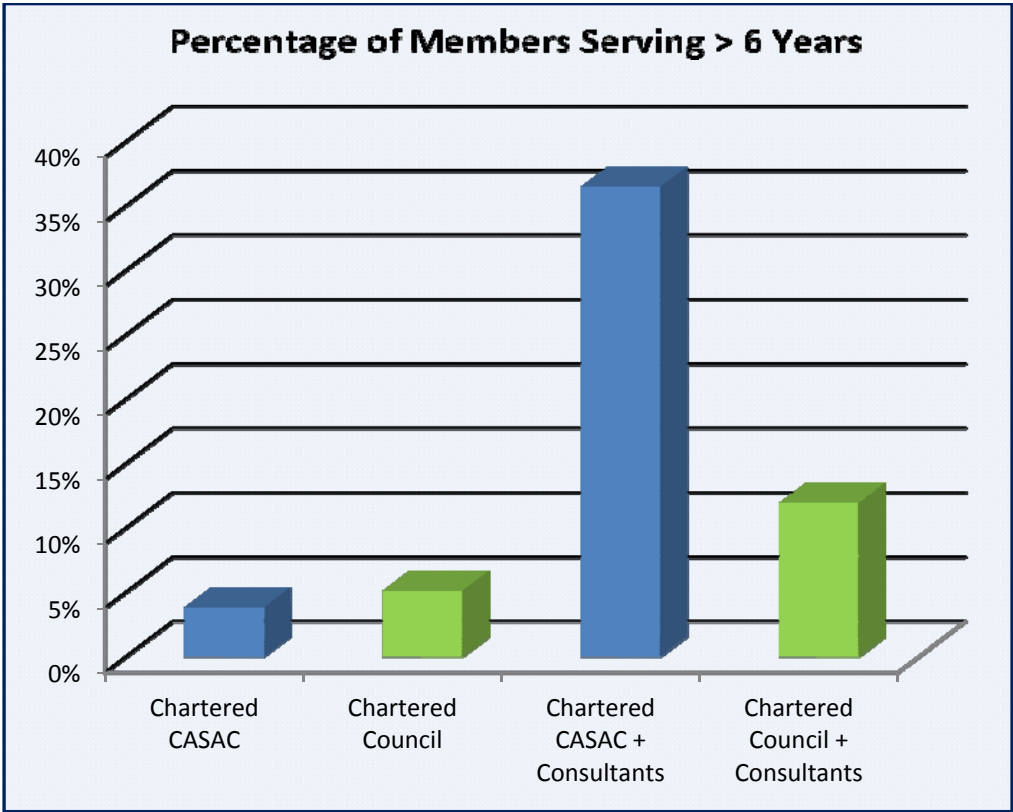
The EPA augmented both the CASAC and Council with review panels and subcommittees comprised of consultants that provided technical advice on important matters under consideration by the FAC. While not voting members of the FAC, these consultants could influence the FAC's advice with their input. Therefore, we applied the 6-year term limit to all types of FAC and consultant services starting in 1998, including service on chartered FACs, subcommittees and review panels. If time served as a charter FAC member and review panel consultant or subcommittee member were combined, the percentage of experts exceeding 6-year terms is greater than the percentage for charter members only.

During FYs 1998 through 2012, the CASAC had 74 members either serve as one of the seven chartered FAC members or as an expert consultant on a NAAQS review panel. When this combined service is considered, 27 of 74 members (or 36 percent of CASAC members) served more than 6 years. Of the 27 CASAC members/consultants who served more than 6 years, the years of service as a

member and/or consultant ranged from 7 years (12 members/consultants) to 15 years (one member/consultant).

During FYs 1998 through 2012, the Council had 67 members serving either directly on the FAC, on a related subcommittee, or as a consultant. When this combined service is considered, eight members (or 12 percent of Council members) served more than the 6 years. Of the eight members who served more than 6 years, the years of service ranged from 7 years (six members) to 10 years (one member). Figure 1 shows the percentage of all CASAC- and Council-related members with length of service of more than 6 years.

Figure 1: Percentage of CASAC and Council members serving more than 6 years, FY 1998-FY 2012.



Source: OIG analysis of CASAC and Council membership lists.

Conclusions

Neither the FACA nor its implementing regulations prescribe membership term limits for FAC members. However, the EPA has established a policy on membership terms to help provide fresh perspectives on FACs. The EPA’s policy applies only to charter FAC members and not expert consultants who serve on review panels or members selected to serve on subcommittees. In particular, the CASAC review panelists provide significant input regarding the EPA’s criteria

and standards for ambient air quality. Our analysis indicated the SAB Staff Office was achieving its goal of about two-thirds turnover on its NAAQS review panels. This turnover ratio is intended to balance the need for fresh perspectives versus maintaining continuity and experience.

Chapter 5

Committee Balance

In general, we found that the CASAC and Council were balanced with respect to the primary functions of the FACs and the required scientific “points of view.” The FACA and its implementing regulations require FACs to be fairly balanced but allow agencies discretion in how they achieve balance. The EPA’s guidance instructs DFOs to describe the agency’s plan to attain fairly balanced membership for their FACs and to prepare membership grids showing proposed members’ qualifications and background. The SAB Staff Office prepared membership grids for the CASAC and Council. The Staff Office also described the factors that it considered for selecting members in Federal Register notices announcing opportunities for the public to nominate members. SAB Staff Office management and staff told us that their primary concern in achieving balance for the CASAC and Council was ensuring that the members have the necessary range of technical expertise. With the EPA’s release of its updated FAC Handbook in March 2012, the EPA added steps to its FAC membership selection process to help achieve FAC balance. In our view, this new process will provide additional assurance that balance is achieved on these FACs.

FACs Should Be Fairly Balanced in Terms of Viewpoints Represented and Functions Performed

FACA requires that the membership of FACs be “fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee.” In the preamble to the 2001 FACA Final Rule, the GSA stated it believed FACA’s provisions were broad enough to allow agency discretion in achieving membership balance. However, the rule included a list of possible considerations for agencies in developing a plan for achieving balance. These include the:

- Committee’s mission.
- Geographic, ethnic, social, economic or scientific impact of the committee’s recommendations.
- Specific perspectives required, such as those of consumers, technical experts, the public at-large, academia, business or other sectors.
- Need to obtain divergent points of view on the issues before the committee.
- Relevance of state, local and tribal governments to the development of the advisory committee’s recommendations.

Title 41 CFR Part 102-3.60 requires agencies to describe their plans for achieving balance on discretionary FACs. These plans are not required for non-discretionary

FACs such as the CASAC and Council. However, GSA guidance⁹ issued in 2011 “strongly recommended” these plans for non-discretionary FACs as well.

The EPA’s FAC Handbook (prior and current versions) incorporates FACA requirements on balance and describes the EPA’s procedures for ensuring this requirement is met. The EPA’s Handbook requires that the justification statements that accompany a request to charter or renew a charter for both discretionary and non-discretionary FACs describe plans for achieving balance. The Handbook lists general guidelines to consider in achieving balance. The 2012 updated FAC Handbook incorporated an additional consideration for members with experience with issues of concern to low-income, rural, urban, medically underserved, sensitive/vulnerable, or disproportionately impacted community populations, and whether that experience would be useful.

The membership grid is a key tool prepared by the EPA as part of the annual membership process. The EPA uses the membership grid to review and ensure balance. For each FAC, the DFO must create a membership grid that provides a snapshot of the FAC makeup, including both current members and proposed candidates for membership. The membership grid is part of the overall membership package, which is submitted to the Administrator for approval.

Both the CASAC and Council are statutorily mandated FACs with specific membership requirements mandated by the CAA. The CASAC’s seven members must include at least one physician, one member of the National Academy of Sciences, and one person representing state air pollution control agencies. The Council must have at least nine members and include recognized experts in the fields of health and the environmental effects of air pollution, economic analysis, environmental sciences and such other fields the Administrator deems appropriate.

Preparation of Balance Plans Could Provide More Transparency to Efforts to Achieve Balanced CASAC and Council Committees

In general, we found the CASAC and Council were balanced with respect to the primary functions of the FACs and the required scientific “points of view.” We noted that prior to 2011, the justification packages for these FACs did not describe the plan for attaining balanced membership. However, in Federal Register notices announcing opportunities for the public to nominate members for service on the Council and CASAC, the SAB Staff Office described factors it considers when selecting FAC members. These factors included relevant scientific perspectives, which, among other factors can be influenced by work history and affiliation.¹⁰ As part of the annual membership process, the SAB Staff

⁹ FAC Membership Balance Plan, GSA Committee Management Secretariat, Office of Committee and Regulatory Management, January 2011.

¹⁰See e.g., 69 Fed. Reg. 33,900-01 (June 17, 2004).

Office prepared membership grids for the CASAC and Council which summarized the proposed FAC membership in terms of members' expertise, affiliation category (e.g., academic, state, private sector, nongovernmental organization), and geographic location (state). The SAB Staff Office used a similar process in forming panels that work under the auspices of the chartered FACs.

SAB Staff Office DFOs told us they address balance from the standpoint of scientific and technical expertise. If a potential or current member were to express a public opinion on matters before the FAC, this might create an appearance of a lack of impartiality. One DFO told us the SAB Staff Office would address such a concern specifically with that individual, not by balancing the panel with an opposing point of view.

New Agency Procedures Designed to Improve Diversity and Balance

In March 2012, the EPA updated its FAC Management Handbook and incorporated new procedures for achieving diversity and balance on the EPA's FACs. The updated Handbook:

- Added a consideration for whether members with experience with issues of concern to low-income, rural, urban, medically underserved, sensitive/vulnerable populations, or communities experiencing disproportionate environmental or public health burdens, could be useful on the FAC.
- Requires an outreach plan for obtaining a diverse pool of nominees. The plan must be submitted to the EPA's OFACMO for review and concurrence. The outreach plan should describe in detail how the DFO intends to solicit a diverse set of nominees, including women and minorities. For example, it should explain the specific forms of public solicitation the DFO plans to use and the organizations and academic institutions the DFO plans to contact.

The SAB Staff Office developed an outreach plan for the April 2012 CASAC charter renewal. Further, the SAB Staff Office developed a draft outreach plan for the April 2013 Council charter renewal. The balance plan for CASAC and the Council, prepared to support charter renewal, describes the plan for ensuring that the committees are balanced in terms of scientific points of view (including statutory requirements for membership). The Outreach Plan, developed to support the annual membership process, is designed to ensure that membership recommendations draw upon a "diverse set of nominees, including women and minorities." While there is overlap between the goals of diversity and balance, they are not synonymous.

Conclusions

Agencies have discretion in determining how balance is achieved on their FACs. In requiring descriptions of plans to achieve balance for non-discretionary FACs, the EPA has established procedures for balance that go beyond the minimum requirements established by the regulations. Preparing membership balance plans and implementing outreach plans as described in the EPA's updated FAC Handbook should make the selection process more transparent and help ensure that balance is achieved on the CASAC and Council.

Chapter 6

Peer Review

In addition to assessing the EPA's management of CASAC and the Council, we reviewed the EPA's conformity with OMB and the EPA's peer review policies and guidance with respect to three National Center for Environmental Assessment analyses supporting NAAQS revisions. All three analyses were conducted in conjunction with and included in larger assessment documents that synthesized numerous studies and analyses. These assessment documents underwent formal peer review by the CASAC. The requester questioned whether CASAC review of assessment documents sufficed for the rigor and specificity of a separate peer review of each individual analysis.

We determined that two of the three analyses were sufficiently peer reviewed before the EPA publicly disseminated them by placing them in the rulemaking docket. However, one of the NCEA analyses containing influential scientific information—a re-analysis of data from an ozone health effects study—was not peer-reviewed in accordance with OMB and the EPA's guidance. OMB and the EPA's guidance call for all ISI to be peer reviewed before public dissemination. However, NCEA did not have a formal process for determining whether individual analyses and work products met the definition of ISI. Thus, NCEA did not subject its ozone data re-analysis to peer review before disseminating it in support of the ozone NAAQS. The analysis was later peer reviewed and published in a journal article. This peer review did not alter the conclusions of the analysis as presented in the EPA documents. Thus, the lack of peer review prior to public dissemination did not appear to affect the ozone NAAQS rulemaking. Nonetheless, proper peer review of the EPA's internal analyses before dissemination to the public is an important tool for ensuring the quality and integrity of the agency's scientific information.

Federal and Agency Guidance Require Peer Review of Influential Scientific Information Before Public Dissemination

Peer review involves the review of a draft product for quality by specialists in the field who were not involved in producing the draft. OMB's *Final Information Quality Bulletin for Peer Review* establishes government-wide guidance for peer review of government science documents. The OMB bulletin requires each agency to subject ISI to peer review prior to dissemination. It defines ISI as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." The OMB bulletin provides agencies broad discretion in determining the type of peer review and the procedures used to select reviewers.

The EPA's *Peer Review Handbook* (3rd Edition) incorporates the provisions of the OMB bulletin and outlines the agency's policy, procedures and processes for peer review. Consistent with OMB guidelines, the EPA's *Peer Review Handbook* states that "[t]he principle underlying the Peer Review Policy is that all influential scientific and technical work products used in decision making will be peer reviewed" (underlining in original). However, it cites exceptions to this principle. One of these exceptions states that peer review is not necessary for ISI if an application of an adequately peer reviewed work product does not depart significantly from its scientific or technical approach.

The EPA's *Peer Review Handbook* states that, generally, determinations as to whether a work product is "influential" will occur on a case-by-case basis. The agency decision maker should determine whether a work product is ISI. The applicable assistant administrator or regional administrator is the ultimate agency decision maker and is accountable for the decisions regarding the identification of ISI, and the mechanisms of peer review used for these work products. The assistant administrator or regional administrator may designate office directors or division directors as the front-line decision maker.

NCEA's Review of One Analysis Did Not Adhere to OMB Requirements and EPA Peer Review Guidance for Influential Scientific Information

We reviewed NCEA's compliance with OMB and the EPA's peer review guidance for three work products NCEA produced in support of ambient air quality standards for ozone, sulfur dioxide and nitrogen dioxide. EPA included parts of these three analyses in larger assessment documents that the CASAC peer reviewed. These three NCEA work products were:

1. A reanalysis of data from a previously published clinical study on the effects of human exposure to ozone (ozone reanalysis).
2. An analysis of the results of earlier human clinical studies on the effects of human exposure to SO₂ (SO₂ analysis).
3. An update to a previously published meta-analysis on the effects of human exposure to NO₂ (updated NO₂ meta-analysis).

In our view, all three analyses fit the description of ISI. However, NCEA did not have its ozone reanalysis peer reviewed before it was disseminated to the public. As such, the EPA did not adhere to OMB and EPA peer review guidance for this particular analysis. The SO₂ analysis was sufficiently peer reviewed. The updated NO₂ meta-analysis primarily updated and re-presented previously peer reviewed information, and thus was not required to be peer reviewed again per the EPA's guidance. Details concerning the development, dissemination and peer review of each of the three analyses follow.

2007 Ozone Reanalysis

In response to a CASAC comment on the second draft of the 2006 ozone air quality criteria document, NCEA decided to include the results of a recent human exposure study (Adams study)¹¹ in the final air quality criteria document. According to NCEA staff, in reviewing the Adams study they observed certain traits in the study's data which caused them to question whether the data would show statistically significant effects of ozone exposure at less than 0.08 parts per million. In reviewing the final air quality criteria document, one CASAC member also questioned whether additional statistical analysis of the data would show statistically significant effects at ozone levels below 0.08 ppm. These observations led NCEA to re-analyze the Adams study data using a different statistical approach. NCEA concluded that there was a statistically significant effect of ozone at 0.06 ppm as compared to filtered clean air (0.00 ppm). NCEA placed the results of its reanalysis¹² in the ozone rulemaking docket in June 2007 without having it peer reviewed.

NCEA's 2007 ozone reanalysis met the definition of ISI. The Adams study was the first such study to present human exposure data at ozone levels below 0.08 ppm. At that time, the level of the ozone standard was 0.08 ppm averaged over 8 hours. NCEA's reanalysis concluded that ozone effects occurred at levels below 0.08 ppm. Thus, NCEA reasonably could determine that its reanalysis would have an impact on the 2008 NAAQS ozone rulemaking process.

At a technical conference in December 2006, NCEA made a presentation on the health effects of exposure to air pollutants. This presentation included NCEA's initial ozone analysis illustrating the distribution of effects for individuals and group mean estimates at levels below 0.08 ppm. In January 2007, NCEA staff discussed the ozone reanalysis with the EPA's OAQPS. OAQPS asked NCEA if it could include the ozone reanalysis in the OAQPS staff paper for the 2008 NAAQS ozone rulemaking. However, NCEA did not want to do so at that time because staff believed it might constitute new analysis that had not been peer reviewed. Thus, OAQPS only presented NCEA's general observations about the Adams study in the staff paper and not the detailed statistical analysis. NCEA had the reanalysis internally reviewed by EPA scientists and addressed public comments received at a March 2007 CASAC meeting. In NCEA's view, it was appropriate to include the reanalysis after these internal reviews. Thus, they entered the reanalysis into the rulemaking docket in June 2007.

¹¹ Dr. William Adams, *Comparison of Chamber 6.6-h Exposures to 0.04–0.08 PPM Ozone via Square-wave and Triangular Profiles on Pulmonary Responses*, Inhalation Toxicology, February 2006.

¹² Dr. James Brown, *The effects of ozone on lung function at 0.06 ppm in healthy adults*, EPA memorandum, June 14, 2007.

NCEA's 2007 ozone reanalysis was published in an August 2008 peer reviewed journal article.¹³ However, this peer review was after NCEA disseminated its reanalysis in the June 2007 memorandum.

2008 SO₂ Analysis

In 2007, in support of the SO₂ NAAQS review, NCEA began working on a draft analysis of SO₂ human exposure data from studies conducted in the 1980s and 1990s. This draft analysis was circulated to CASAC in December 2007, and CASAC encouraged NCEA to proceed with the analysis. NCEA's SO₂ analysis was included in the EPA's second draft integrated science assessment¹⁴ for sulfur oxides in 2008. NCEA concluded that human responses to SO₂ concentrations increased as exposures to SO₂ increased and that more pronounced effects were observed at lower concentrations among SO₂-sensitive asthmatics. As part of the normal NAAQS review process, CASAC peer reviewed the draft integrated science assessments. Prior to submitting the second draft ISA to CASAC for peer review, the EPA formally requested the CASAC to review its analyses of data from human clinical studies. We reviewed the CASAC comments on the SO₂ analysis and, in our view, this review fulfilled OMB and EPA peer review requirements.

After the SO₂ NAAQS final rule was issued, NCEA's SO₂ analysis was again peer reviewed and published in a December 2010 journal article.¹⁵

2008 NO₂ Meta-Analysis

During a May 1, 2008, CASAC meeting (one of several held for the 5-year review of the nitrogen dioxide NAAQS), NCEA and CASAC discussed a 1992 NO₂ meta-analysis¹⁶ of 19 studies of individuals with asthma included in the 1993 criteria document. CASAC recommended that NCEA present this data in the current NO₂ ISA. Before including the 1992 meta-analysis in the ISA, NCEA removed one study from the analysis¹⁷ and added a recent study that it considered to be of a similar nature to the other studies. NCEA also added a concentration range (i.e., 0.1 ppm) to its presentation that was not included in the original 1992 meta-analysis. NCEA's conclusions on the effects of NO₂ exposure were essentially the same in its 2008 update as those from the 1992 meta-analysis.

¹³ Dr. James Brown et al., *Effects of Exposure to 0.06 ppm Ozone on FEV in Humans: A Secondary Analysis of Existing Data*, Environmental Health Perspectives, August 2008.

¹⁴ *Integrated Science Assessment for Sulfur Oxides – Health Criteria (Second External Review Draft)*, Table 3-1 and related text, May 2008.

¹⁵ Dr. Douglas Johns et al., *Analysis of the concentration-respiratory response among asthmatics following controlled short-term exposures to sulfur dioxide*, Inhalation Toxicology, December 2010.

¹⁶ Dr. Lawrence J. Folinsbee, *Does Nitrogen Dioxide Exposure Increase Airways Responsiveness?*, Toxicology and Industrial Health, Vol. 8, No. 5, 1992.

¹⁷ According to NCEA, one study in the 1992 meta-analysis was based on a specific exposure while all the others were based on non-specific exposures. Thus, in NCEA's view, this one study should not be included in the 2008 analysis.

An NCEA branch chief told us that the updated NO₂ meta-analysis was not submitted for publication because the revisions made to the original NO₂ meta-analyses were not a new analysis that would merit publication in a journal. Further, she said all of the information about the revisions to the original meta-analysis was included in the ISA so a separate memorandum was not necessary. Both the original 1992 meta-analysis and NCEA's 2008 update of that meta-analysis were ISI. However, the 2008 updated meta-analysis did not require peer review. The EPA's *Peer Review Handbook* notes that peer review is not necessary for ISI if it is an application of an adequately peer reviewed work product that does not depart significantly from its scientific or technical approach. In our view, NCEA's 2008 update did not depart significantly from the original 1992 meta-analysis. Further, it was an acceptable application of an adequately peer reviewed work product. NCEA essentially re-presented the results of the original meta-analysis. Moreover, the conclusions about the health effects of NO₂ exposure did not change. On July 17, 2012, the U.S. Court of Appeals for the District of Columbia upheld the EPA's final NO₂ rule and reached a similar conclusion regarding the 2008 meta-analysis. The court noted that the EPA's meta-analysis "merely updated" the original Folinsbee meta-analysis.¹⁸

NCEA Did Not Have a Process for Determining Whether Internal Analyses Were Influential Scientific Information

According to an NCEA branch chief, NCEA does not have a process for determining whether internal NCEA analyses are "influential" and does not make "influential calls" on such documents. She said NCEA focuses on determining which internal analyses are most relevant to the larger assessment documents that are peer reviewed by CASAC. She said that it would be impossible to have every internal analysis peer reviewed due to time constraints. She also said that NCEA does not ask CASAC to peer review each individual analysis.

We reviewed NCEA emails and found no evidence of an NCEA process for determining whether a work product is influential. However, a January 2007 email showed that some NCEA staff were concerned about sending the ozone reanalysis to the docket without having the individual analysis peer reviewed. In the email, NCEA staff did not discuss whether the work product was ISI or whether peer review was required to meet OMB and EPA guidance. In our view, the lack of a process to assess whether internal analyses are ISI is a weakness in NCEA's management controls. This lack of control allowed the 2007 ozone reanalysis to be included without peer review and without clear accountability for the decision to proceed even though internally staff had some concerns.

¹⁸ *American Petroleum Inst. v. EPA*, 684 F.3d 1342, 1349 (D.C. Cir. 2012), *rehearing en banc denied* (D.C. Cir. Sept. 24, 2012), *cert. denied*, 133 S. Ct. 1724 (April 2013).

Subsequent Peer Review Did Not Alter Overall Conclusions of NCEA's Ozone Reanalysis

The ozone reanalysis was published in a peer reviewed journal article after the EPA publicly disseminated it. However, the peer review did not result in significant changes to the journal manuscript. Many of the peer review comments for the ozone reanalysis were editorial and required only small revisions to the text. One peer reviewer commented that the authors (including two NCEA staff members) could have more clearly described their analysis and suggested that the authors include a more rigorous defense of their analytical strategy. The authors cited text that described and defended the analysis, and did not significantly change the manuscript. The external peer reviewers' comments did not materially alter NCEA's original results or conclusions as they were presented in the EPA's documents supporting the revised NAAQS for ozone.

Conclusions

NCEA did not have a process to determine whether internal analyses were ISI and to document its decision regarding the need for peer review. Such a process would provide accountability for decisions about the need for peer review and help assure that NCEA complies with OMB and EPA peer review guidance. In the absence of a formal process to determine whether a work product is influential, NCEA is at risk of including ISI in broader assessment documents for public dissemination without the requisite peer review.

Recommendation

We recommend that the assistant administrator for the Office of Research and Development:

5. Direct NCEA to implement a process to review NCEA scientific analyses that support the EPA's rulemakings and determine the appropriate type of peer review for these work products. This process should:
 - a. Determine and document whether such analyses are influential scientific information.
 - b. Document the rationale for the type of peer review chosen for ISI, including any decision not to have such analyses externally peer reviewed before they are publicly disseminated.

Agency Comments and OIG Evaluation

The agency agreed with our recommendation and provided a corrective action plan that meets the intent of the recommendation. The recommendation is resolved and open pending the agency's completion of the agreed-to corrective action.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in \$000s)	
Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Claimed Amount	Agreed-To Amount
1	10	Instruct DEOs and assistant DEOs on the proper process for handling potential conflicts of interests for SGEs, including the process for implementing any applicable steps to remedy the conflicts of interest.	C	Designated Agency Ethics Official	8/14/13		
2	19	Develop procedures to adequately document the resolution of ethical concerns. This should include: <ul style="list-style-type: none"> a. Preparing written determinations as to why members with independence concerns or the appearance of a lack of impartiality are allowed to serve on FACs, subcommittees and panels, including any steps recommended for mitigating these concerns or appearances. b. Documenting that all recommended steps for mitigating independence concerns, such as recusals from certain meetings, are implemented. 	O	Director, Science Advisory Board Staff Office	9/30/13		
3	20	Periodically review the SAB Staff Office's resolution of independence concerns and appearances of a lack of impartiality, including the sufficiency of recordkeeping documentation, and recommend corrective actions to the SAB Staff Office as appropriate.	O	Designated Agency Ethics Official	9/30/13		
4	20	Develop a framework to guide decisions regarding public pronouncements made by current or prospective FAC members related to topics under consideration by the FAC.	O	Director, Science Advisory Board Staff Office	12/31/14		
5	34	Direct NCEA to implement a process to review NCEA scientific analyses that support the EPA's rulemakings and determine the appropriate type of peer review for these work products. This process should: <ul style="list-style-type: none"> a. Determine and document whether such analyses are influential scientific information. b. Document the rationale for the type of peer review chosen for ISI, including any decision not to have such analyses externally peer reviewed before they are publicly disseminated. 	O	Assistant Administrator, Office of Research and Development	9/30/13		

¹ O = recommendation is open with agreed-to corrective actions pending
C = recommendation is closed with all agreed-to actions completed
U = recommendation is unresolved with resolution efforts in progress

EPA Response to Draft Report

July 22, 2013

MEMORANDUM

SUBJECT: Response to Office of Inspector General Draft Report No. OPE-FY12-0001
*Response to Congressional Request on the EPA's Management of Clean Air
Federal Advisory Committees*, dated June 17, 2013

FROM: Lek G. Kadeli, Principal Deputy Assistant Administrator
Office of Research and Development (ORD)

Brenda Mallory, Acting General Counsel
Office of General Counsel (OGC)

Christopher Zarba, Acting Director
Science Advisory Board (SAB) Staff Office

TO: Arthur A. Elkins, Jr., Inspector General
Office of Inspector General (OIG)

Thank you for the opportunity to respond to the OIG draft report titled, *Response to Congressional Request on the EPA's Management of Clean Air Federal Advisory Committees*. We have provided a summary of the agency's overall position and our response to the OIG's recommendations. For the one recommendation with which the agency does not agree, we have provided the legal basis and a proposed alternative to the given recommendation. For your consideration, we have included our technical comments as attachments to supplement this response.

AGENCY'S OVERALL POSITION

The EPA appreciates the opportunity to comment on this report and in general agrees with the OIG's recommendations. For findings and recommendations related to the Office of General Counsel, we have provided clarifying information about the identity and parameters of the position that oversees the agency's ethics program.

AGENCY’S RESPONSE TO REPORT RECOMMENDATIONS

Agreements

No.	Recommendation	High-Level Intended Corrective Action(s)	Estimated Completion by- Quarter and FY
1	Designated Agency Ethics Official (DAEO) ¹ to instruct deputy ethics officials and assistant deputy ethics officials on the proper process for handling potential conflicts of interest for SGEs, including the process for implementing any applicable steps to mitigate the conflicts of interest.	DAEO will review reference material already available from OGC/Ethics and the Office of Government Ethics to ascertain whether any additional SGE-specific guidance is necessary or warranted. OGC notes, however, that conflicts issues are necessarily fact-specific, so it may not be possible or prudent to issue blanket guidance. ¹⁹	4 th Quarter FY 2013
2	Develop procedures to sufficiently document the resolution of ethical concerns. This should include: a) Preparing written determinations as to why members with independence concerns or the appearance of a lack of impartiality are allowed to serve on FACs, subcommittees and panels, including any steps recommended for mitigating concerns or appearances. b) Documenting that all recommended steps for mitigating independence concerns, such as recusals from certain meetings, are implemented.	a) To enhance documentation of decisions on potential conflict of interest (COI) of experts serving on FACs, subcommittees and panels, the SAB Staff Office will document the nature of the issue and any remedies (e.g., divestiture, partial recusal) applied. If there is an issue of appearance of loss of impartiality but no statutory COI under 18 USC 208, the SAB Staff Office will document any decision to authorize participation. b) The SAB Staff Office will develop a standard opening statement for Designated Federal Officers to use at the beginning of all public meetings. The statement would note that all participating committee members/panelists are in compliance with ethics	4 th Quarter FY 2013 4 th Quarter FY 2013

¹⁹ Subsequent to this action plan, the Senior Counsel for Ethics and Alternate Agency Ethics Official clarified the response to Recommendation 1 to note that she had already advised the SAB Director and selected staff about the proper process for handling conflicts of interest, and would instruct ethics officials across the Agency in her monthly meetings on August 13 and 14, 2013.

No.	Recommendation	High-Level Intended Corrective Action(s)	Estimated Completion by- Quarter and FY
		requirements and note any recusals for the record. The SAB Staff Office will ensure that meeting minutes accurately reflect these opening statements.	
3	Designated Agency Ethics Official (see endnote) to periodically review the SAB Staff Office's resolution of independence concerns and appearances of a lack of impartiality, including the sufficiency of recordkeeping documentation, and recommend corrective actions to the SAB Staff Office as appropriate.	<p>Pursuant to 5 CFR § 2638.203, the DAEO is responsible for managing EPA's ethics program, including ensuring that financial disclosure reports are consistently reviewed and that records are kept, when appropriate, on advice rendered.</p> <p>OGC/Ethics has been working in closer coordination with the new SAB Acting Director and staff on an as-needed basis to ensure proper resolution of concerns, including additional consultation and instruction. The DAEO will ascertain whether any additional review beyond what is already occurring is warranted.</p>	4 th Quarter FY 2013
5	<p>Direct NCEA to implement a process for reviewing NCEA scientific analyses that support the EPA's rulemakings to determine the appropriate type of peer review for these work products. This process should:</p> <p>a) Determine and document whether such analyses are influential scientific information.</p> <p>b) Document the rationale for the type of peer review chosen for ISI, including any decision not to have such analyses externally peer reviewed before they are publicly disseminated.</p>	<p>The Agency is in the process of revising the Peer Review Handbook. The new edition of the Handbook will emphasize the planning process and include procedures for creating a record-of-decision for the classification of a work product and the type of peer review planned for a work product. The National Center for Environmental Assessment (NCEA), within the Office of Research and Development, is in the process of addressing this recommendation by establishing a policy that includes the following steps.</p> <p>a) NCEA work products will be evaluated to determine whether they are ISI, in accordance with EPA's Peer Review Handbook, and the Division Director will document his or her</p>	4 th Quarter FY 2013

No.	Recommendation	High-Level Intended Corrective Action(s)	Estimated Completion by- Quarter and FY
		<p>determination.</p> <p>b) NCEA will conduct a peer review for any work product that is determined to be ISI, in accordance with EPA’s Peer Review Handbook, and NCEA will document the rationale for the type of peer review conducted.</p>	

Disagreement

OIG Recommendation No. 4:

Designated Agency Ethics Official (see Endnote 1) to provide clarification or instruction to Deputy Ethics Officials for assessing whether public statements create an appearance of a lack of impartiality with respect to when the statements were made and the expert’s role at the time of the statement.

Agency’s Response:

Pursuant to 5 CFR § 2638.203, the DAEO is responsible for managing the Agency’s ethics program, including ensuring that EPA employees adhere to the conflict of interest statutes set forth in Title 18 of the United States Code and to the Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR Part 2635. The Standards of Ethical Conduct include, at 5 CFR Part 2635, Subpart E, specific provisions for “Impartiality in Performing Official Duties.”

The OIG recommendation falls outside the purview of federal ethics. These regulations set forth the standard that an employee is responsible, in the first instance, for identifying whether any of his “covered relationships” will cause a reasonable person with knowledge of the relevant facts to question his ability to carry out his official duties with respect to a specific party matter impartially. Typically, the SAB does not deal with “specific party” matters but rather with matters of general applicability. Further, a public statement does not fall within the “covered relationships” set forth at 5 CFR 2635.502, and therefore OGC ethics is not the responsible party overseeing these decisions.

From a policy perspective, however, when an individual has made public statements about a matter that will be considered by the advisory panel that may raise a concern about whether the individual has an open mind. The agency’s current Peer Review Handbook recommends that staff avoid selecting people for a peer review if they have publicly expressed an opinion on the matter to be considered by the peer review. The Handbook also acknowledges the challenge of selecting advisory committee members who have the requisite experience or technical expertise and who have not made public statements. For this reason, the Handbook allows EPA the discretion to decide to include members who have made public statements.

Alternative to Given Recommendation:

The SAB Staff Office will develop a framework to guide decisions regarding public statements.

Estimated Completion by Quarter and FY:

1st Quarter FY 2014

CONTACT INFORMATION

If you have any questions for OGC, please contact Justina Fugh, Senior Counsel for Ethics and Alternate Designated Agency Ethics Official at (202) 564-1786, or Daniel Fort, Ethics Officer, at (202) 202-564-2200. For questions regarding the SAB Staff Office component of this response, please contact Christopher Zarba, Acting Director at (202) 564-0760 or Angela Nugent, Special Assistant, Science Advisory Board Staff Office at (202) 564-2218. Finally, for questions to the EPA's Office of Research and Development, please contact Deborah Heckman at (202) 564-7274 or John Vandenberg at (919) 541-4527.

Attachments

- A. Technical Comments from the Office of Federal Advisory Committee Management and Outreach
- B. Technical Comments from the SAB Staff Office
- C. Technical Comments from the ORD

ENDNOTE

¹ Please note that the General Counsel, a Presidentially appointed/Senate confirmed position, has neither a statutory nor regulatory role in EPA's ethics program. OGC/Ethics therefore assumes that the OIG intended to identify the Designated Agency Ethics Official as the correct action official. Brenda Mallory was designated by the Administrator pursuant to 5 CFR 2638.202(b) and (c) when she became the Principal Deputy General Counsel. Although Ms. Mallory is also currently acting as the General Counsel, the acting position does not imbue her with her authority to oversee EPA's ethics program. Rather, that authority derives from her appointment as the Designated Agency Ethics Official (DAEO).

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