

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUL - 7 2011

MEMORANDUM

OFFICE OF RESEARCH AND DEVELOPMENT

Office of Research and Development (ORD) Response Office of Research and SUBJECT: Development Should Increase Awareness of Scientific Integrity Policies, Project No. OA-FY10-0193 FROM: Kevin Y. Teichman Deputy Assistant Administrator for Science Office of Research and Development TO: Melissa M. Heist Assistant Inspector General Office of Audit

Thank you for the opportunity to comment on the Office of Inspector General (OIG) draft audit report, *Office of Research and Development Should Increase Awareness of Scientific Integrity Policies* (Project No. OA-FY10-0193), dated June 8, 2011. We appreciate the OIG's recognition that EPA has a commitment to scientific integrity and that "ORD has [scientific integrity] controls in place that include policies, procedures, training, and peer review." While we also appreciate that the recommendations in your draft report are subject to change, we agree with the OIG's recommendations as currently proposed. In fact, EPA is already taking these and additional steps to enhance scientific integrity at the Agency.

The Agency has taken many steps to address scientific integrity including mandatory ethics training, quality systems requirements, our peer review policy, our Peer Review Handbook, and establishing cross-Agency Councils such as EPA's Science and Technology Policy Council. Attached is a copy of the memorandum we sent to Dr. John P. Holdren, Director of the Office of Science Technology Policy, where we provide greater detail regarding the many actions the Agency has undertaken to address scientific integrity.

Recently, the Agency has established a workgroup to revise and update the Principles of Scientific Integrity e-training course. Under the aegis of the EPA national Partnership Council, the workgroup consists of representatives from every major EPA union and several management officials. In response to advice from the OIG, the Agency will make the training mandatory for scientific and technical staff. Further, the updated course will contain real-life examples and will have links to current contact information for reporting instances of scientific and research misconduct. We expect to have the course completed by September 30, 2011.



Relevant to the subject OIG draft report, EPA is in the process of developing a new Agency-wide policy on scientific integrity. EPA has also named an Acting Scientific Integrity Official, and Deputy Scientific Integrity Officials will be established in each of the Regions and Offices. Together, these individuals will become EPA's Scientific Integrity Committee and will be responsible for overseeing scientific integrity and serving as one option (the OIG being the second) to address allegations of scientific integrity violations. EPA's Scientific Integrity Committee will also be charged with standardizing the Agency's scientific integrity training and ensuring that appropriate EPA staff members complete the appropriate training courses.

We agree with your conclusion that "periodically testing controls that ORD has in place would help assure that ORD utilizes the right control activities while striving to achieve scientific integrity." We would like to point out that ORD's Management Integrity Program has recently implemented a new risk assessment protocol. The risk assessment protocol is centered on program operations and facilitates the periodic testing of controls. These protocols may need to be augmented as the Scientific Integrity Committee and the Agency-wide policy are put into place.

Finally, in your transmittal memorandum, you state:

"This draft report is subject to revision by the OIG and, therefore, does not represent the final position of the OIG on the subjects reported."

We understand that the findings and conclusions are the premise to developing your recommendations. As required by EPA Order 2750, our written response to the final report will address any recommendations that may be included at that time. We will consider any recommendations on their own merit and, if applicable, provide a corrective action plan and/or offer alternative solutions to the report's recommendations. If you have any questions, please contact Norman Adkins at (919) 541-0872.

Attachment

cc: Arthur Elkins Paul Anastas Erin Barnes-Weaver Kevin Teichman Bill Sanders Amy Battaglia Mary Greene Norman Adkins



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APR 1 8 2011

OFFICE OF RESEARCH AND DEVELOPMENT

 Dr. John P. Holdren
Assistant to the President for Science and Technology and Director of the Office of Science and Technology Policy
Executive Office of the President
Washington, DC 20502

Dear Dr. Holdren:

In your December 17, 2010 memorandum¹ on the subject of "scientific integrity," you charged the Federal agencies with the development of policies in four areas: *foundations of scientific integrity in government, public communications, use of Federal advisory committees,* and *professional development of government scientists and engineers.* You also asked agencies to report on actions taken to "develop and implement policies" in these four areas within 120 days. This letter and its attachment are EPA's response to your request.

Science is the backbone of EPA's decision-making. Scientific integrity is central to our identity and the credibility of our work. Our ability to pursue the Agency's mission to protect human health and the environment depends upon it. The policies, decisions, guidance and regulations that impact the lives of all Americans every day are grounded, at a most fundamental level, in sound science. It is therefore the responsibility of this Agency to always conduct, utilize, and communicate science with the highest degree of honesty, integrity, and transparency to the American public.

For forty years, EPA has implemented policies that establish and uphold these principles of scientific integrity. EPA is strengthening this commitment by developing an Agency-wide scientific integrity policy to be finalized by October 15, 2011. This policy will make our historic, exemplary programs for quality, peer review, and independence even stronger and more cohesive to ensure that our scientific work is conducted in an environment that is free of political interference or suppression. The development of this policy on scientific integrity will be conducted under the same principles of transparency and openness that it aims to implement. Additionally, we will establish an Agency senior scientific integrity official to champion scientific integrity across EPA. This official will chair a standing committee of scientific integrity officials representing each EPA office. These senior-level employees will provide oversight for the implementation of scientific integrity at EPA.² We plan to designate the senior

¹ http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf

² EPA's Office of the Inspector General will maintain its independent authority to conduct research misconduct investigations as authorized by EPA Order 3120.5 (Policy and Procedures for Addressing Research Misconduct).

EPA scientific integrity official and assemble the standing committee by May 15, 2011, and develop operating procedures for the committee by June 15, 2011.

As part of our comprehensive scientific integrity policy, EPA will take the following specific actions to address the four policy areas that you outlined on December 17, 2010:

- Foundations of Scientific Integrity in Government: EPA has an existing framework of principles that was formed in collaboration with union partners of the National Partnership Council. We are updating EPA's *Principles of Scientific Integrity* and will incorporate them in our Agency-wide policy.
- **Public Communications:** EPA is currently developing formal Agency-wide policy for the communication of science and technology information by our employees. This policy will be part of our Agency-wide scientific integrity policy and will ensure accurate, transparent, and accessible communications of our science to the public. Further, while it is already current Agency practice to encourage scientists to engage with the public and media, this new policy will ensure that there are no barriers for scientists when communicating with the press and the public and reinforce our expectation that they adhere to their fields of expertise when doing so.
- Use of Federal Advisory Committees: EPA has a strong tradition of accessing external scientific expertise through the appropriate use of federal advisory committees (FACs). Following your lead, we have directed our FACs to follow procedures that are consistent with the expectations outlined in your December 17, 2010 memo. In addition, we will finalize and disseminate a new Agency-wide handbook for use by these committees and, as always, we will continue to comply with all relevant statutory and regulatory requirements.
- Professional Development of Government Scientists and Engineers: We will continue to encourage our scientists and engineers to engage and interact with the wider scientific community and will incorporate critical information about professional development incentives and opportunities in our updated scientific integrity training module.

The attached document details the Agency's current collection of policies, actions, and programs that uphold the four areas of scientific integrity. While we emphasize those that are EPA-specific, we also include some government-wide requirements that are key components of scientific integrity at EPA.

Thank you for this important opportunity to document actions that EPA has taken, is taking, and will take to implement and promote scientific integrity. If you have additional questions, please do not hesitate to contact me at 202-564-6620.

Sincerely yours, and T. Anastas

Paul T. Anastas, Ph.D. EPA Science Advisor Page 2

Attachment: Scientific Integrity at the U.S. Environmental Protection Agency

Foundations of Scientific Integrity in EPA

Ensure a Culture of Scientific Integrity

At EPA, ensuring a culture of scientific¹ integrity is central to our identity and the credibility of our work. To operate an effective research and regulatory Agency like EPA, it is essential that political officials not suppress or alter scientific or technological findings. Soon after entering office as EPA Administrator, Lisa Jackson issued the "Transparency in EPA's Operations" (23 April 2009)² memorandum to reaffirm EPA's commitment to operate "in a fishbowl" and provided guidelines for ensuring transparency in EPA's interactions with all members of the public. This was a reassertion of values that Administrator William Ruckelshaus had first articulated in his "Fishbowl Memo" (19 May 1983).³ In that memo, Administrator Ruckelshaus sought to establish a culture of integrity and openness for all employees by promising that under his leadership, EPA would operate "in a fishbowl" and "will attempt to communicate with everyone from the environmentalists to those we regulate, and we will do so as openly as possible."

To reinforce and advance the principles in the President's scientific integrity memo, Administrator Lisa Jackson issued her statement on scientific integrity, the "Compass Memo" (8 May 2009),⁴ to all EPA staff. In this communication, the Administrator stated that "Science must be the compass guiding our environmental protection decisions." Shortly afterward, in testimony before the Senate Environment and Public Works (SEPW) Committee (9 June 2009).⁵ she "pledged to uphold values of scientific integrity every day."

Furthermore, in her "Compass Memo" and SEPW testimony, Administrator Jackson described how EPA has fostered this culture of scientific integrity through its Principles of Scientific Integrity and voluntary online training for scientists and engineers. These Principles were developed with EPA's National Partnership Council (NPC), a partnership of Agency labor unions and management. Administrator Carol Browner issued the Principles on November 29, 1999, and Administrator Christine Todd Whitman reaffirmed them on July 10, 2002. The Principles of Scientific Integrity sets forth the Agency's commitment to conducting science objectively, presenting results fairly and accurately, and avoiding conflicts of interest. Currently, the Agency is working with the NPC to review, and revise if needed, the Principles of Scientific Integrity and to update our online training. The improved training will include additional information for scientists and engineers about opportunities for professional development and how EPA encourages their professional growth. When the revised online training is complete,

¹ In this document, "science" and "scientific" are expansive terms that refer to the full spectrum of the scientific process, including basic science, applied science, engineering, and technology. ² http://www.epa.gov/Administrator/operationsmemo.html

³ http://www.epa.gov/history/topics/policy/fishbowl.htm#memo

⁴ http://www.epa.gov/Administrator/scientificmemo.html

⁵ http://www.epa.gov/ocir/hearings/testimony/111_2009_2010/2009_0608_lpj.pdf

EPA staff will be encouraged to take it, whether as a refresher or for the first time, and it will be provided to new employees. In addition, as part of EPA's commitment to transparency, the training will be shared on the internet to help the public understand how EPA operates.

EPA employees are provided with mandatory annual ethics training pursuant to 5 CFR 2638 Subpart G (Executive Agency Training Programs). In addition, EPA has provided its online ethics training to more than a dozen different Federal Agencies for their use as well. This training refreshes staff on general ethics topics and focuses on a specific theme or topic of interest. Over the past several years, these focus areas have included:

- > 2010: A Window to the World: Ethics and Social Media
- > 2009: Quest for the Ultimate Ethics Treasure
- > 2008: Adventures in the House of Ethics: Misuse of Position
- > 2007: Outside Activities: Your Life Outside of EPA
- > 2006: Essential Ethics for EPA Employees
- ➤ 2005: Interacting With Contractors
- > 2004: The Hatch Act
- > 2003: Post-Government Employment
- ➢ 2002: Conflicts of Interest
- ➤ 2001: Misuse of Office & Resources

In addition to general ethics training, EPA laboratory scientific staff receive annual scientific ethical conduct training. Accredited EPA laboratories provide annual Laboratory Ethics and Data Integrity Training for scientists and engineers engaged in generating scientific data to support cleanups, enforcement, and environmental assessments. This training serves as a refresher that fulfills accreditation standards and reinforces an understanding of the laboratory ethics policy.

Strengthen the actual and perceived credibility of Government research

EPA has always been committed to using external independent consultations, including external peer review, in order to ensure the scientific integrity of its scientific work products. EPA renews this commitment in its formal scientific integrity policy and emphasizes that political interference with the scientific process or Agency scientists is not acceptable whether that interference comes from within the Agency or other parts of the Federal government.

Quality environmental information is integral to EPA's mission to protect human health and the environment. EPA has robust systems for quality and peer review to ensure that data and research used to support policy decisions are credible and high quality. EPA's Quality Policy was updated in 2008 (CIO Policy 2106.0).⁶ The Agency's Chief Information Officer (CIO) is the Senior Management Official responsible for EPA's Quality Program. EPA's Quality and Information Council (QIC), a group of cross-Agency senior managers, reviews and evaluates how well EPA is meeting its quality goals and objectives.

⁶ http://www.epa.gov/irmpoli8/policies/21060.pdf

EPA's Quality Program includes Agency-wide policies procedures, guidance and standards that enhance scientific integrity of EPA's environmental data and research results. The *Policy and Program Requirements for Mandatory Agency-wide Quality Systems* (CIO Policy 2105.0)⁷ requires EPA environmental programs to implement Quality Management Systems that comply with ANSI/E4 - 1994.⁸ The primary goal of this policy is to ensure that environmental data are of sufficient quantity and quality to support their intended use. Under this Quality Systems, EPA regional and program offices develop and implement supporting quality systems. EPA's quality requirements may also apply to contractors, grantees, and other recipients of EPA's financial assistance. EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (IQG, 2002)⁹ focus on the dissemination of products and services that are credible, reliable and reproducible with the goal of promoting openness and transparency in communicating with the public.

Following applicable EPA quality assurance and peer review policies and procedures helps to ensure that the Agency produces scientific products that are consistent with "scientific integrity criteria."¹⁰ For example, EPA's regional offices frequently make multi-million dollar permit and cleanup decisions that may face controversy and litigation. Adherence to EPA's quality assurance policies builds confidence that the information supporting these high-impact decisions are technically and legally defensible.

To assure that scientific products undergo appropriate peer review by qualified experts, EPA issued a Peer Review Policy (2006)¹¹ and *Peer Review Handbook* (2006).¹² The *Peer Review Handbook* is a how-to manual that is used by staff across EPA and is often referred to by external stakeholders as a model of good peer review practices. It should be noted that peer review is not new in the Agency, as the Agency-wide peer review policies have been in place in the Agency since 1993.¹³ The Peer Review Policy establishes EPA's policy for peer review of scientifically and technically based work products, including economic and social science products, that are intended to inform Agency decisions. It includes specific expectations for varying levels of scientific products including influential scientific information (ISI) and highly influential scientific assessments (HISA). In compliance with OMB's 2004 Final Information Quality Bulletin for Peer Review, EPA posts a Peer Review Agenda¹⁴ for its HISAs and ISIs.

In an approach that is similar to peer review, EPA's National Remedy Review Board reviews proposed Superfund response decisions at both National Priority List (NPL) and non-NPL sites for proposed actions that exceed \$25 million. In addition, some EPA regional offices

⁹ http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf

⁷http://www.epa.gov/irmpoli8/policies/21050.pdf

⁸ Later updated as ANSI/ASQ E4-2004, Quality Systems for Environmental Data and Technology Programs -Requirements with Guidance for Use, Milwaukee, Wisconsin 2004.

¹⁰ "Quality Science in the Courtroom: U.S. EPA Data Quality and Peer Review Policies and Procedures Compared to the Daubert Factors," G. M. Brilis, J. C. Worthington, A. D. Wait, *Environmental Forensics*, Vol. 1, No. 4, December 2000, pp. 197-203.

¹¹ http://www.epa.gov/peerreview/pdfs/peer_review_policy_and_memo.pdf

¹² http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf

¹³ http://www.epa.gov/peerreview

¹⁴ http://cfpub.epa.gov/si/si_public_pr_agenda.cfm

have established a parallel process for less expensive cleanups. Before completing the Record of Decision for the cleanup of a Superfund site, the Remedial Project Manager must present and defend the rationale for the recommended remedy to a regional board to ensure its soundness.

EPA's quality and peer review programs are further supported by its Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information (2003). This document describes the assessment factors and considerations generally used by the Agency to evaluate the quality and relevance of scientific and technical information. These general assessment factors are founded in the Agency guidelines, practices, and procedures that constitute EPA's information and quality systems, including existing program-specific quality assurance policies.

The Agency has in place clearly articulated policies against scientific misconduct, including inappropriate alterations of work products, in two important documents:

- Scientific Misconduct in the Conduct and Discipline Manual (EPA Order 3120.1) includes discipline guidelines for fabrication, plagiarism, misrepresentation, and causing a subordinate to engage in scientific misconduct.
- Policy and Procedures for Addressing Research Misconduct (EPA Order 3120.5) provides policy on reporting, procedures, investigations, and adjudication of research misconduct by EPA employees, contractors, and recipients of assistance agreements.

Through several cross-Agency councils, EPA has developed guidance documents for the development and application of science in specific functional areas. These guidance documents promote transparency and quality for our work products. The Council for Regulatory Environmental Modeling (CREM), a cross-Agency council of senior managers, was established to promote consistency and consensus among environmental model developers and users. The CREM developed the Guidance Document on the Development, Evaluation and Application of Environmental Models (2009).¹⁵ This guidance provides a simplified, comprehensive resource for modelers across the Agency on best modeling practices. These guidelines are intended to ensure the quality, utility, and regulatory relevance of the models that EPA develops and applies and the transparency of modeling analyses and model-based decisions. The Forum on Environmental Measurements (FEM), a standing committee of senior EPA managers, issued its Policy for Assuring the Competency of Environmental Protection Agency Laboratories in 2004.¹⁶ This FEM policy requires all Agency laboratories to maintain a Quality System and undergo independent assessments. EPA's Program in Human Research Ethics (PHRE)¹⁷ includes the Agency's Human Subjects Research Review Official, who provides review for all Agency human subjects activities. In addition, the PHRE includes the Human Studies Review Board, a federal advisory committee (FAC) that provides advice to EPA on third party human studies and other aspects of human studies research. The basic policy for EPA's protection of human subjects in research is found in 40 CFR Part 26.

¹⁵ http://www.epa.gov/crem/library/cred_guidance_0309.pdf

¹⁶ http://www.epa.gov/fem/pdfs/labdirective.pdf

¹⁷ http://www.epa.gov/phre/

The Administrator's June 2009 SEPW testimony also included details of new EPA processes that advance transparency and scientific integrity:

- EPA's new process for developing Integrated Risk Information System (IRIS) assessments is more transparent and timely, while ensuring the highest level of scientific integrity. For example, all written scientific comments received through interagency science consultation and discussion become part of the public record. To guarantee the scientific quality of IRIS assessments, the process includes the opportunity for public comment and relies on a rigorous, open, and independent external peer review. Changes in EPA's scientific judgments from public and peer reviewers' comments are documented and explained clearly to maximize the transparency of the final product.
- EPA's new process for National Ambient Air Quality Standards (NAAQS) considers the latest peer-reviewed science and the expert advice of the Clean Air Scientific Advisory Committee (CASAC)¹⁸ on the science and the standards. This 5-year process ensures timeliness, scientific integrity, and transparency. It preserves steps that contribute to these attributes, such as the kickoff workshop, the integrated review plan, and more concise, policy-relevant assessments of science, as well as risk and exposure. At the same time, because of concerns expressed by the CASAC and others, the use of an advance notice of proposed rulemaking has been discontinued. In its place, EPA staff prepare a policy assessment document. By reinstating the policy assessment document in the revised NAAQS process, EPA ensures that both the public and CASAC will be able to see, and comment on, a transparent staff analysis of the scientific basis for alternative policy options for consideration by the Administrator.

EPA has implemented appropriate whistleblower protections. Agency employees are entitled to the protections afforded to them under the Whistleblower Protection Act of 1989 and, in certain circumstances, to the employee protection provisions of certain environmental statutes. Also, the Agency's Office of the Inspector General (OIG) maintains a confidential and anonymous hotline to which employees can report known or suspected violations of law. In addition, in compliance with the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002, all EPA employees are required to take annual training designed to familiarize them with their rights under the applicable anti-discrimination and whistleblower protection laws.

Facilitate the free flow of scientific and technological information

As part of the Administration's Open Government Initiative, EPA's Office of Environmental Information (OEI) has a robust Open Government Initiative.¹⁹ OEI efforts are intended to expand and promote access to scientific and technological information by making it available online in open formats, including through the Data.gov portal. In addition, EPA continues to use conventional means of open government, including reading rooms to share final

¹⁸ The CASAC is a FACA committee consisting entirely of SGEs.

¹⁹ http://www.epa.gov/open

opinions and orders made in adjudicating cases, final statements of policy and interpretations that were not published in the Federal Register, and other materials of public interest. OEI also administers EPA's responses to requests for information under the Freedom of Information Act (EPA regulations at 40 CFR Part 2).

EPA maintains a number of publicly available databases that store environmental data including standard terminology to assist in their interpretation and models underlying our regulatory proposals and policy decisions. The Envirofacts²⁰ data warehouse contains information from many of the Agency's major programs, including air, drinking water, wastewater, solid waste, Toxics Release Inventory, Brownfields, Superfund, and compliance information. In addition, the System of Registries²¹ and System Inventory Services (SIS)²² provide users with extensive information on terminology within EPA's data systems, inventories of data systems, and other essential descriptive information on the resources.

Another example of EPA's efforts to improve transparency can be found in the CREM's Models Knowledge Base²³, an inventory of the computational models that are developed, used, and/or supported by EPA's offices. For each model, the Models Knowledge Base provides metadata on its development, conceptual basis, scientific detail and evaluation; technical requirements and how to use it; information on its inputs and outputs; and directions for downloading it and links to further information. CREM is integrating its Models Knowledge Base into SIS to streamline management of information on models.

Establish principles for conveying scientific and technological information to the public

EPA has several mechanisms for communicating scientific and technological findings to the public and the research community. The Science Inventory is a searchable database of EPA science activities conducted by EPA and through EPA-funded assistance agreements. Records in the Science Inventory provide descriptions of the activity, associated products, contact information, peer review actions, and links to available printed material and Web sites. The Science Inventory also contains EPA's Peer Review Agenda, a compilation of planned and ongoing EPA science activities and products that meet the Office of Management and Budget's peer review requirements for "influential scientific information" or "highly influential scientific assessments."

EPA's Action Development Process (ADP, 2004) provides detailed processes and procedures for the development of regulations, including the development of Analytic Blueprints that formalize scientific input at the beginning of the process. In addition, we wish to explore approaches that may better distinguish science and policy judgments in proposed rules.²⁴ This

²⁰ http://www.epa.gov/enviro

²¹ http://iaspub.epa.gov/sor_internet/registry/sysofreg/home/overview/home.do

²² http://iaspub.epa.gov/sor_internet/registry/systmreg/home/overview/home.do

²³ http://www.epa.gov/crem/knowbase/index.htm

²⁴ To that end, a recommendation of the *Final Report from the Science for Policy Project* (Bipartisan Policy Center, August 2009, http://www.bipartisanpolicy.org/library/report/science-policy-project-final-report) is being considered. It states that agencies should develop guidance "to ensure that when ... developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy."

development of risk information for the regulatory process is supported by EPA's Guidance for Risk Characterization²⁵ and Risk Characterization Handbook.²⁶ The Guidance contains principles for developing and appropriately characterizing risk in EPA's assessments. The Handbook presents technical approaches that promote scientific integrity by ensuring that critical information from each stage of risk assessment is used to form conclusions. When used together with the ADP, these documents encourage an accurate presentation of risk science information to inform decisionmaking.

Public Communications

EPA is currently developing formal Agency-wide guidance for the communication of science and technology information by our employees. This guidance will be part of our Agency-wide scientific integrity policy and will ensure accurate, transparent, and accessible communications of our science to the public. Further, while it is current Agency practice to allow scientists access to the media, this new guidance will both ensure that there are no barriers for scientists when communicating with the press and the public and reinforce our expectation that they adhere to their fields of expertise when doing so.

Use of Federal Advisory Committees

At EPA, FACs are overseen by the Office of Federal Advisory Committee Management and Outreach (OFACMO) with legal support from the Office of General Counsel. All EPA FACs comply with the requirements of the Federal Advisory Committee Act (5 USC App. 2) and the regulations issued by the General Services Administration (GSA) (41 CFR Part 102-3). In addition, EPA's scientific FACs have been directed to follow procedures that are consistent with the policy expectations of the December 17, 2010, memo. OFACMO is finalizing a new Agency-wide guidance manual and a ten-chapter FACA Handbook for use by FACA committees.

EPA adheres to current standards governing conflict of interest as defined in statute and implementing regulations. The Office of General Counsel Ethics Office oversees the procedures for Special Government Employees (SGEs) who serve on scientific FACs. These procedures include the Confidential Financial Disclosure Form for SGEs serving on Advisory Committees (EPA Form 3110-48), EPA Ethics Advisory 08-02: "Ethics Obligations for Special Government Employees," and an online Office of Government Ethics course available on the internet. In addition, the 2009 Addendum to EPA's *Peer Review Handbook* entitled: "Appearance of a Lack of Impartiality in External Peer Reviews,"²⁷ provides an elucidation of the regulatory definition of "appearance of a lack of impartiality" for individuals who serve on peer review panels, criteria for applying this definition, and illustrative examples.

²⁵ http://www.epa.gov/spc/pdfs/rcguide.pdf

²⁶ http://www.epa.gov/spc/pdfs/rchandbk.pdf

²⁷ http://www.epa.gov/peerreview/pdfs/spc_peer_rvw_handbook_addendum.pdf

Professional Development of Government Scientists and Engineers

Professional development of the Agency's scientists and engineers is critical to maintaining and enhancing the high quality of our EPA staff. To this end, the Agency has a host of policies that promote and facilitate, as permitted by law, the professional development of EPA scientists and engineers.²⁸ In particular, scientists and engineers in ORD and other EPA offices are encouraged to publish their research findings in peer-reviewed journals and to present their research findings at professional meetings. We take pride in our exceptional staff and their accomplishments in the external scientific community. Currently many EPA staff participate in scientific societies as presenters, peer reviewers, session and conference chairs, and officers. For example, in March 2011 more than 100 EPA scientists participated in the Society of Toxicology's annual meeting in Washington DC.

EPA scientists and engineers are allowed to receive honors and awards for their research and discoveries. EPA encourages its scientists and engineers to be part of the external science and engineering enterprise and wants them to accrue the professional benefits of such honors and awards. However, it is important to note certain ethical restrictions and limitations that may apply to these external honors and awards.²⁹

²⁸ In accordance with EPA Ethics Advisory 92-04, the Agency encourages employees to participate and hold office in professional societies and associations, subject to applicable conflict of interest considerations. With regard to Government scientists and engineers serving as editors or editorial board members of journals or in positions of responsibility within professional or scholarly societies, some clarification of the December 17, 2010 Holdren memo may be required. If the employee has fiduciary interest in the organization, the goal in the memo may conflict with ethics rules for Federal scientists. EPA cannot appoint anyone to serve in their official capacity in an organization where they have a fiduciary duty except where specific statutory authority exists (e.g., 20 USC 5590(b)(1)(B) that directs the Administrator to appoint the Director of the Office of Environmental Education as an "ex-officio member" of the Board of Directors of the Environmental Education Foundation). Otherwise, unless a waiver is obtained, it is a conflict of interest under 18 USC 208 for Federal employees to serve in their official capacities in a position where there is a fiduciary duty. Generally speaking, serving on an editorial board or as journal editor would not be considered to be positions with fiduciary duties. However, serving as an officer or on the board of directors of an organization would often be considered positions with fiduciary duties. It should also be noted that Government employees may serve in their personal capacities in organizations even when they have a fiduciary role. However, in these cases the interests of the organization would be imputed to the employee. As such, the employee would have a conflict of interest concerning the organization that could be waived subject to

provisions under 18 USC 208. ²⁹ At EPA, as for the Federal government in general, honors and awards are considered "gifts from outside sources" that are regulated by the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR Part 2635 204(d)). These gifts are limited to an aggregate market value of \$200 if such gifts are a *bona fide* award or incident to a *bona fide* award that is given for meritorious public service or achievement by a person who does not have interests that may be substantially affected by the performance or nonperformance of the employee's official duties or by an association or other organization the majority of whose members do not have such interests. There is one exception: "Awards and Honorary Degrees" can permit gifts from outside sources with an aggregate market value in excess of \$200 (*e.g.*, Nobel Prize) may be accepted upon a written determination by an agency ethics official that the award is made as part of an established program of recognition. Similarly, an employee may accept an honorary degree from an institution of higher education based on a written determination by an agency ethics official that the timing of the award of the degree would not cause a reasonable person to question the employee's impartiality in a matter affecting the institution.

In addition, EPA provides internal and government-wide awards for its scientists and engineers, including the Science Achievement Awards (SAA), the Scientific and Technological Achievement Awards (STAA), and the Presidential Early Career Award for Scientists and Engineers (PECASE). As part of EPA's honor award program, the SAA recognize scientists and engineers who have excelled in their disciplines. Nominations are sought for EPA employees who have excelled in a scientific area related to environmental protection, including: air quality, biology/ecology, chemistry, earth sciences, engineering, health sciences, waste management, water quality, and environmental economics. The awards are given in conjunction with the appropriate professional society that participates in the selection process. The STAA awards are selected by a FACA panel established by EPA's Science Advisory Board so that this internal award is determined by independent experts. PECASE awardees are selected for their pursuit of innovative research at the frontiers of science and technology and their commitment to community service as demonstrated through scientific leadership, public education, or community outreach.

Through the Federal Technology Transfer Act (FTTA, 1986), EPA scientists and engineers can collaborate with their external peers. The FTTA (15 USC 3701 to 3716) provides incentives for the transfer of technologies developed in Federal government laboratories to private industry. At EPA, the FTTA program promotes collaboration between private and federal researchers. Staff from EPA's FTTA program and OGC provide on-site training and one-on-one visits with Agency scientists to explain and encourage patenting. The FTTA external partners benefit from Cooperative Research and Development Agreements (CRADA) by tapping into EPA's resources and knowledge base to conduct joint research and technology commercialization. At any given time, EPA's FTTA program has approximately 100 active CRADAs.

Each year about ten new patents are issued to EPA scientists. Under the FTTA, U.S. government agencies are required to pay the employee(s)-inventor(s) at least 15% of the royalties the agency receives under any licensing agreement (the remaining 85% goes to the government lab). EPA exceeds this requirement by giving 35% to the employee(s)-inventor(s) (and 65% to the government lab).