



U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Audit Report

Office of Research and Development Should Increase Awareness of Scientific Integrity Policies

Report No. 11-P-0386

July 22, 2011



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Abbreviations

EPA	U.S. Environmental Protection Agency
GAO	U.S. Government Accountability Office
NPC	National Partnership Council
OIG	Office of Inspector General
ORD	Office of Research and Development
OSTP	Office of Science and Technology Policy
STPC	Science and Technology Policy Council

Cover photo: Analysis performed at the Cincinnati Laboratory. (EPA photo)

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At a Glance

Catalyst for Improving the Environment

Why We Did This Review

The U.S. Environmental Protection Agency (EPA), Office of Inspector General, initiated this review to determine the process EPA uses to address scientific/research misconduct. Specifically, we sought to determine whether EPA's Office of Research and Development (ORD) has controls to address scientific integrity and research misconduct, and whether those controls are effective.

Background

Since 2000, a number of federal and EPA policies on ensuring the integrity of government science have been issued. ORD is EPA's lead office for integrating science into environmental protection policies. EPA Order 3120.5 implements the federal policy on research misconduct, and ORD and others formulated the *Principles of Scientific Integrity* and the Principles of Scientific Integrity E-Training to further highlight professional ethics for EPA scientists.

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

The full report is at:
www.epa.gov/oig/reports/2011/20110722-11-P-0386.pdf

Office of Research and Development Should Increase Awareness of Scientific Integrity Policies

What We Found

ORD has internal controls that include policies, procedures, training, and peer review. However, ORD should improve how it evaluates the effectiveness of its policies and procedures for scientific integrity and research misconduct. Currently, ORD does not test its policies and procedures because ORD asserts that few reported instances of misconduct means that it generally does not occur. However, few identified instances of research misconduct could signal that staff lacks awareness of key criteria and reporting requirements necessary to identify and report misconduct.

We issued an electronic survey to 1,371 ORD science staff and received 488 responses. We found that 65 percent of respondents were unaware of EPA Order 3120.5, and 32 percent were unaware of EPA's *Principles of Scientific Integrity*. We also found that ORD has not updated the Principles of Scientific Integrity E-Training since June 2005. The existing e-training is not mandatory for ORD staff and does not include actual examples to aid understanding by training participants. Those who have not completed the training may be unaware of key criteria regarding scientific integrity. To facilitate reporting of research misconduct, ORD should increase awareness of the process. Without these additional internal control efforts, ORD risks having its science called into question, potentially lessening the credibility of its work.

What We Recommend

We recommend that the Assistant Administrator for Research and Development periodically test the effectiveness of controls in place to address scientific integrity and research misconduct. We also recommend that ORD work with EPA offices to initiate outreach on EPA Order 3120.5 to raise awareness on roles/responsibilities and reporting steps, and to identify EPA staff and managers who should complete the Principles of Scientific Integrity E-Training. Lastly, we recommend that ORD continue to work with unions to update and implement e-training. Such updates should include making the e-training mandatory for all ORD staff, ensuring that the updated course contains actual examples, and creating a system for maintaining current contact information for reporting instances of scientific integrity and research misconduct. ORD agreed with our recommendations and subsequently followed up with its corrective action plan. We have reviewed the corrective action plan and milestone dates, and found them acceptable. As such, we are closing this report upon issuance, and no further response is required.



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

THE INSPECTOR GENERAL

July 22, 2011

MEMORANDUM

SUBJECT: Office of Research and Development Should Increase
Awareness of Scientific Integrity Policies
Report No. 11-P-0386

FROM: Arthur A. Elkins, Jr.
Inspector General

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

TO: Paul Anastas
Assistant Administrator for Research and Development

This is our report on the subject audit conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents 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.

The estimated direct labor and travel costs for this report are \$266,685.

Action Required

On July 7, 2011, your office provided its response and subsequently provided its corrective action plan. We have reviewed the corrective action plan and milestone dates, and found them acceptable. As such, we are closing this report upon issuance, and no further response is required. Your response will be posted on the OIG's public website, along with our memorandum commenting on your response. We have no objections to the further release of this report to the public. 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 Melissa Heist, Assistant Inspector General for Audit, at (202) 566-0899 or heist.melissa@epa.gov; or Patrick Gilbride, Director, Risk Assessment and Program Performance Audits, at (303) 312-6969 or gilbride.patrick@epa.gov.

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Chapter 1

Introduction

Purpose

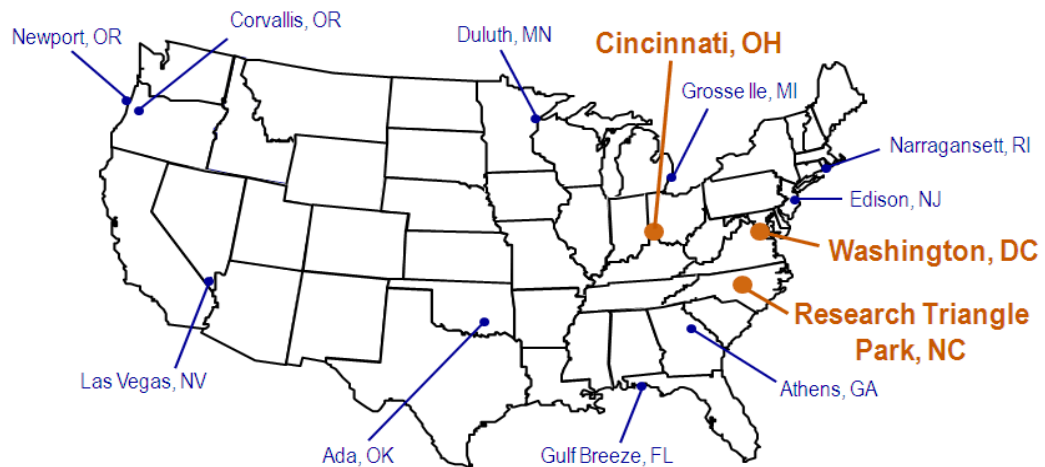
We sought to determine the process the U.S. Environmental Protection Agency (EPA) uses to address issues related to scientific integrity and research misconduct. Because the Office of Research and Development (ORD) leads integrating science into environmental protection policies within EPA, we focused on ORD using the following objectives:

- Does ORD have controls to address scientific integrity and research misconduct?
- How effective are the controls ORD has in place to address scientific integrity and research misconduct?

Background

ORD is EPA's lead office for the production, review, and integration of scientific and technical knowledge into environmental protection policies and regulations. ORD conducts work within its labs, centers, and offices. ORD is headquartered in Washington, DC, and has laboratories and centers across the country, with its main research facilities in Ohio and North Carolina (figure 1). ORD's enacted fiscal year 2011 budget was \$582.1 million, authorizing 1,907.2 full-time staff.

Figure 1: ORD's locations



Source: ORD intranet site (accessed May 2011).

History of Policies on Scientific Integrity and Research Misconduct

In 2000, EPA's National Partnership Council (NPC)¹ developed the *Principles of Scientific Integrity* as a policy statement establishing a set of professional ethics for EPA scientists. The EPA Administrator promulgated the *Principles of Scientific Integrity* on March 28, 2000. They state:

It is essential that EPA's scientific and technical activities be of the highest quality and credibility if EPA is to carry out its responsibilities to protect human health and the environment. Honesty and integrity in its activities and decision-making processes are vital if the American public is to have trust and confidence in EPA's decisions.

The *Principles of Scientific Integrity* require all employees to:

- Ensure that their work is of the highest integrity
- Represent their own work fairly and accurately
- Represent and acknowledge the intellectual contributions of others
- Avoid financial conflicts of interest and ensure impartiality
- Be cognizant of and understand the specific programmatic statutes
- Accept the affirmative responsibility to report any breach
- Welcome differing views and opinions on scientific and technical matters

On December 6, 2000, the Executive Office of the President issued the government-wide Federal Policy on Research Misconduct. The Federal Policy on Research Misconduct applies to all federally funded and conducted research and research proposals. The Federal Policy on Research Misconduct required all federal agencies that conduct or support research to implement the policy by December 6, 2001.

On March 18, 2003, EPA implemented its Policies and Procedures for Addressing Research Misconduct through EPA Order 3120.5. The order defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results; or ordering, advising or suggesting that subordinates engage in research misconduct. EPA Order 3120.5 applies to all research conducted, sponsored, or funded, in whole or in part, by EPA (including research done by EPA contractors), as well as to research proposals submitted to EPA. The order applies to all Agency employees, contractors, and recipients of assistance agreements. The order directs each to

¹ According to its charter, the NPC promotes implementation of partnership concepts throughout the Agency to investigate, study, discuss, and propose solutions to the Administrator on a wide range of issues affecting EPA employees, or to make specific decisions when delegated authority to do so by the Administrator. The NPC comprises one officer from each local union that represents EPA bargaining unit employees, the president of any national councils having exclusive recognition in EPA, and a group of senior management officials designated by the Administrator.

report allegations to the appropriate EPA staff and/or management, and to the OIG under certain conditions.² While EPA retains the ultimate oversight authority for EPA-supported research, research entities bear primary responsibility for preventing and detecting research misconduct.

In June 2005, EPA's NPC developed the Principles of Scientific Integrity E-Training to acquaint EPA's professional scientists with the details and implications of the *Principles of Scientific Integrity*. ORD played a major role in assisting the NPC's development of the *Principles of Scientific Integrity* and the e-training.

On March 9, 2009, the President signed the "Memorandum for the Heads of Executive Departments and Agencies—Scientific Integrity." The memorandum directed the President's Office of Science and Technology Policy (OSTP) to "develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch."

EPA responded to the President's memorandum on May 9, 2009. In the memorandum, "Scientific Integrity: Our Compass for Environmental Protection," the EPA Administrator asked EPA's Science Policy Council³ to strengthen policies and procedures that ensure scientific integrity within the Agency, including:

- Inventorying all of EPA's guidelines and policies that relate to scientific integrity to look for gaps and possible areas for improvement
- Updating and reaffirming EPA's *Peer Review Handbook* and recommending how to improve implementation of peer review policies across programs and regions
- Working with the NPC to reaffirm the Agency's *Principles of Scientific Integrity* and update the e-training.

On December 17, 2010, the director of OSTP issued a memorandum to guide executive departments and agencies in implementing the Administration's policies on scientific integrity. OSTP's memorandum outlined five areas:

1. Foundations of Scientific Integrity in Government
2. Public Communications
3. Use of Federal Advisory Committees

² EPA OIG must be notified immediately of any allegation of research misconduct that involves the following: public health or safety is at risk, agency resources or interests are threatened, circumstances where research activities should be suspended, there is a reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the investigation, the research entity believes that the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved, and circumstances where the research community or public should be informed.

³ EPA established the Science Policy Council in 1993 and reconstituted it in 2010 as the Science and Technology Policy Council (STPC). The STPC serves as a mechanism for addressing EPA's many significant science policy issues that go beyond regional and program boundaries. The STPC is chaired by the Science Advisor to the Agency (ORD's Assistant Administrator) and comprises senior managers from EPA programs and regions.

4. Professional Development of Government Scientists and Engineers
5. Implementation

The memorandum directed all agencies to report within 120 days the actions taken to develop and implement policies on scientific integrity. EPA responded to this memorandum on April 18, 2011 (see “Noteworthy Achievements” section).

Internal Control Standards

A November 1999 report by the U.S. Government Accountability Office (GAO), *Standards for Internal Control in the Federal Government*, defines “internal control” as an integral component of an organization’s management that provides reasonable assurance of effective and efficient operations and compliance with applicable laws and regulations. Office of Management and Budget Circular A-123 (revised 2004) provides corresponding goals, stating, among other matters, that agency managers take timely and effective action to correct internal control deficiencies. As GAO recognized, an internal control comprises the plans, methods, and procedures used to meet missions, goals, and objectives and, in doing so, supports performance-based management. Internal control is not one event, but a series of actions and activities that occur throughout an entity’s operations and on an ongoing basis. In this sense, internal control is management control built into the entity to help managers achieve their aims on an ongoing basis. GAO identified five internal control standards (table 1).

Table 1: GAO’s Standards for Internal Control in the Federal Government

Control Environment	This establishes and maintains an environment throughout the organization that sets a positive and supporting attitude toward internal control and conscientious management. This includes establishing goals, objectives, and performance measures at the entity and activity level.
Risk Assessment	A precondition to risk assessment is the establishment of clear, consistent agency objectives. The internal control risk assessment process includes assessing risks the agency faces from both internal and external sources. Managers need to comprehensively identify risks and should consider all significant interactions between the entity and other parties as well as internal factors at both the entity-wide and activity levels.
Control Activities	These are policies, procedures, techniques, and mechanisms that implement management’s direction to achieving goals. These help ensure that management’s directives are carried out.
Information and Communication	This includes data and information (performance and financial) to determine whether the organization meets its goals and objectives and maintains accountability over resources.
Monitoring	This assesses the quality of performance over time and ensures that audits and other review findings are promptly resolved.

Source: OIG’s summary of GAO’s *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1, November 1999.

All EPA organizations are required to develop and implement a systematic strategy for reviewing internal controls. These reviews provide managers and

employees reasonable assurance that their programs operate effectively and efficiently. It is important for a science organization such as ORD to have internal controls to ensure adequate review and action on its research products and those produced by others receiving EPA funds.

Noteworthy Achievements

ORD developed an ad hoc committee to work with the Science and Technology Policy Council (STPC) to respond to OSTP's December 17, 2010, memorandum. EPA's April 18, 2011, response stated that the Agency would strengthen its commitment to scientific integrity by developing an Agency-wide scientific integrity policy by October 15, 2011. The response also said that EPA would establish a senior scientific integrity official to champion scientific integrity across EPA and form a standing committee of officials representing each EPA office. EPA's response also emphasized Agency activities in four areas: foundations of scientific integrity in government, public communications, use of federal advisory committees, and professional development of government scientists and engineers. Additionally, ORD continues to work with the NPC and employee unions to update the e-training and believes that the e-training could serve as a best practice for other agencies.

ORD has an extensive process for peer review that addresses both internal and external peer reviews, as well as conflicts of interest. EPA believes that its peer review process can function as a model for other federal agencies. According to the *Peer Review Handbook*, the peer review process helps the Agency ensure that it bases decisions or positions on credible science products.

Lastly, to address internal-control-related program risks, ORD stated that it recently implemented a risk assessment protocol for its labs, centers, and offices. The protocol included scientific integrity as one potential risk category and asked respondents to address the likelihood of risk events that compromise scientific integrity and actions to mitigate risks. ORD plans to complete an office-wide risk assessment by August 31, 2011.

Scope and Methodology

We conducted our work from July to October 2010 and from February to June 2011⁴ in accordance with generally accepted government auditing standards. Those standards require that we plan and perform our review to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions.

⁴ We suspended our work from October 2010 until February 2011, for a total of 120 days, to address a higher-priority assignment.

To address our first objective, we reviewed policies, procedures, and guidance on scientific integrity and research misconduct. We also interviewed EPA staff to determine the number of allegations of misconduct and internal controls in place to mitigate allegations. Specifically, we interviewed OIG hotline and investigations staff, ORD staff and managers, and EPA union representatives.

To address our second objective, we compared controls EPA had in place against those of other science agencies, such as the National Science Foundation, the U.S. Department of Health and Human Services, the U.S. Department of the Interior, and the National Oceanic and Atmospheric Administration. We also discussed various control activities with ORD managers.

We also issued an electronic survey to 1,371 ORD staff to better understand how many instances of research misconduct staff reported, as well as to gauge staff awareness of key scientific integrity criteria and reporting requirements. We received 488 responses, for a response rate of over 35 percent.⁵ We analyzed survey results to address our objectives. Appendix A contains our blank survey instrument, and appendix B provides summary survey results by question.

Prior Audit Coverage

We reviewed two EPA OIG reports issued in 2009, as well as a U.S. Department of the Interior OIG report issued in 2010:

- In *No Violations Found Regarding Removal of Comments from an External Peer Review*, Report No. 09-P-0084, issued January 16, 2009, the EPA OIG Office of Counsel found that EPA did not violate existing federal law or guidance when it removed comments from a peer-reviewed report and published an explanatory message in the report and online.
- In *EPA Can Improve Its Process for Establishing Peer Review Panels*, Report No. 09-P-0147, issued April 29, 2009, the EPA OIG determined that, although laws, regulations, guidance, and other relevant requirements governing EPA's peer review process are adequate to produce objective scientific review, EPA could improve in some areas.
- In *Interior Lacks a Scientific Integrity Policy*, Report No. WR-EV-MOA-0014-2009, issued April 28, 2010, the U.S. Department of the Interior OIG found that Interior had no comprehensive scientific integrity policy to consistently address scientific misconduct allegations. The report found that all Interior bureaus but one lacked wide-ranging scientific integrity policies or procedures to track allegations of scientific misconduct.

⁵ Given the anonymous nature of our survey and the length of time the survey was available, respondents could have potentially submitted more than one survey. We did not address this possibility in our analysis.

Chapter 2

Opportunities Exist for ORD to Better Address Scientific Integrity and Research Misconduct

Although ORD has internal controls in place, it should improve the way in which it evaluates the effectiveness of its policies and procedures for scientific integrity and research misconduct. Currently, ORD does not test its policies and procedures because ORD asserts that few reported instances of misconduct means that it generally does not occur. However, few identified instances of research misconduct could signal that staff lacks awareness of key criteria and reporting requirements necessary to identify and report misconduct. Our electronic survey of 1,371 ORD science staff found—that out of 488 responses—65 percent of respondents were unaware of EPA Order 3120.5, and 32 percent were unaware of EPA’s *Principles of Scientific Integrity*. In addition, ORD has not updated the Principles of Scientific Integrity E-Training since June 2005. The existing e-training is not mandatory for ORD staff and does not include actual examples to aid understanding by training participants. Those who have not completed the training may be unaware of key criteria regarding scientific integrity. To facilitate reporting of research misconduct, ORD should increase awareness of the process as well as ensure the confidentiality of those ORD staff who report alleged instances to managers or supervisors. Without these additional internal controls, ORD risks having its science called into question, potentially lessening the credibility of its work.

ORD Has Controls in Place to Address Scientific Integrity but Does Not Test Them

ORD has controls in place to address internal control standards, such as:

Control Environment

- Culture and commitment to integrity
- EPA Order 3120.5
- *Principles of Scientific Integrity*
- *Peer Review Handbook*

Monitoring

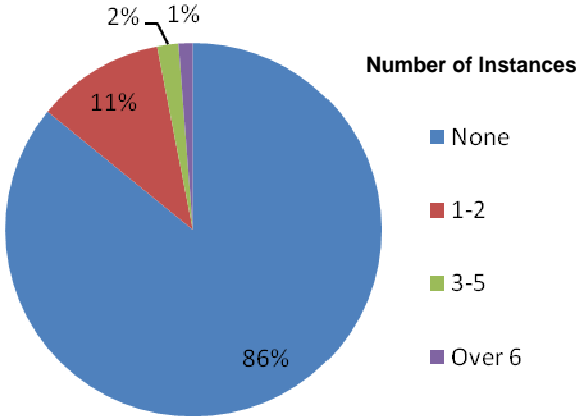
- Rigorous internal peer review
- External peer review

Information and Communication

- Principles of Scientific Integrity E-Training

ORD believes the controls put in place have resulted in few instances of misconduct. Indeed, in fiscal year 2010, the OIG hotline received 5 allegations of lab, scientific, or research fraud out of 514 formal hotline referrals. Moreover, our electronic survey of 1,371 ORD science staff found—that of 488 responses—14 percent of respondents had knowledge of an instance of research misconduct in the past 5 years, with 11 percent reporting one to two instances (figure 2).

Figure 2: Number of instances of research misconduct reported by respondents



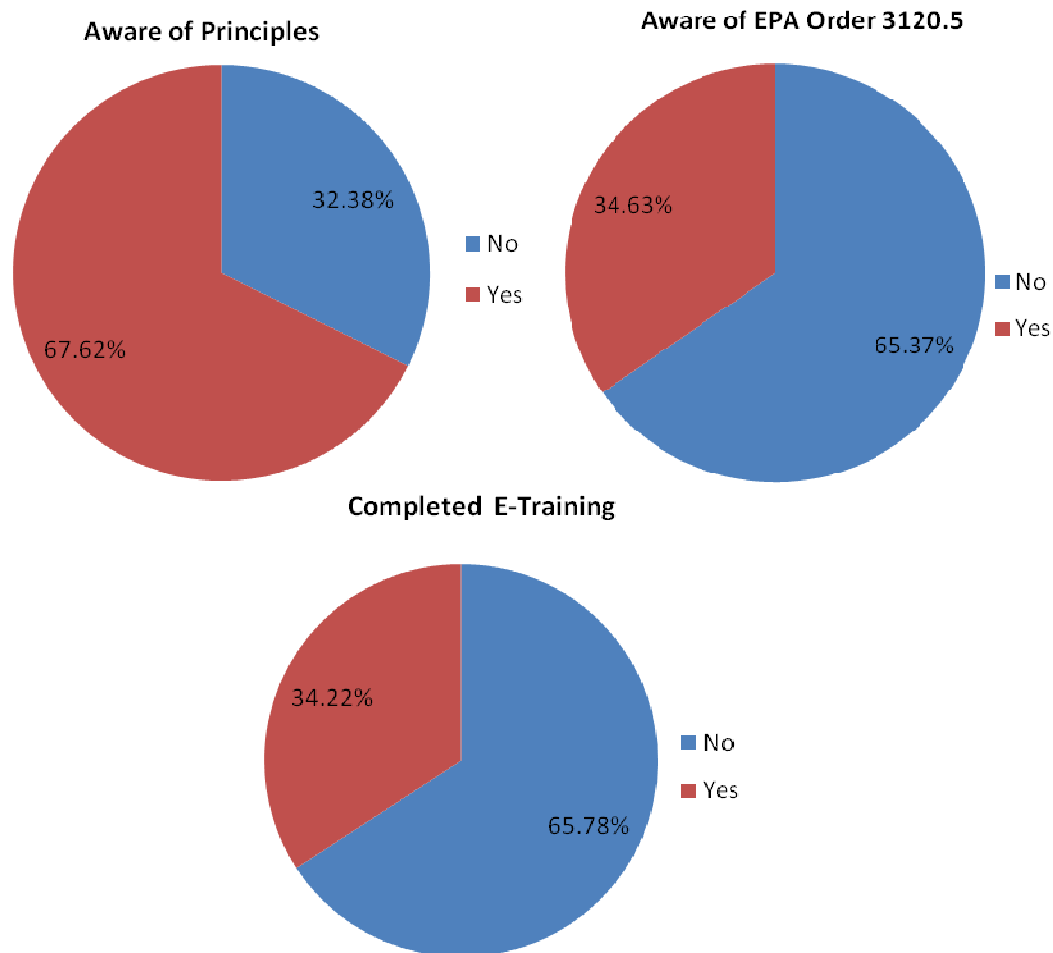
Source: EPA OIG survey results.

However, ORD cannot assert with certainty the effectiveness of controls because ORD does not test its controls. ORD should periodically test controls to ensure staff awareness of how to identify and report instances of research misconduct. Testing controls will help ensure ORD’s research is of the highest quality.

ORD Staff Unaware of Key Criteria and Reporting Requirements

Overall, our electronic survey results demonstrated that many respondents were unaware of key criteria intended to help them identify and report instances of research misconduct, and were also unaware of reporting requirements. Figure 3 illustrates that 32 percent of survey participants were unaware of EPA’s *Principles of Scientific Integrity*, 65 percent were unaware of EPA Order 3120.5, and 66 percent did not complete the e-training. Appendix B provides a summary of survey results by question.

Figure 3: Levels of awareness of key criteria and training completion



Source: EPA OIG survey results.

In the final section of our survey, we asked for additional feedback and allowed participants to share comments or concerns. The following recurring narrative responses may explain the low number of reported instances:

- Uncertainty regarding steps to take to report an instance
- Fear of retaliation or that managers and supervisors will not maintain confidentiality
- Need for better or additional formal training or outreach on scientific integrity and research misconduct

This feedback demonstrates the importance of testing the effectiveness of controls ORD has in place to help staff identify and report allegations related to scientific integrity and research misconduct. ORD’s Deputy Assistant Administrator for Science has committed to addressing our survey results by raising staff awareness of criteria and reporting requirements.

Principles of Scientific Integrity E-Training Should Be Updated and Mandatory

In her May 2009 memorandum on scientific integrity, the EPA Administrator tasked the STPC to work with the NPC to update the Principles of Scientific Integrity E-Training. Although the NPC in turn directed EPA's unions and ORD to update the e-training, it has not been updated since its creation in June 2005.

Narrative responses to our survey question inviting ORD staff to provide comments related to the e-training included staff:

- Not remembering whether they took the course
- Being unaware of the existence of the e-training or having no recollection of being asked to take the training
- Not remembering the e-training course content

In 2010, ORD formed the Principles of Scientific Integrity Workgroup, consisting of EPA union and management representatives, to update the e-training. Since its inception, the workgroup has met twice via teleconference to discuss updates to the e-training. As part of this process, ORD will work with EPA Office of General Counsel Ethics Program staff and the Office of Administration and Resources Management Labor and Employee Relations staff to update contact lists that staff would use to report instances of scientific integrity or research misconduct.

An ORD senior advisor indicated that the primary purpose of the e-training course is to provide scientists and engineers with contact information should they experience or identify instances of scientific integrity or research misconduct. However, the e-training summary/certificate screen links to outdated EPA union and OIG contact information. However, that screen also contains a link that takes the trainee directly to the Office of General Counsel Ethics Program updated webpage that lists current contact information for EPA Ethics Officials. As the workgroup updates the e-training, it should consider linking directly to updated web pages with current union representative and OIG contact information, as it does for contact information for EPA's ethics officials.

The currently available 2005 version of the e-training includes a discussion of the *Principles of Scientific Integrity*, and contains a section on "Misconduct: Violations of the Principles of Scientific Integrity." However, since the current e-training is not mandatory for ORD staff, those who do not complete the e-training may be unaware of available internal control guidance for scientific integrity issues, such as the *Principles of Scientific Integrity* or EPA Order 3120.5. Making the e-training mandatory for appropriate ORD staff would clearly connect staff to the e-training as well as increase staff awareness of scientific integrity guidance.

The workgroup should also add actual examples of misconduct into the e-training to aid participants' understanding and to make the training more meaningful. The National Science Foundation OIG takes this approach by combining civil/criminal criteria with actual stories, and it posts completed case summaries on-line as educational materials. The workgroup should also consider more formal training in addition to the e-training format;⁶ however, one workgroup member emphasized that online training can potentially reach more attendees.

ORD management estimates that the workgroup will complete its updates to the e-training by July 2012. At that point, ORD will submit the updated e-training for concurrent review and approval by the NPC's executive committee and the STPC. ORD hopes to offer the updated e-training to ORD staff by September 2012. The workgroup should consider the narrative responses to our electronic survey when updating the e-training.

Conclusion

Periodically testing its controls would help assure that ORD utilizes the right control activities while striving to achieve scientific integrity. Further, raising awareness of key criteria and updating the e-training will help strengthen ORD's internal control environment to address instances of research misconduct. These efforts could improve the credibility of ORD's scientific research.

Recommendations

We recommend that the Assistant Administrator for Research and Development:

1. Periodically test the effectiveness of controls to address scientific integrity and research misconduct.
2. Work with Agency offices to:
 - a. Initiate proactive outreach on EPA Order 3120.5 to raise awareness of roles/responsibilities and reporting steps.
 - b. Identify staff and managers outside of ORD who should complete mandatory Principles of Scientific Integrity E-Training.
3. Continue working with the unions to update and implement the Principles of Scientific Integrity E-Training. Changes to the course should include:
 - a. Making the e-training mandatory for all ORD staff.

⁶The National Science Foundation OIG considers online training to be an inappropriate delivery format for such an important subject as research misconduct and believes that formal, in-class training represents the best method for communicating how to address instances of scientific integrity and research misconduct.

- b. Ensuring that the updated course contains real-life examples.
- c. Creating a system for linking to current contact information for reporting instances of scientific integrity and research misconduct.

Agency Comments and OIG Evaluation

ORD agreed with our recommendations and noted many steps it has already taken to enhance scientific integrity at the Agency. Examples of how EPA addresses scientific integrity include mandatory ethics training, quality systems requirements, a peer review policy and *Peer Review Handbook*, and establishing cross-Agency councils such as EPA's STPC.

In response to our review, the Agency will make the Principles of Scientific Integrity E-Training mandatory for scientific and technical staff. The updated course will contain real-life examples and will have links to current contact information for reporting instances of scientific and research misconduct. ORD expects to have the course content completed by July 2012 and training completed by September 2012.

EPA is also in the process of developing a new Agency-wide policy on scientific integrity. EPA has named an acting scientific integrity official and will establish deputy scientific integrity officials in each of the regions and offices. The Agency noted that these individuals will together become EPA's Scientific Integrity Committee, responsible for overseeing scientific integrity, and will serve as one option (the OIG being the other) to address allegations of scientific integrity violations.

ORD agreed with our conclusion regarding periodically testing its controls and noted that the 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 Agency puts the Scientific Integrity Committee and the Agency-wide policy into place.

We believe ORD's planned corrective actions address the intent of our recommendations. Appendix C includes ORD's full response.

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	11	Periodically test the effectiveness of controls to address scientific integrity and research misconduct.	O	Assistant Administrator for Research and Development	12/31/2012		
2	11	Work with Agency offices to: <ul style="list-style-type: none"> a. Initiate proactive outreach on EPA Order 3120.5 to raise awareness of roles/responsibilities and reporting steps. b. Identify staff and managers outside of ORD who should complete mandatory Principles of Scientific Integrity E-Training. 	O	Assistant Administrator for Research and Development	12/31/2011		
3	11	Continue working with the unions to update and implement the Principles of Scientific Integrity E-Training. Changes to the course should include: <ul style="list-style-type: none"> a. Making the e-training mandatory for all ORD staff. b. Ensuring that the updated course contains real-life examples. c. Creating a system for linking to current contact information for reporting instances of scientific integrity and research misconduct. 	O	Assistant Administrator for Research and Development	09/30/2012		

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

Survey Instrument



SCIENTIFIC INTEGRITY AND RESEARCH MISCONDUCT SURVEY



Our intent is to determine the effectiveness of Agency policies and procedures in place to help EPA staff identify and report instances/allegations related to **scientific integrity** and **research misconduct**.

If necessary, click on the twistie (▶) next to each section heading to access the questions. Please answer each question in the space provided. Your responses may trigger secondary questions. All survey questions in Sections I and II are mandatory, but associated text input responses are optional. This survey must be completed in its entirety once the survey is started and should take approximately 15 minutes to complete. When you have completed the survey and pressed the "Submit Survey" button (as part of Section IV), the completed survey will be sent to the Office of Inspector General and the survey database will close.

Section I: Respondent Information

The following information is for OIG purposes only and will remain confidential.

1. What is your current grade level?

- GS-7/9
- GS-11/12
- GS-13
- GS-14/15
- SES
- Title 42 Appointee

2. How long have you worked for EPA's Office of Research and Development (ORD)?

- Less than 1 year
- 1-2 years
- 3-5 years
- 6-9 years
- 10-20 years
- 21+ years

3. Which of the following best describes your current job function?

- Manager
- Manager with research responsibilities
- Supervisor
- Supervisor with research responsibilities
- Research Scientist
- Research Assistant
- Other

i. (Please specify [max 1,000 characters])

4. In which job series is your current position listed?

- 0028 - Environmental Protection Specialist
- 0400 - Natural Resources Management and Biological Sciences
- 0800 - Engineering and Architecture
- 1300 - Physical Sciences
- 1500 - Mathematics and Statistics
- Other

i. (Please specify [max 1,000 characters])

5. Current Lab, Center, or Office?

- Immediate Office of the Assistant Administrator (IOAA)
- National Center for Computational Toxicology (NCCT)
- National Center for Environmental Assessment (NCEA)
- National Center for Environmental Research (NCER)
- National Exposure Research Laboratory (NERL)
- National Health and Environmental Effects Research Laboratory (NHEERL)
- National Homeland Security Research Center (NHSRC)
- National Risk Management Research Laboratory (NRMRL)
- Office of Administrative and Research Support (OARS)
- Office of Resources Management & Administration (ORMA)
- Office of Science Information Management (OSIM)
- Office of Science Policy (OSP)
- Office of the Science Advisor (OSA)
- Other

i. (Please specify [max 1,000 characters])

Enter text here

Section II: Survey Questions

1. Are you aware of EPA's Principles of Scientific Integrity?

- Yes
- No

On a scale from one to five, where one is not at all useful and five is very useful, please indicate how useful you found the Principles of Scientific Integrity.

1 = Not Useful ----- 5 = Very Useful

- 1
- 2
- 3
- 4
- 5

2. Are you aware of EPA Order 3120.5 - EPA's Policy and Procedures for Addressing Research Misconduct?

- Yes
- No

On a scale from one to five, where one is not at all useful and five is very useful, please indicate how useful you found EPA Order 3120.5.

1 = Not Useful ----- 5 = Very Useful

- 1
- 2
- 3
- 4
- 5

3. Did you complete the E-Training course on the Principles of Scientific Integrity?

- Yes
- No

On a scale from one to five, where one is not at all useful and five is very useful, please indicate how useful you found the E-Training.

1 = Not Useful ----- 5 = Very Useful

- 1
- 2
- 3
- 4
- 5

Please provide any suggestions related to the training [max 1,000 characters].

4. Do you know how to report instances/allegations relating to scientific integrity and research misconduct?

- Yes
- No

To whom would you feel comfortable reporting your information:

i. Supervisor

- Yes
- No

Why not [max 1,000 characters]?

ii. Union

- Yes
- No

Why not [max 1,000 characters]?

iii. OIG

- Yes
- No

Why not [max 1,000 characters]?

iv. Other (please specify [max 1,000 characters])

5. If you disagree with a decision ORD management makes which you believe does not align with the results of your scientific research, do you have a process in which to register your disagreement?

- Yes
- No

Please describe the process [max 1,000 characters].

6. If you disagree with a decision EPA management makes which you believe does not align with the results of your scientific research, do you have a process in which to register your disagreement?

- Yes
- No

Please explain (e.g. the need for a process, or how the process could be improved) [max 1,000 characters].

7. In the past 5 years, how many instances/allegations related to scientific integrity and/or research misconduct do you have personal/direct knowledge or involvement?

- None
- 1-2
- 3-5
- Over 6

Please indicate whether these instances were reported and to whom [max 1,000 characters]:

8. Do you think it would be helpful for the Agency to provide additional outreach/education on scientific integrity and research misconduct (i.e. on identifying and reporting instances)?

- Yes
- No

Section III: Additional Comments

Please provide any additional comments, questions, or input regarding EPA's process for addressing scientific integrity and research misconduct. You may also use this space to communicate any concerns to the OIG team and, if you feel comfortable, include your name and contact information so that the OIG team can contact you to follow-up, if necessary. Your name and contact information will remain confidential. [4000 character limit]

Section IV: Survey Completion

Once you have completed the survey, please press the "Submit Survey" button to send it to the Office of Inspector General and close the survey database. Use this button only when you are ready to submit the completed survey.

Thank you for your participation!

Survey Analysis Results by Question

Section I: Respondent Information:

1. What is your current grade level?

GS-7/9	17	3.48%
GS-11/12	120	24.59%
GS-13	155	31.76%
GS-14/15	179	36.68%
SES	11	2.25%
Title 42 Appointee	6	1.23%
	488	100.00%

2. How long have you worked for EPA's Office of Research and Development (ORD)?

Less than 1 year	25	5.12%
1-2 years	41	8.40%
3-5 years	52	10.66%
6-9 years	54	11.07%
10-20 years	185	37.91%
21+ years	131	26.84%
	488	100.00%

3. Which of the following best describes your current job function?

Manager	15	3.07%
Manager with research responsibilities	39	7.99%
Other	52	10.66%
Research Assistant	41	8.40%
Research Scientist	308	63.11%
Supervisor	7	1.43%
Supervisor with research responsibilities	26	5.33%
	488	100.00%

4. In which job series is your current position listed?

0028 (Environmental Protection Specialist)	12	2.46%
0400 (Natural Resources Management & Biological Sciences)	169	34.63%
0800 (Engineering and Architecture)	59	12.09%
1300 (Physical Sciences)	181	37.09%
1500 (Mathematics and Statistics)	20	4.10%
Other	47	9.63%
	488	100.00%

5. Current Lab, Center, or Office?

IOAA	6	1.23%
NCCT	8	1.64%
NCEA	41	8.40%
NCER	8	1.64%
NERL	108	22.13%
NHEERL	184	37.70%
NHSRC	14	2.87%
NRMRL	97	19.88%
ORMA	2	0.41%
OSA	6	1.23%
OSP	11	2.25%
Other	3	0.61%
	488	100.00%

Section II: Survey Questions

1. Are you aware of EPA's Principles of Scientific Integrity?

No	158	32.38%
Yes	330	67.62%
	488	100.00%

How useful are the Principles?

1 (Not Useful)	15	4.55%
2	20	6.06%
3	142	43.03%
4	109	33.03%
5 (Very Useful)	44	13.33%
	330*	100.00%

*Please note that the usefulness percentages reported above are for a total number of 330 responses, corresponding to the number of respondents who are aware of EPA's Principles.

2. Are you aware of EPA Order 3120.5 - EPA's Policy and Procedures for Addressing Research Misconduct?

No	319	65.37%
Yes	169	34.63%
	488	100.00%

How useful is EPA Order 3120.5?

1 (Not Useful)	6	3.55%
2	14	8.28%
3	58	34.32%
4	66	39.05%
5 (Very Useful)	25	14.79%
	169*	100.00%

*Please note that the usefulness percentages reported above are for a total number of 169 responses, corresponding to the number of respondents who are aware of EPA Order 3120.5.

3. Did you complete the E-Training course on the Principles of Scientific Integrity?

No	321	65.78%
Yes	167	34.22%
	488	100.00%

On a scale from one to five, where one is not at all useful and five is very useful, please indicate how useful you found the E-Training.

1 (Not Useful)	9	5.39%
2	9	5.39%
3	75	44.91%
4	55	32.93%
5 (Very Useful)	19	11.38%
	167*	100.00%

*Please note that the usefulness percentages reported above are for a total number of 167 responses, corresponding to the number of respondents who completed the E-Training course.

4. Do you know how to report instances/allegations relating to scientific integrity and research misconduct?

No	252	51.64%
Yes	236	48.36%
	488	100.00%

To whom would you feel comfortable reporting your information:

i. Supervisor

No	60	12.30%
Yes	428	87.70%
	488	100.00%

ii. Union

No	241	49.39%
Yes	247	50.61%
	488	100.00%

iii. OIG

No	171	35.04%
Yes	317	64.96%
	488	100.00%

5. If you disagree with a decision ORD management makes which you believe does not align with the results of your scientific research, do you have a process in which to register your disagreement?

No	291	59.63%
Yes	197	40.37%
	488	100.00%

6. If you disagree with a decision EPA management makes which you believe does not align with the results of your scientific research, do you have a process in which to register your disagreement?

No	307	62.91%
Yes	181	37.09%
	488	100.00%

7. In the past 5 years, how many instances/allegations related to scientific integrity and/or research misconduct do you have personal/direct knowledge or involvement?

None	419	85.86%
1-2	54	11.07%
3-5	9	1.84%
Over 6	6	1.23%
	488	100.00%

8. Do you think it would be helpful for the Agency to provide additional outreach/education on scientific integrity and research misconduct (i.e. on identifying and reporting instances)?

No	156	31.97%
Yes	332	68.03%
	488	100.00%

Section III: Additional Comments

Please provide any additional comments, questions, or input regarding EPA's process for addressing scientific integrity and research misconduct.

153 of the 488 respondents (31%) provided additional comments.

Agency Response to Draft Report



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

July 7, 2011

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: Office of Research and Development (ORD) Response *Office of Research and Development Should Increase Awareness of Scientific Integrity Policies*, Project No.OA-FYIO-0193

FROM: Kevin Y. Teichman
Deputy Assistance Administrator of Science
Office of Research 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-FYIO-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, 2011.⁷

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

⁷ On July 21, 2011, ORD provided their corrective action plan and adjusted the training completion date to September 2012.



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

April 18, 2011

OFFICE OF
RESEARCH AND DEVELOPMENT

ATTACHMENT

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,
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/hlstory/topics/policy/fishbowl.htm#memo>

⁴ <http://www.epa.gov/Administrator/scientificmemo.htm>

⁵ http://www.epa.gov/ocir/hearings/testimony/ll1_2009_2010/2009_060B-pj.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 received 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 System, 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

⁷ http://www.epa.gov/irmpoli8/policies/21_050.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.

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

¹⁰ "Quality Science in the Courtroom: U.S. EPA Data Quality and Peer Review Policies and Procedures Compared to the Daubert Factors," G. M. Brills, 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_policyand_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-uidance_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 prepared 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. In addition, 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. DEI also administers EPA's responses to requests for information under the Freedom of Information Act (EPA regulations at 40 CFR Part 2).

EP A 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/soInternet/registry/sysofregfhome/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 Characterization*²⁵ 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 decision making.

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 ST AA 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 (FITTA, 1986), EPA scientists and engineers can collaborate with their external peers. The FIT A (15 USC 3701 to 3716) provides incentives for the transfer of technologies developed in Federal government laboratories to private industry. At EPA, the FIT A program promotes collaboration between private and federal researchers. Staff from EPA's FITTA program and OGC provide on-site training and one-on-one visits with Agency scientists to explain and encourage patenting. The FIT A 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 FITTA program has approximately 100 active CRADAs.

Each year about ten new patents are issued to EPA scientists. Under the FITTA, 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).

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