FY 2015 Annual Report

Scientific





2015 Annual Report on Scientific Integrity

The Annual Report chronicles the implementation of EPA's Scientific Integrity Policy in fiscal year (FY) 2015. Since February 2012, EPA's Scientific Integrity Policy has provided both a vision and a roadmap for ensuring scientific integrity at the Agency. The Policy lists the components of a culture of scientific integrity and offers a framework for ensuring Agency-wide participation in that culture. Although scientific integrity is treated as a single issue in the Policy, maintaining scientific integrity requires investment from and the collaboration of many parts of EPA. This year, instead of publishing a bound report, the scientific integrity activities of FY 2015 are reported online.

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Scientific Integrity in FY 2015

Accomplishments in the EPA Regions and Offices

In FY 2015, EPA program and regional offices took a variety of approaches to further implement the Scientific Integrity Policy at EPA. In this section, EPA regions and programs highlight their accomplishments in promoting a culture of scientific integrity by increasing transparency, supporting robust science, and encouraging professional development for employees. <u>View the full list of accomplishments in the last section of this report</u>.

New Products

In FY 2015, the Scientific Integrity Official, with the help of the Scientific Integrity Committee, developed the following new products that further promote adherence to the Scientific Integrity Policy.

Ethics and Professional Development

Developed as a joint project by the Scientific Integrity Program and the Office of General Counsel's Ethics Office, this online training familiarizes EPA employees with the federal ethics laws and regulations and scientific integrity issues that employees might face while pursuing professional development opportunities. The training is a valuable resource for employees with questions or concerns about ethically participating in professional development activities. Since the training is modular, employees can search and skip to relevant topics as needed. The modules are organized by the ethics and integrity issues within an employee's "official capacity" as a government employee bound by federal ethics laws and regulations, and an employee's "personal capacity," or when an employee is representing one's own views and opinions, not necessarily the views of EPA.

Office of Inspector General Coordination Procedures

In FY 2015, the Scientific Integrity Official and the Office of Inspector General updated procedures for coordinating the evaluation of allegations of a loss of scientific integrity, research misconduct, and plagiarism.

Timeliness Standard Operating Procedures

In FY 2015, the Scientific Integrity Official and the Scientific Integrity Committee responded to the Office of Inspector General's recommendation that EPA's Scientific Integrity Official develop standard operating procedures detailing how staff are to comply with the EPA's Scientific Integrity Policy requirement to provide timely responses to requests for information by media, the public, and the scientific community. The Scientific Integrity Official collaborated across the Agency to create a definition of timeliness.

FY 2015 Allegations

As of September 30, 2015, EPA had received 81 allegations of a loss of scientific integrity since the Scientific Integrity Policy was published in 2012. Of those, 34 were active, 23 had been adjudicated; four were determined to not be scientific integrity issues; 17 were inactive; and three were reassigned.

Of the 81 allegations received as of the end of FY2015, the Agency received 37 within fiscal year 2015. This represents 0.5% of the total number of EPA employees and a slight decrease from the number received in FY2014 (which was 40).

Of the 37 allegations that were received in FY2015, 30 were made informally (where the person submitting the allegation prefers to not reveal their identity) and seven were made formally. In FY2014, 57.5% were informal; in FY2015, 81% were informal.

Of the 30 informal reports received in FY2015, only two came from outside the Agency. Seventeen came from EPA offices and programs and 11 came from regional offices. Of the seven formal allegations in FY2015, three came from outside the Agency, three from EPA offices and programs, and one from regional offices. There was a slight decrease in external allegations in FY2015, including both informal and formal allegations, compared to external allegations received in FY2014. There was a slight increase in internal allegations in FY2015 (32), compared to FY2014 (28).

The allegations received in FY2015 relate to several topics regarding scientific integrity. Eight allegations concern authorship and attribution; six concern suppression or delay of release of a scientific report or information; five concern scientific methods; five are conflicts of interest; three concern interference with science by a manager; and three are about data quality.

Allegations regarding authorship and attribution increased slightly in FY2015. EPA offices produce numerous authored scientific products every year. Some of these allegations

concern whether an employee's contribution to a work product was significant and warrants a designation of authorship. The Scientific Integrity Official is prepared an Authorship Best Practices document, which released in FY2016.

Summary of Adjudicated Allegations

Thirteen allegations were adjudicated in FY2015. Eleven of these were substantiated and two were dismissed. Two of these adjudicated allegations concerned authorship disputes; two involved data quality; two concerned potential conflicts of interest; and two were concerns about the delayed release of scientific information. Summaries of the disposition of these allegations are below.

Adjudicated in FY 2015

1. Response to an Allegation of Interference by Manager with Science

• Allegation:

In a 2014 report, the Office of Inspector General (OIG) recommended that EPA's Scientific Integrity Official develop standard operating procedures detailing how staff should provide timely responses to requests for information by media, the public, and the scientific community.

• Summary:

The Scientific Integrity Official and the Scientific Integrity Committee collaborated across the Agency to respond to the OIG recommendation. See Timeliness.

2. Response to an Allegation of Unsubstantiated EPA-Funded Report

• Allegation:

The complainant alleged that EPA contractors engaged in scientific misconduct in preparation of a research report. The complainant asked that EPA either retract the report or qualify the study's conclusions.

• Summary:

EPA qualified the report by attaching a statement explaining that the Agency does not have the data upon which the report's conclusions were based and that subsequent research did not reach the same conclusions as the report.

3. Response to an Allegation of Inappropriate Use of Data That are below the Laboratory's Reporting Limit

 Allegation: The complainants, Quality Assurance (QA) staff and laboratory staff in a U.S. EPA Regional Laboratory, raised the following concerns:

- A Project Manager requested raw data for a project, some of which were below the laboratory's reporting limit, for use in statistical analyses to evaluate "instrument noise."
- The QA staff's supervisor asked them to review a QA project plan (QAPP) developed by a Project Manager who also works for the supervisor. The QA staff were concerned that the supervisor had a conflict of interest by managing both the QA reviewers and the Project Manager.
- Summary:

A Scientific Integrity Review Panel met with all involved parties to discuss their different perspectives. The parties agreed to a process that will ensure that the data are used appropriately. Regarding the QA staff's concerns about potential conflicts of interest, the panel recommended that the Regional QA manager (who is not in the QA staff's organizational unit) review any QAPPs that are developed within the QA staff's unit.

4. Allegation of Flaws in an EPA-Funded Study

• Allegation:

The complainant alleged that an EPA-funded study was flawed and should not be cited as a basis for an EPA standard.

• Summary:

The supporting materials did not reveal significant flaws in the study. Therefore, the allegation had no basis and was dismissed.

5. Pressure to Have Diverse FACA Panels

• Allegation:

The complainant said that Agency FACAs are under pressure to have diversified membership. The pressure could result in selection of panel members who may not have the strongest scientific qualifications.

• Summary:

The Scientific Integrity Official directed outreach efforts at the appropriate parties.

6. Allegation of Interference by Manager with Science

• Allegation:

Management allegedly was interfering with a scientific assessment. The employee was pressured to change the conclusions of a risk assessment.

• Summary:

The matter was resolved when the manager agreed to stop interfering with the employee's scientific assessment.

7. Allegation of Interference by Manager with Science

• Allegation:

When new information came in after a peer review, management pressured staff to hold a new peer review that would include members with clear conflicts of interest.

• Summary:

The matter was resolved, because staff did not accept comments from any reviewers with conflicts of interest.

8. Manager Allegedly Delaying Publication

• Allegation:

Management approval of a scientific poster was delayed due to a disagreement about the appropriate methodology.

• Summary:

The employee and manager reached an agreement. The employee edited the poster and the manager approved it.

9. Response to an Allegation of EPA Withholding Data and of EPA using Flawed Data

• Allegation:

The complainant alleged that EPA refused to release crucial scientific data that supported decision-making. The complainant also raised concerns about replication, reproducibility, and reanalysis of certain data sets.

• Summary:

EPA found that the Agency previously had provided the data that was in its possession and that these data had been reanalyzed through a rigorous process. In addition, the Agency noted that science is often most effectively advanced by new studies that attempt to demonstrate that the results of previous research did not happen by chance or occurred because of undetected confounders or bias.

10. Authorship Issue

• Allegation:

The complainant alleged that management had wrongfully removed the complainant's name from a conference presentation.

• Summary:

The complainant reported that the issue was resolved through communication with the manager.

11. Allegation of Interference by Manager with Publication

• Allegation:

Management asked an employee to stop sharing a newsletter with the public, although it had been shared with the public for many years.

 Summary: The complainant reported that the issue was resolved through communication with the manager.

12. Allegation of Local Government Agency Publication Delay

• Allegation:

The complainant alleged that a local government was delaying the release of an EPA report.

• Summary: The Scientific Integrity Official helped to expedite the release of the report.

13. Allegation of Authorship Issue

• Allegation:

This internal complaint concerned a dispute about authorship regarding three related projects.

• Summary: The Scientific Integrity Official facilitated the resolution, with the parties negotiating an agreement

Additional Allegations that were Adjudicated in FY 2014

1. Request by 24 Scientists that Federal Agencies Remove Barriers that Prevent Agency Scientists from Sharing Their Expertise with the Public

- Allegation: The complainant, a non-profit organization that represents scientists, conveyed the following concerns expressed by a group of scientists:
 - After a chemical spill, the U.S. Environmental Protection Agency and the Centers for Disease Control and Prevention failed to adequately respond to questions raised by the public and journalists;
 - These agencies' public affairs officers should not act as gatekeepers of information, especially during emergencies;
 - Policies should be updated to allow unfettered access to scientists with expertise that could help protect public health; and,
 - Other agencies, like National Oceanic and Atmospheric Administration, have shown that providing unfettered access to its scientists helps to build public faith and trust.

• Summary:

EPA's Associate Administrator for External Affairs responded that:

- In this particular case, the state environmental agency had the lead for overseeing and coordinating response activities;
- EPA had responded in a timely fashion to more than two dozen media outlets; and,
- EPA is committed to transparency and to communicating with reporters.

2. Request that EPA Publish Conflict of Interest Waivers on its Website

• Allegation:

The complainant was concerned that EPA had not published information about Conflict of Interest Waivers granted to date for Science Advisory Board (SAB) panel members.

• Summary:

The Scientific Integrity Official responded that EPA had not granted any Conflict of Interest Waivers for SAB panel members to date. That is the reason that none are on the website. The allegation was dismissed.

3. Researchers Allegedly Omitted Data and Drew Erroneous Conclusions

• Allegation:

The complainant claimed that researchers engaged in scientific misconduct, omitting data and drawing erroneous conclusions about a scientific topic.

• Summary:

In response, the OIG issued a report on the subject in May 2014. According to the OIG report, EPA followed applicable regulations when conducting the study. The allegation was dismissed.

4. Request for EPA to Modify its New Guidance, "Conflict of Interest Review Process for Contractor-Managed Peer Reviews"

• Allegation:

The complainant, a non-profit organization, said that it welcomed the Agency's recently released guidance, "Conflict of Interest Review Process for Contractor-Managed Peer Reviews." However, it had concerns about its implementation and offered suggestions for improving the guidance.

• Summary:

The Agency responded that it would fully implement the process before assessing whether additional changes were needed.

Scientific Integrity FY 2015 Outreach

Scientific integrity outreach is key to implementing the Scientific Integrity Policy. In FY 2015, outreach included presentations at regional offices and laboratories, development of outreach materials, participation in conferences and other events, and organization of stakeholder meetings. These outreach activities are detailed in this section.

Outreach

In FY 2015, the Scientific Integrity Official gave 42 presentations, visiting regional offices and laboratories in seven EPA Regions. The Scientific Integrity Official also delivered presentations to various headquarters programs and offices, including: Office of Land and Emergency Management, Office of Research and Development (ORD) Communications, ORD Management Council, the Administrator's Office, Office of Science Coordination and Policy (within the Office of Chemical Safety and Pollution Prevention (OCSPP)), Office of Diversity, Advisory Committee Management and Outreach (ODACMO), National Center for Environmental Economics (NCEE), Office of Ground Water and Drinking Water (OGWDW), Office of Air and Radiation (OAR), and OCSPP. The presentations and seminars included important rights and protections described in the Scientific Integrity Policy, the work of the Scientific Integrity Program, and updates on the allegations process and allegations.

The scientific integrity program also developed outreach materials to distribute across the Agency, including copies of the Annual Report, brochures, posters, and a fact sheet.

In FY 2015, the Scientific Integrity Official participated in four external events. These included providing materials for EPA's exhibitor's booths at scientific professional society meetings – Society of Environmental Toxicology and Chemistry (SETAC) and the American Association for the Advancement of Science (AAAS). The Scientific Integrity Official was an invited speaker at Stanford University Center for Advanced Study in the Behavioral Sciences Conference on Best Practices in Science and co-organized and participated in a symposium at the Ecological Society of America (ESA) annual meeting on "Science under Scrutiny."

EPA Annual Scientific Integrity Stakeholder Meeting

May 27, 2015

Hosted by the American Chemistry Council

Welcome and Introductions:

• Dr. Rick Becker of the American Chemistry Council (ACC) opened the meeting and introduced Dr. Francesca Grifo (OSA), the EPA Scientific Integrity Official (ScIO). There were 50 attendees.

Dr. Grifo's Presentation:

• Dr. Grifo presented PowerPoint slides conveying the historical context of EPA's Scientific Integrity Policy (Policy), how the Agency defines Scientific Integrity, current initiatives, the status of allegations and other aspects of the Policy's development and implementation. Dr. Grifo emphasized the importance of public trust.

Question and Answer Period

- Dr. Larry Reiter, a public member of the ACC Strategic Science Team, asked who determines what constitutes the "timely" release of scientific information. Dr. Grifo responded that there is a strategic window within which to release information. For example, if a document is final on January 1, that does not mean it must be released January 2. Factors such as external developments and circumstances affect when a document might appropriately be released, although one year would very likely not be justifiable as a strategic window. Each instance will be different.
- Dr. Reiter elaborated by presenting "two sides of the coin" regarding timeliness and asked how Dr. Grifo's office might respond in either case. In one instance, data are generated and are being moved into peer reviewed publication but have not yet reached completion of the process; however, the data are of great interest to a regulatory program that wants to use them before the data have completed the peer review process. In the other instance, a report might not be ready for peer review, but it might be somewhat inconvenient for the report to be released by EPA given some other policy or ongoing activity within the Agency. What is the role of Dr. Grifo's office in dealing with such situations? Dr. Grifo responded that her office looks into situations that are brought to her attention. If someone charged that a publication was being held up by EPA, her office would look into it. In a recent case, through discussions with key personnel, a report was released after approximately 2 months. Dr. Grifo noted that she has not observed "nefarious delay," only delay as part of a strategic release within a broader context of interests and goals. Dr. Grifo's office does not have the staff to serve as "timeliness police," but she can respond to allegations. Discussions have proven extremely effective.
- Jamie Conrad of Conrad Law & Policy Counsel noted that the logic model Dr. Grifo presented in her slides identified public trust in the Policy as an outcome. In the 2014 annual report, 11 of the 40 allegations referenced were formal allegations filed by external entities. He asked when, and to what extent, Dr. Grifo could provide information about the kinds of issues and circumstances raised in the allegations; trust in the process requires some transparency about the outcome of the allegations made. Dr. Grifo agreed, and noted that in the 2014 report her office had adjudicated only one allegation, which the report summarized. The summary,

however, excluded details. The allegation was not substantiated, and Dr. Grifo's office does not want to adversely affect a person's career by reporting unsubstantiated allegations. She acknowledged that adjudications of allegations are not being processed as quickly as she would prefer. Her office consists of herself and one fulltime employee, and they are the only two staff working on allegations as well as other activities, for which there is some additional support from a fellow and a student contractor. Allegations, however, are government business and can only be adjudicated by government employees. It is more important to build trust that enables allegations to come forward than to publish potentially unsubstantiated charges that could harm a career. There is a tension between these goals.

- Mr. Conrad added that, with EPA's action development groups, much of the Agency's scientific work is derived from large numbers of people, so many times allegations are not directed at individuals but at processes. In those cases, providing explicit information about the allegations would not harm specific individuals. Dr. Grifo responded that her best recollection of the 62 allegations is that none pertain to process. She agreed that if they addressed large formal processes Mr. Conrad's point would be correct, and if the allegation points to a large group of people rather than an individual, her office would be more comfortable publishing a summary.
- Martin Stephens of Johns Hopkins University asked Dr. Grifo to elaborate on the idea of "insulation from bias" in the research context. He asked if the idea referred to the standard risk of bias considerations, such as random allocation, or a higher level effort to insulate EPA's science from bias. Dr. Grifo responded that at a higher level there are many conflict of interest constraints in place at many different levels. As with "timely" allegations, the ScIO responds to allegations, which currently would pertain to the more ordinary bias considerations that Mr. Stephens mentioned. Her office, however, is always open to hearing about bias at either level.
- A participant ("Ray") inquired about the Policy for dissent from Agency decisions. Noting that no organization likes criticism from staff once a policy decision is made, he asked how Dr. Grifo's office handles dissent, either as a strictly internal or public matter. Dr. Grifo responded that initially dissent is internally managed, with the goal of resolving concerns at the office level through discussions. If that fails, then a dissenting view will be written so that it can either move with the majority view or be part of a charge to peer review; if peer review does not resolve the matter, it becomes a document attached to the decision potentially all the way up to the decision maker, including the Administrator if that is the person making the decision.
- Dr. Becker noted that a slide presented by Dr. Grifo highlighted EPA's Risk Characterization Policy, which external parties consider to be a good document but

not implemented as much as it should be. He asked if Dr. Grifo highlighted the document to emphasize that it needs more attention or because it is a good quality document that integrates the elements of science and communication. Dr. Grifo responded that it was the latter reason. She could not offer an opinion on whether the document is implemented because she has been employed at EPA for only 18 months, but she welcomed any information about instances in which the Risk Characterization Policy is not working.

EPA Annual Scientific Integrity 2015 Non-Governmental Organizations Stakeholder Meeting

April 20, 2015 Hosted by the Union of Concerned Scientists

Welcome and Introductions:

 Michael Halpern of the Center for Science and Democracy, Union of Concerned Scientists (UCS), opened the meeting and asked participants to introduce themselves. Participants included 17 representatives from UCS, Environmental Defense Fund, Natural Resources Defense Council, Society of Environmental Journalists (SEJ), Public Employees for Environmental Responsibility (PEER) and other organizations. Following introductions, the moderator explained that Dr. Francesca Grifo (OSA), the EPA Scientific Integrity Official (ScIO), had requested the meeting to discuss the work of her office over her first year at EPA and future directions, as well as to respond to participants' questions and concerns.

Dr. Grifo's Presentation:

- Dr. Grifo presented PowerPoint slides conveying the historical context of EPA's Scientific Integrity Policy (Policy), how the Agency defines Scientific Integrity, current initiatives and the challenges she faces.
- Dr. Grifo reviewed the accomplishments of her office over the past year, including completion of the annual report, which she made available to participants. Another stakeholder meeting to be hosted by the American Chemistry Council at the end of May will include regulated industry. A white board video training on the Policy will be provided to EPA staff and will focus on how scientific integrity enhances EPA's work and will include a case study demonstrating problems resulting from a failure to consider scientific integrity. She acknowledged that, with a small staff, allegations are not processed in as timely a way as she would like. She reviewed the formal allegation process, but noted most allegations are made informally.

Question and Answer Period

- Joe Davis of the Society of Environmental Journalists (SEJ) commented that many environmental journalists writing on deadline about EPA science that has been released in a journal want to talk to the authors or an Agency expert. Almost universally, SEJ journalists hear from EPA scientists that they cannot talk to the media without press office clearance, but there appears to be no official policy that states scientists cannot talk to reporters without permission. The situation makes reporters' jobs harder and affects the integrity of the science. SEJ has submitted a Freedom of Information Act request seeking any written policy, but in 9 months, SEJ has received no response and has filed an appeal. He stated that the situation is a problem and asked how it can be fixed.
- Dr. Grifo responded that the Policy only states that scientists "should" consult with public affairs prior to talking to the press. Part of the problem, however, is that when Dr. Grifo's office released its annual report with first-time Policy statistics, a Greenwire reporters' headline about the report stated "Allegations at EPA Skyrocket." The press office complains about such headlines and the lack of articles about good news, making the office reluctant to offer scientists without media training to journalists who may misrepresent or misquote the source. For that reason, the press office wants to be present on calls to verify the accuracy of quotes. When the UCS recently issued a media policy scorecard, the Guardian used a 3-year-old quote for its headline. Such examples make it difficult for Dr. Grifo to push back on press office oversight.
- Mr. Davis responded that it is not Dr. Grifo's fault, but many reporters who complain to the SEJ are seasoned science journalists who nevertheless receive the same treatment as other reporters. To help, Dr. Grifo is promoting media training and rotations for media office staff to build trust between scientists in program offices and regions and the Office of Public Affairs (OPA). She underscored the distinction between speaking about science as opposed to speaking about policy, which is not a Scientific Integrity issue. She requested that SEJ and others document times when a scientist cannot be reached so that she can follow up on the matter.
- A stakeholder agreed to fulfill Dr. Grifo's request. Another SEJ stakeholder stated that some Non-Governmental Organizations have worked since the beginning of the Obama Administration on the issues and were very hopeful. She personally and SEJ as an organization, under its new ethics code, would work with Dr. Grifo to address the problem of sensationalized news stories, citing examples of sensationalized journalism. With regard to intimidation, which Dr. Grifo's office seeks to prevent, the stakeholder stated that scientists are intimidated when told they cannot speak with journalists except under surveillance. Once scientists or other sources can speak

without having to repeat the official line, a confirmable different story almost always emerges. Government sources fear that their bosses will discover communication with journalists, an issue SEJ is working on very hard because many in SEJ feel they are "missing the world." Dr. Grifo responded that EPA is doing amazing work which should be well covered in the news. Again she urged journalists to let her know when the system is not working and she will follow up.

- Another stakeholder noted that the Policy fails to clearly state that a scientist can choose not to consult with OPA when speaking with a journalist. Dr. Grifo responded that the Policy also does not state that a scientist "must" be accompanied; it takes a position in the middle of those two positions. Another stakeholder added that "should" is not in the middle, but is 8.5 out of 10 in the direction of a requirement.
- A stakeholder asked about data access regulations and Dr. Grifo responded that Dr. Thomas Burke, EPA's Science Advisor, is working hard on the issue.
- Another stakeholder asked about the Policy's enforcement of the Whistleblower Protection Enhancement Act, which is supposed to protect employees who express a different view. Such protections appear to be missing in many federal agencies' policies. Dr. Grifo requested a written proposal to remedy the situation, which the stakeholder agreed to provide. He stated that protections should be embodied in a Civil Service rule that is enforceable by the Office of Special Counsel.
- Another participant asked about the Personal Views Exception, which many agencies resist. Dr. Grifo responded that she has not heard that the issue is significant; EPA has a solid basis of experience to provide a basis for the Agency's Differing Scientific Opinions Policy, which many regard as an avenue to enable people's scientific information to be discussed. Another stakeholder suggested that EPA, the National Oceanic and Atmospheric Administration (NOAA) and others could disseminate their best practices.
- A participant asked if EPA scientists feel thwarted by the restrictions on traveling. In response, Dr. Grifo noted that there has been a significant decline in available travel funds. The process to request travel permission works well. The participant added that many associations are working on the issue because they have seen a decline in government scientists attending their meetings.
- A stakeholder lauded the resolution of the contractor-managed FACA meetings issue and urged publicizing the news. She also noted the difficulty of the media training issue, which applied to her organization as well, and asked if the EPA ethics training module would be publicly available. Dr. Grifo indicated that she would determine if training that her office produces can be made available outside EPA's Skillport

system. [Update: the training module is not available to the public as of August 2016.]

- Jeff Ruch of PEER asked if the draft policy for reporting and resolving allegations • would be published for public review and comment. Dr. Grifo responded that it was shared with the unions for review, and she offered to explain the policy in detail to Mr. Ruch or any interested parties. Mr. Ruch stated that the process would be stripped of the ability to recommend corrective action if supervisors are found in violation of the Policy. Dr. Grifo responded that those issues are addressed at an EPA level, not by her office. Mr. Ruch asked how scientists could have confidence in the process, and how PEER could recommend filing a complaint, if supervisors suffer no consequences for a lack of Scientific Integrity. Even if filed confidentially, a complainant's identity would be known, but managers could retaliate and state that their actions were not directed at the filing scientist, whose identity is presumed to be unknown. He urged a public review process to vet such issues. He also expressed concern that Dr. Grifo's limited time and resources would be used for communications training, despite a lack of communications policy, and suggested that OPA's budget be used for such purposes. Similarly, the EPA OIG Ombudsman has a statutory duty to provide Agency-wide education on rights and options for all kinds of discrimination regarding disclosures, which broadly includes the Policy. An additional module could address the Policy. Dr. Grifo agreed to inquire into the matter. Mr. Ruch urged OIG to subject itself to the Policy and asked about the status of a "loss of integrity" complaint if it was filed about an OIG information product. Lastly, Mr. Ruch asked if a single "loss of integrity" complaint had been substantiated. Dr. Grifo replied that none had been, but currently her office is reviewing three allegations involving extensive documentation. Mr. Ruch added that there should be career consequences if a "loss of integrity" has been found, which argues for publicly presenting such findings. In some PEER cases, managers dismiss complaints because there are no consequences, so a good example is needed to demonstrate the seriousness of allegations. Dr. Grifo agreed that if a solid case results from investigations, it would be reported in the annual report.
- Dr. Grifo thanked the participants for their input and participation. The meeting concluded at 2:22 p.m. EDT.

A Conversation with the Scientific Integrity Official and the EPA Community June 23, 2015

Participants

There were over 100 participants in attendance online and in person. They represented several EPA program offices and regions.

Review and Updates

Dr. Francesca Grifo (ScIO) opened the meeting. She presented a series of slides providing a review and update on scientific integrity at EPA. Her review covered the definition of scientific integrity and a lack of scientific integrity, the scope and provisions of the Scientific Integrity Policy (Policy), accomplishments to date, procedures for receiving and resolving allegations, current and new initiatives, and other topics. Dr. Grifo noted that most allegations were made anonymously. She opened the meeting to questions.

Question and Answer (Q&A) Period

Dr. Grifo opened the Q&A period by emphasizing that she welcomed any feedback from participants about the meeting and other topics. The following questions were discussed:

- Dr. Grifo was asked if employees will be notified when the new training modules on "ethics and integrity in professional development" are available on Skillport in the coming weeks. She responded affirmatively.
- One participant commented that she was unaware of activities at EPA that Dr. Grifo had mentioned, such as the development of an EPA Framework for Clearance Procedures. She noted that EPA's QA manual includes a requirement that QA managers review reports. Dr. Grifo responded that a member of the Scientific Integrity Committee has worked to ensure that the ScIO's office considers all QA requirements. EPA's QA requirements are the starting point for the Framework for Clearance Procedures under development.
- Dr. Grifo was asked if members of Congress had reacted to EPA's Policy and ongoing implementation activities. Dr. Grifo stated that she was not aware of any reactions from Congress. She added that her office was proud of its work and would gladly communicate it to Congress or other audiences.
- One participant asked when we might see the proposed new inclusions on scientific integrity in the table of penalties for employee misconduct. Dr. Grifo responded that the conversation on the process for developing new inclusions was in its beginning stage, so she could not provide an answer at this time.
- Another participant asked about how the Scientific Integrity program sets priorities between external complaints and internal concerns. Dr. Grifo responded that her office does not distinguish between the two types but instead sets priorities based on urgency; if allegations could have immediate dire consequences, they receive priority attention. Such allegations are triaged, then addressed in the order of their submittal. Each allegation involves extensive investigation and inquiry as well as periods during which an allegation is on hold while awaiting responses to requests

for information. Dr. Grifo added that, regrettably, her office is backlogged but is trying to work as quickly as possible.

- A participant commented that a common concern is that outside entities constantly criticize EPA's science, even if it is solidly grounded, and thereby force the Agency to defend the same science year in and year out. The participant asked if there was any possibility that EPA will develop a policy of informing stakeholders, members of Congress, and sometimes other federal agencies that the science is set and the Agency will no longer repeat its defense of firmly concluded scientific findings. Dr. Grifo responded that such challenges are part of the democratic process and should be viewed from the perspective of the parties making inquiries; they are American taxpayers who support EPA and are part of the process, even if their challenges delay the Agency and are difficult.
- The participant added that, with other federal agencies working on the same issues
 —which occurs often, for example, with emergency response to disasters—there
 might be the possibility of developing common fact sheets, Q&A documents and
 the like. Stakeholders who dislike one agency's conclusions will seek conclusions
 they prefer at another agency; that phenomenon could be reduced if agencies
 provided the same answers to scientific questions. Dr. Grifo responded that the
 goal is to settle jurisdictional issues so that the best science can be obtained. She
 welcomed the opportunity to examine specific cases in which other agencies put
 forth different scientific answers to the same queries.
- One participant asked about the agreement between the Scientific Integrity
 program and the Office of Inspector General regarding who would address
 plagiarism issues. Dr. Grifo responded that the agreement is based on one with the
 OIG that was developed several years ago and states that plagiarism issues will be
 delegated to the ScIO's office. It will be available for discussion at the August
 meeting of the Union Working Group.
- Dr. Grifo noted that participants in the webinar are welcome to send comments or questions to her at any time, now or in the future, and she will reply.
- A participant asked about the length of time that will be allowed for responses to a
 Policy evaluation survey that will be sent Agencywide in coming weeks. Dr. Grifo
 responded that the plan was to keep the survey open for four or five weeks to
 ensure a high response rate. A contractor will use anonymous numbers to track
 responses and will send reminders until a satisfactory response rate is achieved.
 The process could require more weeks than currently anticipated. Martha Otto
 (OSA) emphasized that the survey will be completely anonymous; survey tracking
 numbers and responses will never be associated with names.

- Dr. Grifo reiterated that she welcomed the dialogue on the Policy and looked forward to her second year advocating on the issue of scientific integrity. She thanked the participants for joining the discussion.
- The meeting was adjourned.

Scientific Integrity Policy Accomplishments in the Regions and Offices Fiscal Year 2015

Promoting a Culture of Scientific Integrity

A culture of scientific integrity promotes the quality, collection, processing and communication of scientific information. Many quality assurance systems are already in place to ensure the integrity of the scientific research process. In Fiscal Year (FY) 2015, several new initiatives were introduced to demonstrate EPA's commitment to evidence, objectivity and the quality of scientific information.

As in FY 2014, the FY 2015 OCFO technical guidance highlighted controls over scientific integrity, including implementation of the Scientific Integrity Policy. An updated scientific integrity checklist was created for every national program and regional office to complete for the FY 2015 Federal Managers Financial Integrity Act (FMFIA) assurance letters to the Administrator.

Results of Agency Outreach

A number of regions used the outreach materials provided by the scientific integrity program to encourage a culture of scientific integrity and create local working groups.

Region 4's Deputy Scientific Integrity Official (DScIO) emailed the scientific integrity outreach flyer to Region 4's senior management (Regional Administrator, Deputy Regional Administrator, Division Directors and Deputy Division Directors). The DScIO also placed the flyer on Region 4's intranet site for a seven-week period.

Region 5 reviewed and updated existing Scientific Integrity policies, processes, and training material in 2015. The Region posted the flyers and posters in high traffic locations on every floor.

Region 7's LAN Bulletin board announcements featured EPA's Scientific Integrity Policy in January 2015.

Region 8's Scientific Integrity workgroup was formed in June 2013 and has identified shortand long-term action items associated with the following five scientific integrity goals: Documenting and Resolving Scientific Disagreements; Release/Dissemination of Scientific Information (clearance procedures); Scientific Uncertainty; Professional Development (includes technical training); and Peer Review. The Region is also moving forward with the creation of a Science Council to be modeled after a very successful Council established in Region 1in 1991. The Council's vision is one where EPA management and staff recognize the need for and are fully committed to incorporating scientific and technical excellence into the decision making process. The Region 8 Science Council was to be fully operational by December 2015.

Transparency

At EPA, promoting a culture of scientific integrity is closely linked to transparency.

The Office of Chemical Safety and Pollution Prevention's (OCSPP) Office of Pollution Prevention and Toxics (OPPT) has implemented several initiatives associated with its Enhanced Chemicals Management Program, including a Declassification Project that works with industry submitters to remove Confidential Business Information (CBI) claims made for health and safety data submissions. OPPT is also implementing electronic reporting for regulatory submissions and the office has been upgrading the IT environment to ensure that it meets the Agency's Enterprise Architecture and Security procedures.

Ensuring and Supporting Robust Science

The Office of Solid Waste and Emergency Response (OSWER) (since renamed Office of Land and Emergency Management) has utilized the principles of scientific integrity (objectivity, clarity, reproducibility and utility) in their work throughout FY15 as evidenced in OSWER's 2014 End of Year Accomplishments report: <u>http://www2.epa.gov/aboutepa/oswer-fy-2014end-yearaccomplishments-report-executive-summary</u>. OSWER is also issuing a memorandum that highlights the value of differing scientific opinions, and reminds staff to contact the Deputy Scientific Integrity Official, or designated staff, if they have any questions. It also includes reminders on some best practices for communicating scientific information to the public, and encourages staff to pursue professional development opportunities.

The Office of Water's (OW) Office of Wetlands, Oceans, and Watersheds (OWOW) provided the 2016 Section 303(d) and 305(b) Integrated Reporting guidance to States and EPA with updated information on the use of scientific data and information to accurately assess the water quality status of our nation's waters, including waters impaired by nutrients and nonpoint source pollution.

Clearance Procedures

Clearance procedures increase transparency in the release of research results, ensuring timely review and discouraging unreasonable delays. They also ensure that scientific

products are reviewed by the appropriate supervisors and technical managers before being released to the public. OW's Office of Science and Technology (OST) developed and implemented a process for clearing documents for publication.

Quality Assurance

A variety of mechanisms work to ensure the quality and integrity of EPA scientific products. Quality Management Programs (QMPs) play a large role in the quality assurance of scientific information. Collectively, these programs contribute to a culture that emphasizes the validity of scientific information.

The Office of Enforcement and Compliance Assurance's (OECA) National Enforcement Investigations Center (NEIC) updated its Ethics Policy and Quality Policy to incorporate references to the Agency's Scientific Integrity Policy. Personnel also completed the annual EPA on-line ethics training. NEIC also was assessed by two accreditation bodies (ANSI/ASQ National Accreditation Board, ANAB, and the National Voluntary Laboratory Accreditation Program, NVLAP), and maintained accreditation by both organizations. Laboratory accreditation is highly regarded both nationally and internationally as a reliable indicator of technical competence and scientific integrity. The scope of NEIC's accreditations includes forensic field and laboratory operations that support the Agency's civil and criminal enforcement programs. Finally, NEIC conducted an internal audit to assess conformity to ISO/IEC 17025 and supplemental forensic requirements. Nonconformities were identified and corrective action plans were being implemented as of June 2015.

OECA's Office of Criminal Enforcement, Forensics and Training (OCEFT) Professional Integrity and Quality Assurance unit (PIQA) successfully completed a gap analysis to evaluate OCEFT's progress in implementing the new EPA Office of Environmental Information (OEI) Quality Assurance (QA) Field Activities Procedure. The gap analysis was conducted by EPA Region 4 personnel with support from a contractor. The office is improving several existing quality management system processes and updating controlled documents to conform to the EPA/OEI QA Field Activities Procedure requirements. OCEFT also completed a new policy and procedure for requesting and obtaining forensic field and laboratory support for criminal investigations. The policy will be approved by the OCEFT Director, published on the on-line library, and training will be provided for all affected OCEFT personnel.

OW's Office of Ground Water and Drinking Water (OGWDW) FY15 Quality Assurance Annual Report and Work Plan includes, for example, the Radiochemistry Laboratory Certification for South Carolina and the Review of Supplementary Quality Assurance Project Plans for Work Assignments that supplement generic contract level Quality Assurance Project Plans. OW's Office of Wetlands, Oceans, and Watersheds (OWOW) implemented Quality Assurance Project Plans for both contract and Agency work, for example, the State/EPA National Aquatic Resource Surveys (NARS). The Office of Air and Radiation's (OAR) Office of Radiation and Indoor Air (ORIA) has integrated scientific integrity into its regular quality assurance trainings, and the Office of Air Quality Planning and Standards (OAQPS) revised its Quality Management Plan to include a section summarizing pre-dissemination review guidelines.

Region 3's Air Protection Division (APD) conducted on-site meetings with all eight State and Local agencies on air quality monitoring issues. Much of the focus was on data quality submitted to EPA. APD identified numerous monitoring QA/QC concerns and worked with the science liaisons to correct discrepancies so that the data can be used for regulatory decisions.

In Region 6's Source Water Protection Branch, the Water Quality Protection Division had lead roles in updating the national guidance for Sanitary Surveys and Induced Seismicity. In Region 6, the Multimedia Planning and Permitting Division (MPPD) staff developed a groundwater model for an Air Force Base fuel spill in New Mexico. This model was peer reviewed by EPA and external groundwater experts and now serves as the base model to identify remediation options. The staff develop air modeling protocols, similar to a Quality Assurance Project Plan, with the states and applicants to ensure that modeling is conducted based on EPA's regulations, guidance and best practices. MPPD also actively participates in workgroups to develop and review guidance and regulations including proposed revisions to 40 CFR 51 Appendix W – Guideline on Air Quality Models.

Training

Completion of scientific integrity and ethics training modules is an important aspect of promoting a culture of scientific integrity at EPA.

OECA's NEIC personnel completed the annual EPA on-line ethics training.

In OAR, all appropriate personnel took the annual scientific integrity training. In addition, ORIA's Radiation Analytical Laboratory and Field Operations Center both continue to provide annual Ethics and Data Integrity training as well as regular quality assurance training for all staff. Laboratory personnel in the Office of Transportation and Air Quality (OTAQ) complete a Code of Professional Practice attestation each year, which addresses many topics related to scientific integrity.

In Region 5, a refresher training on Scientific Integrity, Peer Review and Information Quality Guidelines for staff and managers was held in March 2015.

Region 6's Houston Laboratory staff continue to take the annual laboratory ethics training, which covers a wide variety of scientific ethics situations and principles, mostly laboratory focused. It also includes a discussion of the EPA Principles of Scientific Integrity and the Scientific Integrity Policy.

Release of Information to the Public

EPA encourages the transparency of Agency activities through communications tools such as online blogs, newsletters, news releases and official publications. EPA also maintains several online databases to provide open access to Agency information. Special user interfaces allow the public to navigate EPA databases easily. Online tools such as dashboards and calculators allow users to access a variety of datasets, input their own data and model personalized scenarios.

OCSPP-OPPT created a website and outreach to stakeholders on the Toxic Substances Control Act (TSCA) Work Plan of chemicals and the assessment process and schedule. The Office also maintains its highly acclaimed ChemView website, which makes chemical health and ecological hazard and safety documents and data accessible in integrated formats for use by decision makers. The Communications team in OCSPP-OPP is responsible for public outreach and they have a process in place to ensure that a scientist gets to review any changes to their work before it is publicly released.

OAR strives to make scientific data available in other ways. Many of OAR's publications are available through the Technology Transfer Network at www.epa.gov/ttn. OAR's Office of Atmospheric Programs (OAP) maintains EPA's Climate Change Indicators in the United States and provides public access to this peer-reviewed set of indicators and information through the OAP website, which also houses other scientific information and data.

Region 8's Superfund sites make their documents associated with the results of the remedial investigation, feasibility study, proposed plan, human health and ecological risk assessments available to the public. For example, the Draft site-wide Human Health Risk Assessment (December 2014) and site-wide Baseline Ecological Risk Assessment for Asbestos (January 2015) are available to the public on Region 8's internet website.

Peer Review and FACs

Scientific integrity ensures the quality of scientific and technical products by promoting adherence to proper scientific procedures. In FY2015, EPA continued its efforts to promote peer review as an essential component of quality scientific research products.

Peer Review

ORD continued its efforts to ensure the quality of its scientific and technical products by adhering to the requirements of the Agency's Peer Review Handbook. ORD has a network of peer review coordinators who provide advice on implementing the Peer Review Handbook requirements and coordinate peer review activities within their respective organizations. A final check on peer review procedures is accomplished by requiring that all scientific and

technical products be cleared prior to external release using ORD's Clearance Procedures, managed via the Scientific and Technical Information Clearance System (STICS).

OCSPP-OPP ensures that all scientific work products (non-Influential Scientific Information (ISI) and Highly Influential Scientific Assessments (HISA)) undergo either secondary expert review or OPP internal peer review. These reviews are documented and quality assurance staff audit the process.

OAR conducts significant external, independent peer review, frequently using the Agency's Science Advisory Board (SAB) and Clean Air Act Science Advisory Committee (CAASAC), among others. The Office of Air Quality, Planning and Standards (OAQPS) has established peer review coordinators, who help staff determine the level of peer review appropriate for their scientific documents, including classification as ISI or HISA. All scientific products are entered into the Science Inventory.

The Office of Environmental Information (OEI) conducted two peer reviews of a Chemical Hazard Assessment in FY2015; OEI has a system in place to ensure the appropriate peer reviews are conducted and status updates are routinely provided to the Agency Science Activities database.

Region 3's Hazardous Site Cleanup Division (HSCD) has established a peer review process to review all remedial investigations and provide feedback at an early stage of the feasibility study. In addition, HSCD has established a team of staff and managers to review TCE Vapor Intrusion sites to ensure consistent decision making.

FACs

ORD ensures that the management of the Board of Scientific Counselors (BOSC), a federal advisory committee, strictly adheres to all Federal Advisory Committee Act requirements and the Scientific Integrity Policy. Nominations are sought in an open, transparent manner, including through the Federal Register and professional organizations. Members are selected based on their expertise, knowledge and contribution to the relevant area, while also providing a balanced and diverse committee. Members are appointed as Special Government Employees. Reports produced by the BOSC are recognized as products of the Committee and are not revised by ORD.

Professional Development

EPA encourages professional development activities so that EPA's scientists and engineers can maintain their expertise, be active members of their scientific communities and become leaders in their fields. Training activities may include online courses, webinars, in-person workshops or conferences. EPA provides several professional development opportunities for employees and encourages their participation in professional societies.

ORD is emphasizing the importance of peer reviewed publications by Agency scientists through a variety of approaches in performance reviews: 1) instituting a process by which peer reviewed publications are carefully monitored; 2) recognizing those who have published, 3) creating a poster that recognizes recent articles and authors; 4) instituting an award program for paper of the year; and 5) making publication an explicit element of Branch Chief Performance Appraisal and Recognition System (PARS) agreements.

OW's OWOW supports staff scientists to attend professional conferences where they can learn as well as give presentations on their own work.

OAR continues to encourage and support the professional development of its scientific staff by encouraging the presentation of scientific research at professional conferences, collaboration with other researchers both within and outside the agency, preparing peerreviewed journal articles, and working with the communications staff to disseminate scientific information of value to the public. Engineers in OTAQ are active in the Society of Automotive Engineers (SAE) and contribute to the development of international ASTM standards. OAQPS staff continue to gain recognition by publishing scientific papers in high quality scientific journals, including Environmental Health Perspectives, Environmental Science and Technology, American Journal of Epidemiology, and Risk Analysis. Publication is also recognized in evaluations of staff performance. Each division in OAQPS has a structure in place for reviewing scientific articles and presentations authored or co-authored by OAQPS staff.