Scientific Integrity

2019 ANNUAL REPORT

EPA

The mission of the U.S. Environmental Protection Agency is to protect human health and the environment.

EPA works to ensure that:

- Americans have clean air, land and water;
- National efforts to reduce environmental risks are based on the best available scientific information;
- Federal laws protecting human health and the environment are administered and enforced fairly, effectively and as Congress intended;
- Environmental stewardship is integral to U.S. policies concerning natural resources, human health, economic growth, energy, transportation, agriculture, industry, and international trade, and these factors are similarly considered in establishing environmental policy;
- All parts of society – communities, individuals, businesses, and state, local and tribal governments – have access to accurate information sufficient to effectively participate in managing human health and environmental risks;
- Contaminated lands and toxic sites are cleaned up by potentially responsible parties and revitalized; and
- Chemicals in the marketplace are reviewed for safety.

The EPA Scientific Integrity Official (SIO) champions scientific integrity throughout the Agency. The SIO chairs the Scientific Integrity Committee (the Committee) that is comprised of Deputy Scientific Integrity Officials (DSIOs) who represent every EPA program office and region. Science serves as the backbone for decision-making at EPA. The ability of the Agency to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies.

The full text of this report is available on EPA's website at: https://www.epa.gov/scientific-integrity/reports-and-additional-resources

Cover Design by EPA Scientific Integrity Program

EPA Publication number 601R21002

Printed on 100% Postconsumer, Process Chlorine Free Recycled Paper

This page Intentionally left blank

Acknowledgements and Contributors

Acknowledgments

The contributors wish to acknowledge:

The Scientific Integrity Committee, for its role in championing Scientific Integrity throughout the Agency, assistance in gathering the information needed for this report, and helpful review of an ear-lier draft. Additionally, Meghan Lewis, an Oak Ridge Associated Universities contractor in the Office of Science Advisor, Policy and Engagement, for a thorough review to ready the report for release.

Contributors

Francesca Grifo

Francesca is the Scientific Integrity Official (SIO) at the U.S. Environmental Protection Agency. Previously, she was the Director of the Scientific Integrity Program at the Union of Concerned Scientists. She holds a BA in biology from Smith College and a Ph.D. in plant systematics from Cornell University.

Martha Otto

Martha was the Scientific Integrity Program Lead in the Office of the Science Advisor. Martha retired in July 2020 and had over 30 years of experience at the U.S. Environmental Protection Agency in hazardous waste site remediation, innovative treatment technologies, and policy, regulation, and guidance development. She holds a BS in biology and an MS in environmental science and engineering from Virginia Tech.

Belinda Hawkins

Belinda is the Senior Science Advisor to the Scientific Integrity Program. She holds a BS in Environmental Health from Indiana State University and a dual PhD in Pharmacology and Toxicology and Environmental Toxicology from Michigan State University.

Maureen Hingeley

Maureen is a new member of the Scientific Integrity team, joining in March 2020. Maureen has been with EPA for over 15 years, serving as a program coordinator in multiple fields within the Office of Research and Development and the Office of Air and Radiation. Maureen holds a BS in Family and Community Service from East Carolina University.

Vincent Cogliano

Vincent is the Deputy Director for Scientific Programs at California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. He was formerly the Deputy to the Scientific Integrity Official at the U.S. Environmental Protection Agency. He was previously the Di-

rector of EPA's Integrated Risk Information System (IRIS). Vincent holds a BS in mathematics from the Catholic University of America, an MS in mathematics from the University of Michigan, and a Ph.D. in operations research from Cornell University.

Blake Neumann

Blake was an Oak Ridge Associated Universities contractor in the Office of the Science Advisor. He holds a BS in geography from Western Kentucky University, an MS in Environmental Science from SUNY-ESF and an MPA in environmental policy from Syracuse University.

Luke Cook-Griffin

Luke is an Oak Ridge Associated Universities contractor in the Office of Science Advisor, Policy and Engagement. He holds a BS in earth and environmental engineering and a MPA in environmental science and policy from Columbia University.

Avery Williams

Avery is an Oak Ridge Associated Universities contractor in the Office of Science Advisor, Policy and Engagement.

Table of Contents

List of Figures and Boxes iv

Acronyms V

Executive Summary 1

Introduction

- Scientific Integrity in 2019 3
- Scientific Integrity Program Annual Activities 4
  - The Scientific Integrity Committee 4
  - Scientific Integrity Annual Agency Wide Meeting 4
  - Mandatory Onboarding Training 5
  - General Scientific Integrity Training 6
  - Quarterly Briefings 6
  - Promoting a Culture of Scientific Integrity Online 6
  - Certifying Compliance w/ the Scientific Integrity Policy 6

- Scientific Integrity Program Initiatives 7
  - Scientific Integrity Award 7
  - Stakeholder Meeting 8
  - Management Training 8
  - Report by the Government Accountability Office 10
  - Office of Inspector General Audit 11
  - Responding to Scientific Integrity Concerns 12
    - Summary of Requests for Advice 14
    - Summary of Closed Allegations in FY 2019 17

- Scientific Integrity Activities Across EPA 18
  - Transparency and Public Access 18
  - Technical and Peer Review 19
  - Policy and Procedure 21
  - Training and Outreach 22
  - Promoting a Culture of Scientific Integrity 23

Opportunities for Improvement 23

Areas for Future Investment 24

Conclusions 25

Appendices

Appendix I: Annual Employee Conversation on Scientific Integrity Summary 26

Appendix II: Full Accounts of EPA SI Accomplishments 29

Appendix III: Members of the Scientific Integrity Committee 41

Figures & Boxes

Figure 1. Scientific Integrity Onboarding Training

Figure 2. Managers trained in EPA's Regional Offices during FY 2019

Figure 3. Managers trained in Program Offices during FY 2018-2019

Figure 4. How to seek scientific integrity advice or report an allegation

Figure 5. Allegations and Advice by Year

Figure 6. Number of scientific integrity queries received by quarter

Figure 7. Advice Requests by Topic

Figure 8. Advice by Status

Figure 9. Allegations by Topic

Box 1. What is Scientific Integrity?

Box 2. Advice or Allegation?

Box 3. What is Interference?

Box 4. Themes from A Series of Structured Interviews with Senior Leaders

Box 5. Release of Scientific Information to the Public

Box 6. Peer Review and the Use of Federal Advisory Committees

Box 7. Professional Development of Government Scientists and Engineers

Box 8. Promoting a Culture of Scientific Integrity

Acronyms

AA	Assistant Administrators
BEACON	Beach Advisory and Closing Online Notification
CGE	Computable General Equilibrium
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
DSIO	Deputy Scientific Integrity Official
DSO	Differing Scientific Opinion
ELMS	EPA's Lean Management System
EPA	U.S. Environmental Protection Agency
FMFIA	Federal Managers Financial Integrity Act
FY	Fiscal Year
GAO	U.S. Government Accountability Office
IDP	Individual Development Plan
IEC	International Electrotechnical Commission
IOAA	Immediate Office of the Assistant Administrator
IRIS	Integrated Risk Information System
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System
NAAQS	National Ambient Air Quality Standards
NASA	National Aeronautics and Space Administration
NCEE	National Center for Environmental Economics
NCCT	National Center for Computational Toxicology
NCEA	National Center for Environmental Assessments
NEIC	National Enforcement Investigations Center
NERL	National Exposure Research Laboratory
NIH	National Institutes of Health

NIHMS	National Institutes of Health Manuscript Submission
NOAA	National Oceanic and Atmospheric Administration
OAR	Office of Air and Radiation
OCFO	Office of the Chief Financial Officer
OCSPP	Office of Chemical Safety and Pollution Prevention
OCTEA	Office of Communities, Tribes and Environmental Assessment
OECA	Office of Enforcement and Compliance Assistance
OGC	Office of General Counsel
OGWDW	Office of Ground Water and Drinking Water
OIG	Office of Inspector General
OLEM	Office of Land and Emergency Management
OMB	Office of Management and Budget
OMS	Office of Mission Support
OP	Office of Policy
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
OSA	Office of the Science Advisor
OSIM	Office of Science Information Management
OST	Office of Science and Technology
OW	Office of Water
OWOW	Office of Wetlands, Oceans and Watersheds
PFAS	Per- and polyfluoroalkyl substances
QA	Quality Assurance
QAEMS	Quality Assurance Enterprise Management System
QAPP	Quality Assurance Project Plan
QC	Quality Control
RA	Regional Administrators

RTP	Research Triangle Park, NC
SAB	Science Advisory Board
SABSO	Science Advisory Board Staff Office
SACC	Science Advisory Committee on Chemicals
SI	Scientific Integrity
SIO	Scientific Integrity Official
SDMP	Scientific Data Management Plan
SOP	Standard Operating Procedures
STAA	Scientific and Technological Achievement Awards
STICS	Scientific and Technical Information Clearance System
TSCA	Toxic Substances Control Act
UCMR	Unregulated Contaminant Monitoring Rule
USGS	U.S. Geological Survey
WQSA	Water Quality Standards Academy

Executive Summary

The Scientific Integrity Annual Report chronicles the implementation of EPA's Scientific Integrity Policy (the Policy) in fiscal year (FY) 2019. Since February 2012, the Policy has provided both a vision and a roadmap for ensuring scientific integrity at the Agency. The Policy lists the components within a culture of scientific integrity and offers a framework for ensuring Agency-wide participation in that culture. Maintaining scientific integrity requires investment from, and the collaboration of, many parts of EPA. This report documents the investments made across EPA in FY 2019 and identifies areas of focus for future initiatives.

Several initiatives that provide ongoing support for scientific integrity at EPA were continued in FY 2019. These initiatives include convening the Scientific Integrity Committee (the Committee) for quarterly meetings, producing the annual report, holding the Annual Employee Conversation with the Scientific Integrity Official (SIO), hosting a stakeholder meeting on Scientific Integrity at the Agency, providing scientific integrity training, overseeing contractor-led peer reviews, and coordinating with both the Office of Inspector General (OIG) and the Office of General Counsel (OGC).

In FY 2019, the Scientific Integrity Program[1] (the Program) introduced new initiatives across the Agency that strengthened EPA's culture of scientific integrity. The Program introduced an inaugural EPA National Honor Award for Scientific Integrity that recognizes achievements that have significantly advanced the culture of scientific integrity at EPA. Nominees for this award must demonstrate exceptional resourcefulness, creativity, courage, and/or commitment to effectively implementing the Scientific Integrity Policy and to enhancing the culture of scientific integrity at EPA. The Program conducted management dialogues on scientific integrity, through which EPA leaders had open conversations with the Scientific Integrity Official (SIO) about their experiences in scientific integrity and learned more about the role that they play in contributing to the Agency's culture of scientific integrity. The Program finalized language for future Agency grants and contracts to ensure compliance with the Policy, further enhancing EPA's culture of scientific integrity.

The Program focused on deploying a training specifically geared towards managers and supervisors. These management trainings reached participants from eight EPA regional offices and 11 EPA headquarters offices. A total of 491 EPA leaders were trained in FY 2019.

The Scientific Integrity Official continued to work with employees who had scientific integrity questions or concerns. Many issues were resolved informally, preventing the need to report the issues as allegations of violations of the Scientific Integrity Policy. During FY 2019, EPA's Scientific Integrity Program received 56 requests for advice and nine new allegations of lapses of scientific integrity.

The Program also continued its work on developing new guidance and policies. When finalized, "Approaches for Expressing and Resolving Differing Scientific Opinions" will recommend a progression of approaches for managers and employees to use to encourage the expression and resolution of differing scientific opinions.

Scientific integrity remains an ongoing priority for EPA. While many scientific integrity successes occurred in FY 2019, further progress must be made to fully ensure a robust culture of scientific integrity at EPA. This annual report details several highlights from the last year and looks forward to future areas for improvement.

In FY 2019 and beyond, three priority issues present opportunities for ongoing investment:

[1] The Scientific Integrity Program consists of the Scientific Integrity Official and members of the Scientific Integrity Committee

1. Increasing the visibility of scientific integrity at EPA;
2. Embracing and modeling scientific integrity across EPA;
3. Protecting and maintaining EPA's culture of scientific integrity.

Agency investments in these activities ensure the credibility of, and maintain public trust in, EPA science. The SIO and the Committee will continue to work with the Senior Counsel for Ethics, the Office of Inspector General (OIG), and the rest of the Agency to safeguard science and maintain public trust in the quality and integrity of EPA's work every day.

Scientific integrity is the compass that guides EPA in its mission to protect human health and the environment. Scientific integrity ensures that the science that is conducted and utilized at EPA is objective and of the highest quality. Scientific integrity prevents conflicts of interest or policy implications from interfering with or influencing scientific results. Scientific integrity encourages robust scientific discourse, welcomes differing scientific opinions, and supports the professional development of staff. Scientific integrity requires that others be acknowledged for their intellectual contributions. Scientific integrity guarantees that science is communicated openly, transparently, and in a timely manner. Together, each of these elements create a culture of scientific integrity at EPA that inspires public trust in the Agency and ensures that EPA achieves its mission of protecting human health and the environment. See Box 1 for more information on *What is Scientific Integrity*?

1. Introduction

EPA's mission is to protect human health and the environment. This annual report on scientific integrity at EPA contributes to the Agency's ongoing commitment to transparency.

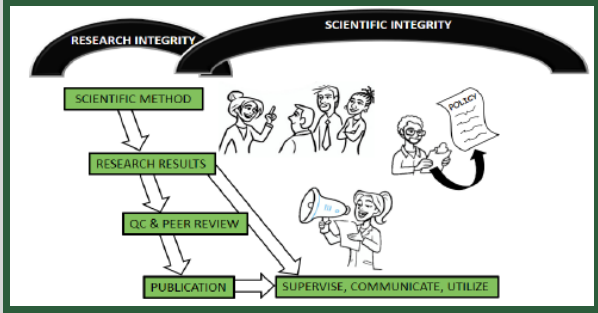
When EPA upholds a culture of scientific integrity:

- Our scientists are able to do their best work;
- Scientific findings and information are generated, reviewed and disseminated in a timely and transparent manner;
- The work of EPA is informed by robust independent science; and
- We increase public trust.

Box 1: What is Scientific Integrity?

Scientific integrity is the adherence to professional values and practices when conducting, communicating, supervising, and utilizing the results of science and scholarship. Scientific integrity ensures objectivity, clarity, reproducibility, and utility. It provides insulation from bias, fabrication, falsification, plagiarism, outside interference, and censorship.

The Agency may make final policy decisions that weigh other factors besides science but are still consistent with EPA's governing statutes. Such decisions, even if they are not consistent with the science, do not necessarily constitute scientific integrity issues. Implementing the Policy requires input from a wide variety of sources across the Agency, which interact to promote and maintain a culture of scientific integrity.



EPA released its Scientific Integrity Policy[2] (the Policy) in February 2012. The Policy lists the components of a culture of scientific integrity and offers a framework for ensuring high standards of scientific integrity at the Agency and Agency-wide compliance. At the end of each fiscal year, EPA reviews the scientific integrity activities at the Agency during that year. This annual report serves to highlight the status of scientific integrity within EPA at the end of FY 2019, including scientific integrity accomplishments, new initiatives, and areas for future investment.

EPA's Scientific Integrity Policy

The Scientific Integrity Policy builds upon existing Agency and government-wide policies and guidance documents to enhance EPA's overall commitment to scientific integrity.

The Policy applies to all EPA employees including scientists, managers and political appointees. Beginning in FY 2019, if a grantee is engaged in conducting science, supervising science, communicating science, or using or applying the results of science, the recipient and the project team must review the Policy and comply with its requirements as part of their agreement with EPA. Contractors, collaborators, and volunteers are also expected to uphold the standards established by this Policy and may be required to do so as part of their respective agreements with EPA.

To promote scientific integrity throughout the Agency, the policy outlines four specific areas: a) the culture of scientific integrity at EPA, b) public communications, c) the use of peer review and Federal Advisory Committees, and d) professional development of government scientists. The policy requires that the Agency support a culture of scientific integrity, enhance transparency within scientific processes, and protect Agency scientists. The policy fosters a culture of transparency regarding

[2] https://www.epa.gov/scientific-integrity/epas-scientific-integrity-policy

the results of research, scientific activities, and technical findings, providing for open communication that is free from political or other interference. The policy recognizes that independent peer review is necessary to ensure the credibility and quality of Agency science and thus is a crucial aspect of scientific integrity. The policy also encourages the appropriate use of Federal Advisory Committees. The policy recognizes that scientific leadership is a key component of advancing the mission of EPA. Agency scientists are encouraged to engage with their peers in academia, industry, government, and non-governmental organizations, consistent with their work responsibilities. See Boxes 2-5 for more information on the four sections of the Policy.

2. Scientific Integrity in FY 2019

Scientific Integrity Program Annual Activities

The Scientific Integrity Committee

The Scientific Integrity Policy established a Scientific Integrity Committee, chaired by the Scientific Integrity Official (SIO). The Committee meets quarterly and consists of senior program office and regional officials who are designated as Deputy Scientific Integrity Officials (DSIOs) for their respective organizations. They provide leadership for the Agency on scientific integrity, jointly assist in the implementation of the Policy, and promote Agency compliance with the Policy. The SIO regularly communicates with Committee members to discuss potential approaches to emerging issues and work together to resolve allegations. The participation of the Committee's experiences brings expertise from across the Agency. Committee members and contact information can be found on the Scientific Integrity internet page and in Appendix III found inside the back cover of this report.[3] In FY 2019, the Committee focused on a number of topics including: scientific integrity language for contracts and grants that include scientific research, the communication of science and/or the utilization of science, new employee on-boarding training, scientific integrity training and outreach to EPA managers, annual certification of compliance with the Scientific Integrity Policy using the Federal Management Financial Integrity Act (FMFIA) annual statements, Approaches to Resolving Differing Scientific Opinion (DSO), procedures for allegations and requests for advice, the Office of Inspector General discussion draft on the Implementation of EPA's Scientific Integrity Policy, allegation and advice queries, and the Government Accountability Office government-wide report, Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research[4]. Additionally, the Committee was briefed on the successful outcomes of the Annual Agency Wide Scientific Integrity Meeting on June 6, 2019, and the Scientific Integrity Annual Stakeholder Meeting held on June 4, 2019. The Committee also launched a new EPA National Honor Award for Scientific Integrity. The Committee welcomed new members (Johanna Hunter, Bill Jenkins, Linda Anderson-Carnahan, and Andy Simons) and thanked outgoing members Jennifer Fulton, David Allnutt, CarolAnn Sicili- ano, Art Johnson and Tom Sinks for their hard work on scientific integrity issues.

Annual Agency-Wide Scientific Integrity Meeting

The Annual Agency-Wide Scientific Integrity Meeting was held on May 6, 2019. It provided an opportunity for EPA employees to learn about scientific integrity at EPA and ask questions. The SIO, Dr. Francesca Grifo, presented to a live audience at headquarters and to the rest of the Agency through a webinar. Over 200 individuals attended the meeting online or in person from

[3] https://www.epa.gov/scientific-integrity/scientific-integrity-epa#Scientific-integrity-committee
[4] https://www.gao.gov/assets/gao-19-265.pdf

EPA program offices and regions. This session improved the visibility of the Policy and increased awareness among EPA employees. The session focused on the distinction between science and policy and stressed the importance of the Scientific Integrity Policy in making EPA science independent and unassailable. The Deputy to the Scientific Integrity Official, Dr. Vincent Cogliano, summarized previous and ongoing Scientific Integrity cases, noting a recent uptick in interference queries. The meeting concluded with a lively question and answer session. A more detailed description of the meeting proceedings can be found in Appendix I.

Mandatory Employee Onboarding Training

Since January 2017, all new EPA employees have been required to take mandatory online scientific integrity training as part of their onboarding requirements. The training video shows the SIO conducting a presentation that features the introductory whiteboard video and discussion, followed by a short quiz. Showing this training to new employees helps them to establish a personal commitment to scientific integrity, which contributes to the overall culture of scientific integrity at EPA. Figure 1 below summarizes the number of employees that have been onboarded since the inception of the onboarding training. Note that the heightened number of employees onboarded during the second quarter of FY 2017 was due to existing employees who were enrolled in the training retroactively. Through the end of FY 2019, 1,052 EPA employees have successfully completed the onboarding training.

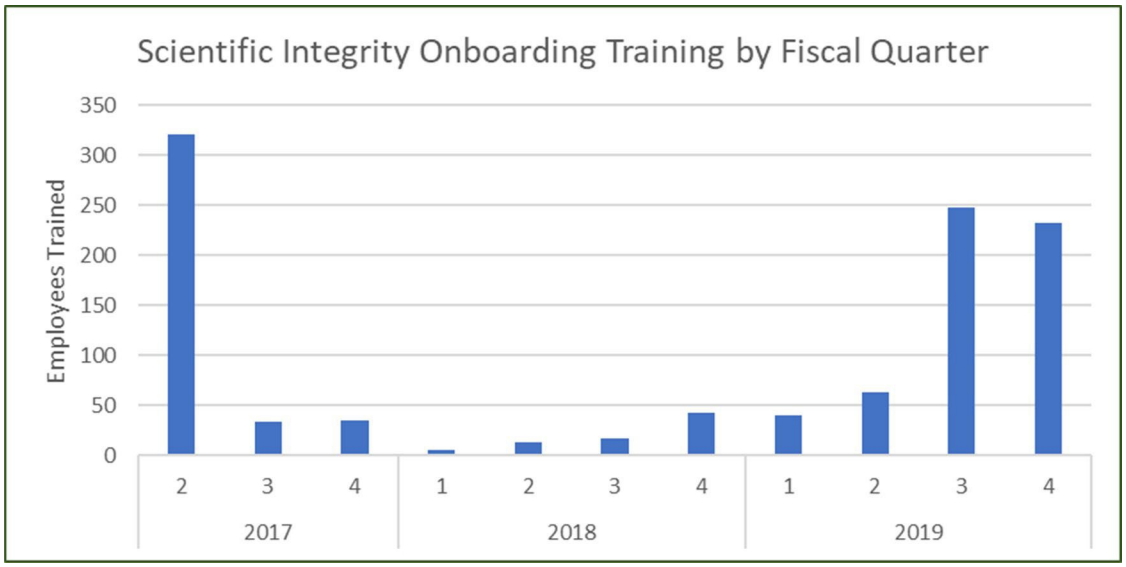


Figure 1. Scientific Integrity Onboarding Training

Scientific Integrity General Training

General training for all interested staff was conducted concurrently with Management Dialogue sessions during visits to regional offices and labs. During FY 2019, the Scientific Integrity team collectively held general training sessions in eight regional offices and one regional lab. Approximately 325 participants were trained through these sessions and additional training of managers and supervisors was conducted through the Scientific Integrity Management Training initiative.

Quarterly Coordination Meetings with the Office of Inspector General and the Office of General Counsel

The SIO maintains regular communication with both the Office of Inspector General (OIG) and the Office of General Counsel (OGC) through quarterly meetings. During these meetings, the SIO and relevant parties discuss current allegations and anticipated courses of actions. These conversations use sanitized allegation summaries that protect identities of the involved parties. The coordination between these offices ensures clarity of roles and responsibilities and is crucial to Agency-wide implementation of the Scientific Integrity Policy.

The handling of scientific misconduct — which includes fabrication, falsification, plagiarism, or misrepresentation in proposing, performing, or reviewing scientific or research activities — is governed by EPA's Scientific Misconduct Policy and is overseen by the OIG. In FY 2019, two allegations were received through the OIG hotline and referred to the SIO. Also, in FY 2019, the SIO referred two allegations to the OIG.

Promoting a Culture of Scientific Integrity Online

As in previous years, in FY 2019 the Scientific Integrity public internet webpages received substantially higher traffic than the intranet pages available to just EPA. The public homepage was viewed a total of 5,069 times and the Scientific Integrity Policy webpage attracted 1,458 views. The Scientific Integrity Policy was downloaded 574 times in FY 2019, which was roughly on pace with FY 2018 numbers. Meanwhile, the Scientific Integrity intranet webpage had 882 views, and the 2019 Annual Employee Conversation with the Scientific Integrity Official was the second most popular scientific integrity intranet page with 322 visits. Additionally, web traffic was notable for the Authorship Best Practices page (238 views), the Best Practices for Clearance page (162 views) and the Dr. Chris Kirkpatrick Whistleblower Protection Act of 2017 page (102 views). Other notable web traffic on the Scientific Integrity intranet webpages included the Authorship Best Practices page (88 views), the Clearance Best Practices page (80 views) and the Whiteboard Training page (67 views).

Certifying Compliance with the Scientific Integrity Policy

The Federal Managers Financial Integrity Act (FMFIA) requires that federal agencies establish internal control and financial systems that provide reasonable assurance of achieving effectiveness and efficiency of operations, compliance with regulations and applicable laws, and relia-

bility of financial reporting[5]. EPA Assistant Administrators (AAs) and Regional Administrators (RAs) must certify that their programs comply each year through an assurance letter to the EPA Administrator, who delivers an overall statement of assurance to the President and Congress. FY 2019 marked the sixth year that AAs and RAs were required to submit an attachment certifying internal controls for scientific integrity. Based on the requirements that are outlined in the Scientific Integrity Policy, programs, offices, and regions were asked to report their accomplishments, potential weaknesses, and overall progress in implementing the Agency's Scientific Integrity Policy. In addition, programs, offices, and regions are required to provide the Scientific Integrity Program with information about their scientific integrity best practices, any new initiatives or challenges and how the Committee or Scientific Integrity Program can be of assistance. This information will be used to create the compilation of activities across the Agency and for discussion by the Scientific Integrity Committee.

Scientific Integrity Program Initiatives

New EPA National Honor Award for Scientific Integrity

In FY 2019, the Scientific Integrity Program launched a new EPA Award for Outstanding Achievement in Enhancing EPA's Culture of Scientific Integrity. The award is designed to recognize achievements that have significantly advanced the culture of scientific integrity at EPA. Nominees demonstrated exceptional resourcefulness, creativity, courage, and/or commitment to effectively implementing the Scientific Integrity Policy and to enhancing the culture of scientific integrity at EPA.

The award may be presented to an individual or to a team of up to twenty individuals through the Senior Executive Service level. The following examples illustrate criteria for this award:

- Made measurable and lasting impact to improve scientific integrity within a program, office, or region or across EPA;
- Demonstrated outstanding efforts in increasing awareness of the Policy, championing the release of independent science, and exhibiting diligence in pursuing transparency surrounding scientific data, interpretations, and conclusions;
- Successfully encouraged colleagues to take responsibility in promoting a culture of scientific integrity;
- Created an environment in which employees feel secure in expressing differing scientific opinions;
- Developed or applied an innovative approach, technique, or tool that is key to promoting a culture of scientific integrity.

Nominations were accepted for the first time in FY 2019. The first winner of the award will be announced in FY 2020.

[5] https://www.gsa.gov/reference/reports/budget-performance/annual-reports/agency-financial-report-2012/managements-discussion-and-analysis/gsa-management-assurances/federal-managers-financial-integrity-act-section-2

Scientific Integrity Annual Stakeholder Meeting

The Agency hosts a public stakeholder meeting in alternate years to provide an opportunity for stakeholders to hear from the EPA SIO and to comment on or ask questions about Scientific Integrity at the Agency. The 2019 meeting was held on June 20, 2019, and 89 individuals attended the meeting (56 in person and 33 online). A variety of stakeholders from non-governmental groups and regulated industry attended. The SIO introduced the new management training initiative rolled out by the Program. The Deputy to the Scientific Integrity Official, Dr. Cogliano, detailed the Program's procedures for dealing with allegations of a violation of the Policy. Participants had an opportunity to ask questions during a lengthy Q&A period, which offered an opportunity to learn more about upcoming Scientific Integrity initiatives, outreach efforts and policies, to understand recent trends in allegations and advice cases, and to get additional clarification on adjudicated cases.

Management Training

Although the management training initiative began in 2018, the bulk of the work took place in 2019. These sessions provided an opportunity for managers to learn about their scientific integrity responsibilities as leaders at EPA, understand what scientific integrity is, know what resources they have access to, learn how to identify lapses in scientific integrity, and discuss their experiences with scientific integrity. Attendees were given the Scientific Integrity Brochure, the Scientific Integrity Factsheet, and scientific integrity posters.

Specifically, managers were apprised of their important role in upholding a culture of scientific integrity, encouraging good policies and practices, leading the way, and mediating negative influences on scientific integrity. Other topics included how to support employees who report a lapse in scientific integrity, promoting and rewarding scientific discussions which include various perspectives, how to recognize inappropriate influences and speak up or seek help to resolve them.

The ScI Team traveled to eight of the ten EPA Regions where 222 managers participated in Management Dialogue sessions. In addition, in FY 2019, the Team held sessions in all program offices (including locations in headquarters, Research Triangle Park, Narragansett, Corvallis, Ann Arbor, and Denver), training 285 managers. In FY 2019, the Scientific Integrity team trained 507 managers and supervisors (see Figures 2 & 3 below). To monitor the quality of this program, all attendees were asked to complete an evaluation of the session that they attended. The participants who responded provided positive feedback that the session was useful, will help them to do their job more effectively, and that they would recommend a colleague attend.

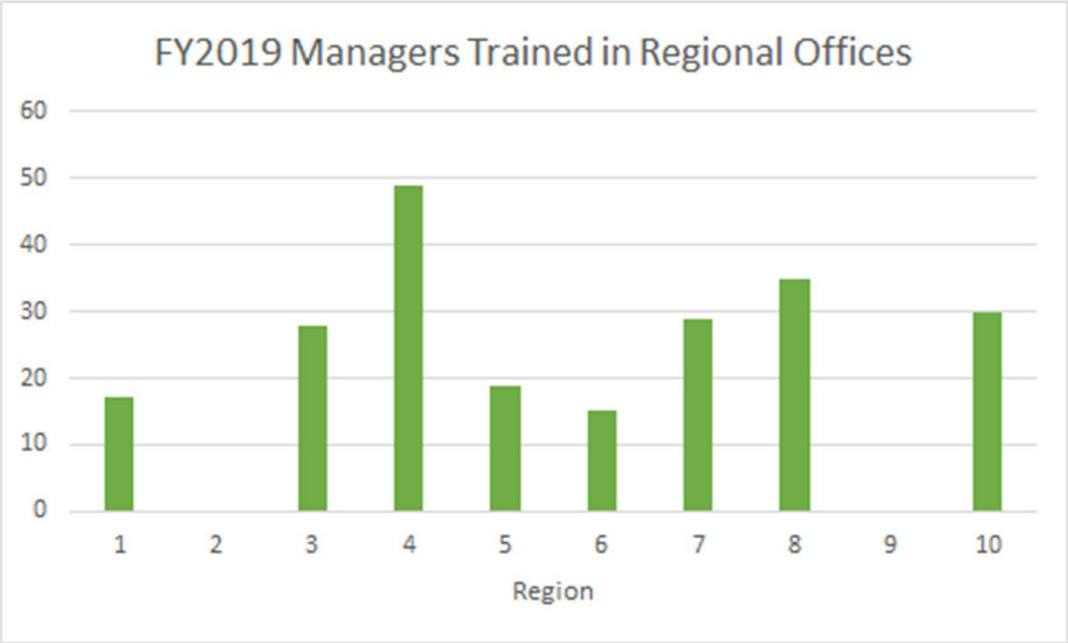
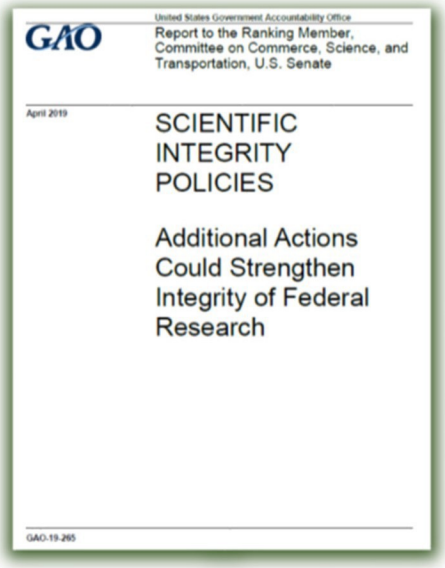


Figure 2. Managers trained in EPA's Regional Offices during FY 2019. Regions 2 and 9 will receive training in FY 2020.

Figure 3. Managers trained in EPA's Program Offices FY 2018-2019.

GAO Scientific Integrity Report

On June 14, 2018, the U.S. Government Accountability Office (GAO) informed EPA that it began an engagement examining the implementation of government scientific integrity policies in response to a request from former Senator Bill Nelson (D-FL). The review focused on three key questions:



1. What are the main components of selected agencies' scientific integrity policies?
2. To what extent do selected agencies have processes in place to reasonably ensure that the objectives of their scientific integrity policies are achieved?
3. To what extent have agencies established processes for reporting and investigating allegations of violations of their scientific integrity policies?

On April 4, 2019, GAO issued a government-wide report, Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research[6]. GAO found EPA's Scientific Integrity Policy addressed the components outlined in the December 17, 2010 Office of Science and Technology Policy memorandum. GAO issued 10 report recommendations to other agencies, including NASA, DOE, NIST, DOT, USGS, and NOAA, to "ensure their policies are protecting scientific integrity." GAO did not issue any recommendations to EPA.

GAO found EPA has taken actions to educate and communicate to staff about the Scientific Integrity Policy; designated a Scientific Integrity Official who is responsible for EPA's implementation of the Policy; taken actions to monitor and evaluate the performance of its Scientific Integrity Activities; and has specific documented procedures for identifying and addressing alleged violations of the EPA scientific integrity policy.

The GAO report highlighted several of EPA's scientific integrity successes, including the impact of EPA's outreach to staff to report scientific integrity issues. Compared to other agencies in GAO's study, EPA had significantly higher "reported alleged violations of scientific integrity policies, ranging from one allegation at USDA/ARS to 70 at EPA. Of EPA's 70 allegations received between FYs 2012 and 2017, 18 were found to be violations." GAO noted EPA's comparatively high number of allegations can be contributed to being

"very proactive in encouraging staff to report scientific integrity issues."

[6] https://www.gao.gov/assets/gao-19-265.pdf

The report also referenced EPA as a best practice for agencies response to scientific integrity violations. Specifically, EPA's "scientific integrity official or a convened committee decides whether a violation occurred, and a designated official from the alleged violator's office decides how to respond to any confirmed violations." GAO positively noted the biennial training requirement in EPA's scientific integrity policy for all EPA staff includes "whistleblower protections and political interference, along with other topics." Lastly, GAO recognized EPA's efforts to "evaluate the effectiveness of its scientific integrity policy and use the results to assess the current culture of scientific integrity."

OIG Scientific Integrity Audit

On August 30, 2018, EPA's Office of Inspector General (OIG) announced a self-initiated project on the Implementation of EPA's Scientific Integrity Policy[7]. The objectives were to deter-mine whether "EPA's Scientific Integrity Policy is being implemented as intended to assure scientific integrity throughout the EPA." Additionally, the OIG looked at the following areas:

- Extent and type of employee concerns, if any, with scientific integrity at EPA.
- Employee awareness of EPA's Scientific Integrity Policy, including the process for reporting potential violations.
- Reasons potential violations may not be reported.
- Adjudication process in general and any concerns (e.g., satisfaction with complaint resolution, timeliness of resolution and other process-related issues).
- Employee and contractor survey results (November 2018) on awareness of the EPA Scientific Integrity Policy.

On August 29, 2019, the OIG issued a Discussion Document of preliminary audit findings for the agency's review. The OIG compared their November 2018 survey results with EPA's 2016 survey of Agency awareness of the Scientific Integrity Policy and found an increased awareness of the Scientific Integrity Policy and how to report an allegation or violation of the Scientific Integrity Policy. However, the survey comparison also found reduced perceived leadership support of scientific integrity and knowledge of review and clearance procedures. The Agency provided technical and clarifying edits to the OIG on the Discussion Document.

In early 2020, the OIG is expected to issue a detailed audit report and recommend EPA "develop procedures for addressing and resolving allegations of SI violations, communicate the outcomes of reports of SI violations, and improve the release of scientific information to

[7] https://www.epa.gov/sites/default/files/2018-08/documents/_epaoig_notificationmemo_8-30-18_scientificintegrity.pdf

the public." The Agency will develop a corrective action plan to address the expected OIG recommendations, which will be included as an appendix in the OIG's publicly released final report.

Scientific Integrity Language for Grants

Beginning in FY 2019, if the recipient of a grant is engaged in conducting, supervising, communicating, or using science or applying the results of science, the recipient and the project team must review the Policy and comply with its requirements as part of their agreement with EPA. These requirements are detailed in Section 33, "Scientific Integrity Terms and Conditions" of "EPA General Terms and Conditions, Effective October 1, 2019 ."[8]

Scientific Integrity Language for Contracts

In FY 2018, EPA issued a proposed rule to address applicability of scientific integrity requirements to EPA contracts by creating a clause on scientific integrity in solicitations and contracts under which a contractor may be required to perform scientific activities or use scientific information to perform advisory and assistance services. This clause was designed to complement the EPA Scientific Integrity Policy to ensure that all scientific work developed and used by EPA and its contractors is accomplished with scientific integrity. The public comment period ended in November 2018. The Agency expects to make a decision on the final rule in FY 2020.

Responding to Scientific Integrity Concerns

The Presidential Memorandum on Scientific Integrity[9] (March 9, 2009) directs that "Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may [have been] compromised." EPA's Scientific Integrity Policy requires "mechanisms to ensure accountability." Accordingly, the Scientific Integrity Program provides a procedure for seeking advice to prevent lapses in scientific integrity and for reporting allegations of possible violations of EPA's Scientific Integrity Policy. Allegations may be reported to the SIO, any DSIO, or the Inspector General Hotline (Figure 4.).

In FY 2018, the Program drafted a new procedure creating a two-pronged approach separating those seeking advice about scientific integrity concerns from those reporting allegations. In general, the new advice track was designed to resolve concerns before they

Figure 4. How to seek scientific integrity advice or report an allegation.

[8] See Section 33 "Scientific Integrity Terms and Conditions" on pp 19-20 of "EPA General Terms and Conditions Effective October 1, 2019" https://www.epa.gov/grants/epa-general-terms-and-conditions-effective-october-1-2019-or-later

[9] https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-_agencies-3-9-09

became a formal allegation by giving informal and early counsel. Eleven allegations and 61 requests for advice were received during FY 2019.

Annual Update on Allegations and Advice

The aim of the advice track is early preventive action to uphold EPA's culture of scientific integrity. Anyone with a question or a concern is encouraged to have a conversation with the SIO (Francesca Grifo), the Deputy to the SIO, or any of the Agency's Deputy SIOs located in each program or regional office. These officials provide timely advice or assistance. If the issue is not one of scientific integrity, they can assist in redirecting it as appropriate such as directing retaliation, waste, fraud or abuse to EPA's Office of the Inspector General. If advice and assistance does not resolve the issue, an allegation may be filed with the SIO or Deputy SIOs. Following the development of the two-track procedure described in Box 2, the Scientific Integrity Program reviewed all prior allegations and reclassified many of them as requests for advice. There have been 179 requests for advice and 84 allegations from 2012 when EPA's Scientific Integrity Policy was issued through September 30, 2019. Figure 5 illustrates allegations and advice requests by year since the Policy was adopted and Figure 6 breaks these submissions down by quarter.

Box 2. Advice or Allegation ?

Advice

- **First conversation.**
- **Is it scientific integrity?**
- **Next steps are clear.**
- **Informational conversation.**
- **Not high profile or directly linked to a threat to public health.**
- **Can be anonymous.**

Allegation

- **Based on current information, it would be aviolation of the Policy.**
- **The submitter is aware of our limitations on confidentiality and wishes to proceed.**
- **Advice is not appropriate.**
- **Previous advice was not effective or effective enough.**

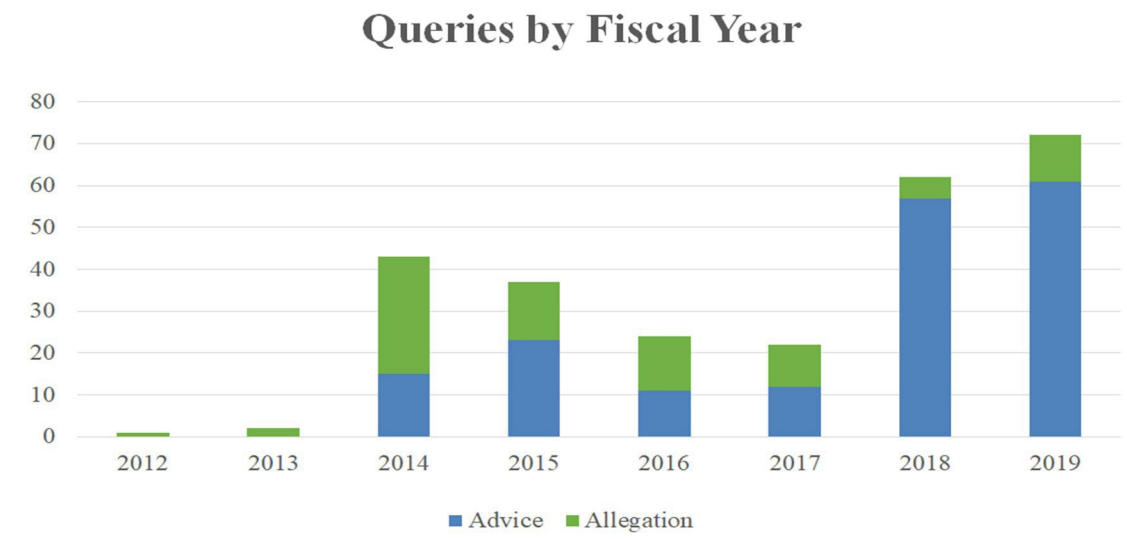


Figure 5. Allegations and Advice by Year

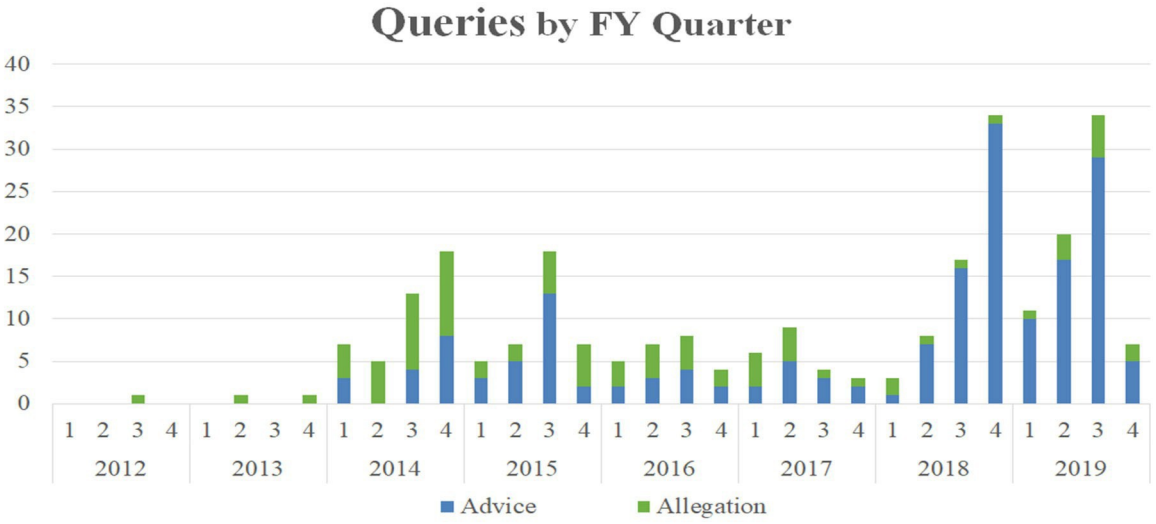


Figure 6. Number of scientific integrity queries received by quarter

Summary of Requests for Advice

In FY 2019, we received 61 requests for advice (Figure 7). These ranged from questions about peer review and attribution (16%) to delay and suppression of scientific products (23%) to interference in science (49%). While this was not a large increase in the number of advice queries from FY 2018, it does represent a jump overall.

One third of the total accumulated over eight years (179) occurred in a single year. It also represents increases in two critical categories of queries – interference and suppression/delay. The number of advice queries that involved interference (Box 3) rose from 22 in FY 2018 to 30 in FY 2019 and delay and suppression rose from 9 in FY 2018 to 14 in FY 2019. One possible explanation for these in- creases is that advice queries can be submitted anonymously. Many of these advice queries were accompanied by a stated fear of retaliation, retribution, or other forms of reprisal, and a clear statement that without that fear, they would have submitted formal allegations. Reprisal and retaliation are prohibited by federal law and all those reporting this to the Scientific Integrity Official are directed to report any in- stances to the EPA Office of the Inspector General. Approximately half of all requests for advice since the policy was enacted have not escalated to allegations and roughly a third have resulted in an allegation being averted (Figure 8.)

Box 3. What is Interference?

The altering of scientific products without scientific justification. For example:

- **Manipulation of science used in decision making;**
- **Removing studies, cherry picking studies for inclusion, or narrowing the scope of the science without scientific justification;**
- **Rejection of models, new methods, information, or procedures;**
- **Downplaying or exaggerating uncertainty;**
- **Using inadequate, outdated, or substandard science**
- **Risk management considerations driving risk assessment decisions;**
- **Changes to minimize risk conclusions or removal of hazards in assessments.16%**

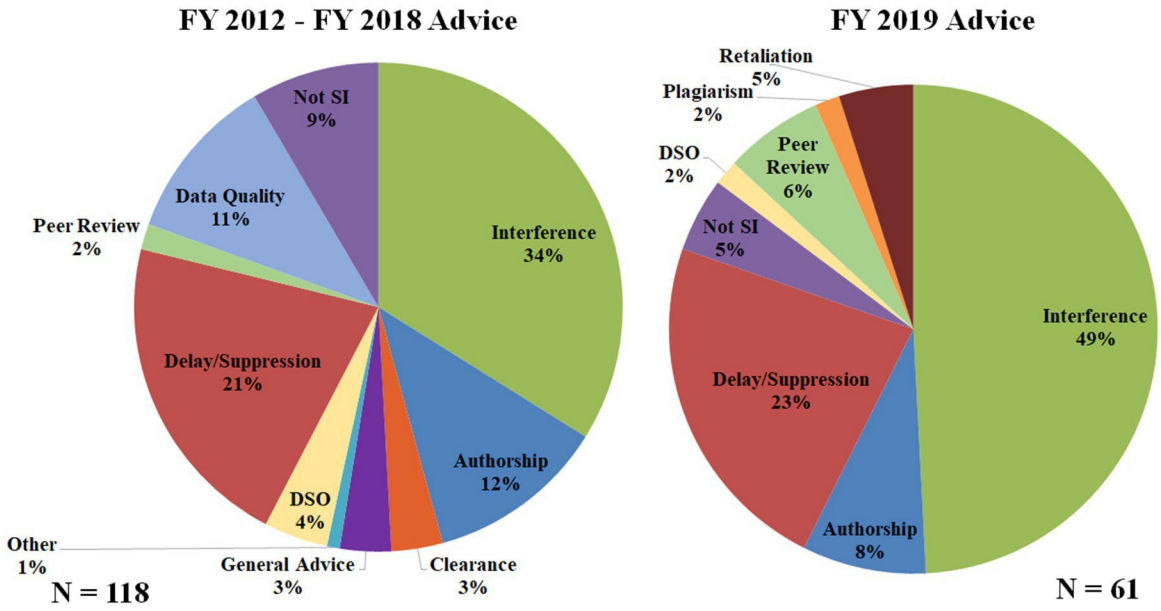


Figure 7. Advice Requests by Topic

Allegations

When advice does not resolve an issue, is not appropriate, or an issue is complex, filing an allegation may be a better option. If an issue concerns an unaddressed significant risk to public health or the environment, submitters are directed to EPA's elevation procedure[10].

Any person, from within or outside EPA, may report an allegation in writing to the SIO, any Deputy SIO, or the Office of Inspector General. Allegation reports should include, when possible, detailed references to the specific provision(s) of EPA's Scientific Integrity Policy that were violated, supporting evidence with a timeline, and the names of witnesses who can provide pertinent information

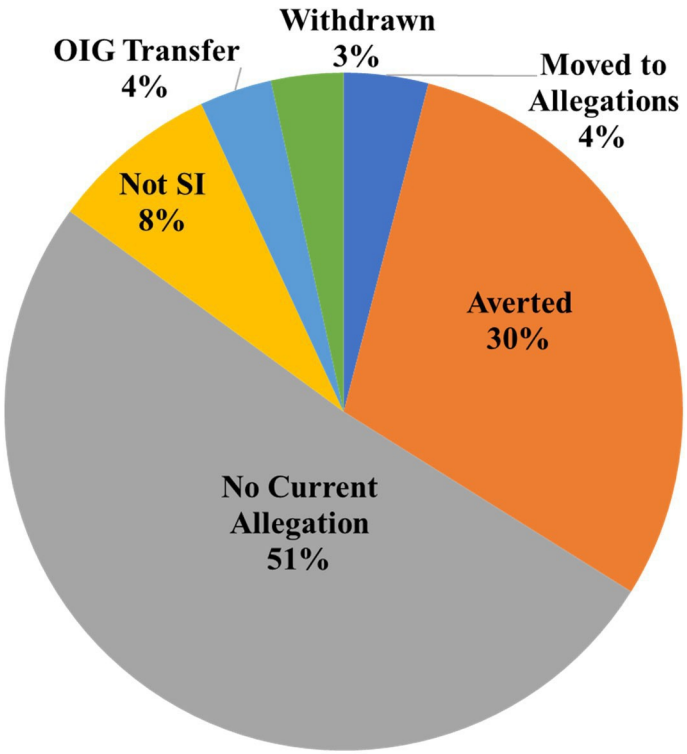


Figure 8. Status of Requests for Advice

Once received, the Scientific Integrity Program screens the allegation, gathers additional pertinent Information, and makes a determination based on the available information, drawing on the experience and expertise of the Scientific Integrity Committee as needed. The determination includes recommendations for corrective scientific action and other preventive measures as appropriate. It is important to note that recommendations are not directed at individual employees but rather at safeguarding the science. Throughout the process, confidentiality is maintained to the extent the law allows and knowledge about the identity of persons sub- mitting or otherwise involved in the allegation is limited to those who need to know.

In FY 2019, we received 11 allegations (Figure 9). This a large increase from the four allegations received in FY 2018. These ranged from questions about peer review and attribution, to interference, delay and suppression of scientific products.

10 https://work.epa.gov/epa/identify-unaddressed-significant-public-health-or-environmental-risk

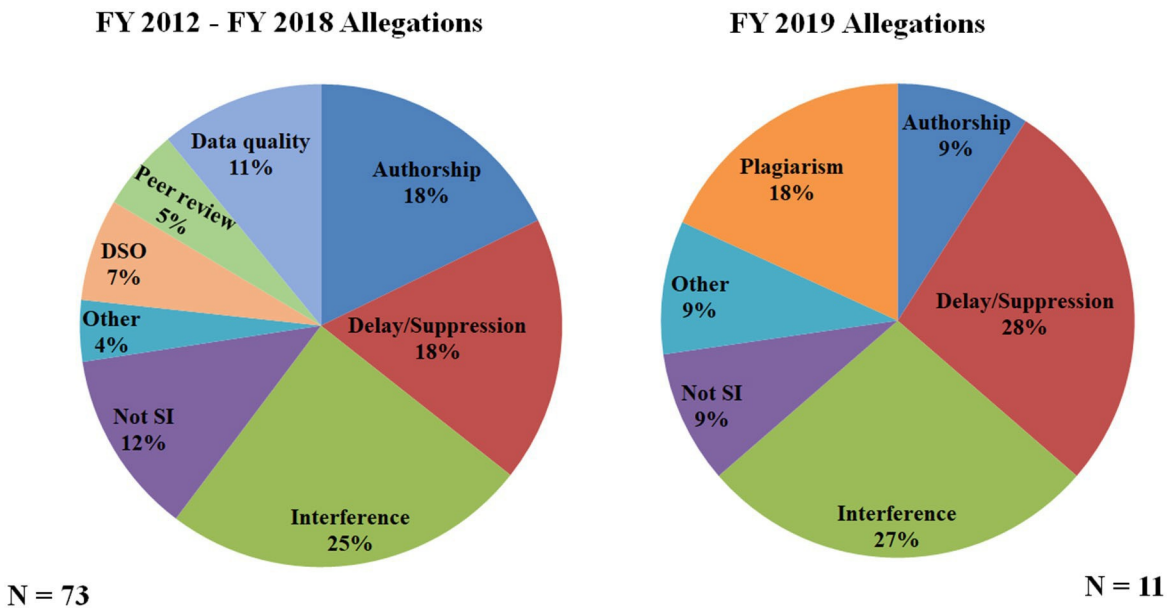


Figure 9. Allegations by Topic

Summary of Closed Allegations in FY 2019

Seven allegations were closed during FY 2019. Summaries of the allegations adjudicated during FY 2019 are listed below.

1. An academic researcher complained that a draft manuscript of theirs was on an EPA website without their knowledge or permission. They also accused EPA of inappropriately using their copyrighted code. This complaint was not substantiated because the scientific integrity investigation found that the manuscript could not be located on an EPA website and the code in question was publicly available.

2. A complainant alleged that illegal procedures were being used in regulatory activities. The SIO reported this allegation to the OIG. The OIG declined to investigate. The submitter subsequently withdrew the allegation with the Scientific Integrity Program to allow new management the opportunity to address the situation.

3. A complainant alleged that EPA used data in a proposed rule without making those data publicly available. This complaint was not substantiated as the scientific integrity investigation found that the data were CBI and legitimately withheld. However, this complaint was included in a compilation of much broader concerns that were reported to the OIG. The OIG completed an investigation and released the report, "EPA Failed to Develop Required Cost and Benefit Analyses and to Assess Air Quality Impacts on Children's Health for Proposed Glider Repeal Rule Allowing Used Engines in Heavy-Duty Trucks" (20-P-0047)[11].

4. A public commenter on a draft Integrated Science Assessment (ISA) requested that the SIO intervene in EPA's response to the peer review conducted by the Clean Air Scientific Advisory Committee. This complaint was not substantiated. The scientific integrity investigation

[11] https://www.epa.gov/sites/default/files/2019-12/documents/_epaoig_20191205-20-p-0047.pdf

found the Federal Advisory Committee Act process was followed and EPA's consideration of peer review and public comments on this ISA was consistent with EPA's Peer Review Handbook.

5. An authorship dispute was investigated and not substantiated.
6. An allegation of fraud was not a violation of EPA's Scientific Integrity Policy and was reported to the OIG.
7. An allegation of management misconduct was not a violation of EPA's Scientific Integrity Policy and was reported to the OIG.

Scientific Integrity Activities Across EPA

In FY 2019, program and regional offices engaged in a variety of activities to enhance the culture of Scientific Integrity across the Agency. EPA offices encouraged greater transparency and public access by improving access to scientific studies, data and reporting through improved online platforms for data sharing. They strengthened transparency by adhering to common best practices, publicizing results and updates on their webpages, and continuing their commitment to effective dialogue with external stakeholders through public meetings and comment periods. EPA offices adopted new tools, approaches and best practices to improve the processes associated with technical reviews and peer reviews, including the use of advisory committees and working to develop a new eClearance system. Program and regional offices enhanced internal and external safeguards to ensure that scientific data, reports and assessments are rigorously reviewed, and to improve quality assurance processes. Some offices consolidated scientific integrity activities and practices into more streamlined processes or codified them into written policies and procedures. EPA offices continued training and outreach activities and developed training initiatives for new skills and technologies and the use of online platforms for information sharing. For a more complete list of the scientific integrity accomplishments that took place in FY 2019 across the Agency, see Appendix II.

Transparency and Public Access

Transparency and public access to scientific information and data are vital components to the creation of a healthy culture of scientific integrity across the Agency. Transparency helps to ensure accountability and adherence to a high standard of scientific integrity. Improving public access provides further safeguards for accountability and oversight, while increasing public engagement with Agency activities.

- EPA offices and regions are participating in the agency's implementation plans[12] for providing increased access to federally funded scientific research, which includes provisions to make economic data and related scientific information supporting peer-reviewed intramural research more accessible consistent with the Open Gov-

12 https://www.epa.gov/data/increasing-access-results-epa-funded-scientific-research

ernment Plan[13] (v5.0) and policies being adopted by the agency. The Office of Research and Development's Office of Scientific Information Management (OSIM) expanded its ScienceHub for use by all EPA program offices and regions. This is a system that helps to manage EPA's research data throughout the life of a research project, making data and metadata publicly available in accordance with EPA's Public Access Plan and better guaranteeing the transparency of and easy access to EPA's scientific data used in published articles and documents. In this way, OSIM helped EPA to collaborate and meet data transparency requirements and the expectations of our external customers.

- The Office of Research and Development's (ORD's) National Center for Environmental Assessment (NCEA) conducts numerous public meetings to facilitate discussion of scientific issues and provide opportunities for public and expert input into the assessment development program. In FY 2019, these meetings included National Academy of Science workshops on key issues for the IRIS assessment program, such as systematic review and integration of scientific evidence and peer input meetings for the development of draft Integrated Science Assessments.
- The Office of Water's (OW's) Office of Ground Water and Drinking Water (OGWDW) collects data for contaminants in drinking water that do not have regulatory standards under the Safe Drinking Water Act through the Unregulated Contaminant Monitoring Rule (UCMR) data collection. Beginning in FY 2019, OGWDW began posting quarterly UCMR 4 data on the EPA website. In FY 2019, OGWDW published EPA's Per- and Polyfluoroalkyl Substance (PFAS) Action Plan to increase transparency on the actions that EPA plans to take to address challenges with Per- and Polyfluoroalkyl Substance in the environment. The Office also supported improved access to data, metadata, and web-based re- porting of results and findings from water quality assessments. The Office of Wetlands, Oceans and Watersheds (OWOW) expanded the use of interactive dashboards as a means of providing data for external exploration and transparency building from the successful launch of the National Lakes Assessment Interactive Dashboard to present the National Rivers and Streams Survey results in a similar format.
- Region 3's Office of Communities, Tribes and Environmental Assessment (OCTEA) plays an integral role in communicating scientific and public health information to states, tribes, communities, and the public. OCTEA collaborates with Headquarters Office of Children's Health, Office of International and Tribal Affairs, Office of Research and Development, and Region 3 divisions and programs in utilizing data and scientific information to support public health programs efforts.

Technical and Peer Review

In addition to transparent and accountable action, the quality of the Agency's science relies on technical review and peer review of scientific reports, data and new products. These processes are facilitated by quality assurance plans, the development of new tools or technologies to aid in this review, internal and external review panels, and procedures and policies to standardize how these reviews are conducted.

[13] https://www.epa.gov/sites/default/files/2018-10/documents/epaopengovplanversion5_0final.pdf

- OSIM/ORD established automated transfer of ORD's peer reviewed articles to PubMed Central. OSIM has created QlikSense dashboards to help ORD Labs and Centers track data publication and manuscript submission progress. OSIM also set up the process to feed QA Track information to the ORD intranet site to facilitate staff searches for QA project plans and standard operating procedures.
- The Office of the Administrator's Science Advisory Board Staff Office (SABSO) is providing comments and conducting review for documents including the proposed rule "Revised Definition of Waters of the United States;" the proposed rule "Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review;" the proposed rule "Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy;" and the proposed rule "Strengthening Transparency in Regulatory Science" to specifically comment on the issues of providing secure access to confidential business information and personally identifiable information as specifically requested by the Administrator. SABSO formed subcommittees and panels to review the All Ages Lead Model, Scientific and Technological Achievement Awards (STAA) 2019 Nominations and provide recommendations to ORD and complete a technical review of EPA's new computable general equilibrium (CGE) model.
- The Office of Enforcement Compliance and Assurance's (OECA's) National Enforcement Investigations Center (NEIC) had several internal and external assessments and audits of the integrated quality, safety and health, and environmental management systems. These audits identified a few non-conformities with ISO/IEC 17025 and other requirements. All non-conformities were addressed through NEIC's robust corrective/remedial action process. NEIC also identified, tracked and, when possible, addressed areas of potential concern that do not reach the level of a non-conformity or potential quality-related improvements, including those identified through the annual management system review. A few actions are still "in-process" as of June 2019; all others have been completed and the Center is actively tracking the incorporated corrections for their effectiveness. This is an indication of NEIC's mature management system programs and commitment to rigorous quality and scientific integrity.
- The Office of Chemical Safety and Pollution Prevention's (OCSPP's) Risk Evaluation Process Rule requires that all draft risk evaluations undergo peer review, and OCSPP's Office of Pollution Prevention and Toxics (OPPT) uses the Agency's Peer Review Handbook and OMB guidance for this purpose. During FY 2020, OPPT will receive the first peer review reports from its SACC committee on the first 10 risk evaluations. The office will then work to address these comments, along with those received from the public, to further refine and improve the risk evaluations before final release. OPPT is committed to transparency and continues to build processes that incorporate public comment and peer review into its work products.

Policy and Procedure

- Office of Air and Radiation's Office of Air Quality Planning and Standards initiated an office-wide effort to integrate all its SI related activities into a single process.
- Several offices developed or refined their clearance procedures for scientific products. OAR's Office of Air Policy and Program Support led the OAR-wide development of a flexible process for clearing staff-authored papers and complying with the

agency policy to increase public access to research publications and underlying data. The Office of Land and Emergency Management initiated a workgroup to develop an office policy for clearance of scientific products. ORD/NCEA utilizes the ORD Scientific and Technical Information Clearance System (STICS) to conduct management re- view and clearance of all NCEA products. NCEA management has included detailed descriptions of these processes in its employee handbook.

- ORD's National Exposure Research Laboratory (NERL) is implementing a pilot Laboratory Information Management System (LIMS) to help develop better data management strategies. These systems are more efficient, less vulnerable to errors, and are routinely used for laboratory analysis by other federal and EPA laboratories.
- ORD/OSIM sponsored an ORD-wide ELMS management system event for Quality Assurance (QA) Project Planning. The event included a balanced team of researchers and QA Managers from across ORD who developed a proposal for migrating from 14 QA project plan (QAPP) templates to one common ORD template and leverage re- use of digitized information that is commonly shared across many research planning and implementation activities.
- In FY 2020, OWOW plans to work collaboratively with other offices at EPA (including ORD) and the US Army Corps of Engineers to advance the development of geospatial datasets of "waters of the United States." The agencies are planning to create a framework under which states, tribes, and Federal agencies could choose to develop datasets for approval for all, some, or none of the ''waters of the United States'' within their boundaries. Outputs from this effort will promote greater regulatory certainty and improved access to data and enhance transparency regarding the jurisdictional determination process. As part of the 2020 effort, OWOW plans to work collaboratively with the US Army Corps of Engineers to develop a geospatial dataset of previously determined Traditional Navigable Waters. This dataset will be made available to the public. All activities that occur under this effort will follow Agency protocols, including peer review policies as applicable, and will be guided by Quality Assurance Project Plans.
- The Remedial Data Management Plan was finalized in June 2019 and implementation of the plan has begun. This plan describes how the Superfund Remedial Program will process and store all data acquired during the Superfund remedial process and more clearly outlies the roles and responsibilities of those generating and working with environmental data.
- Region 3's Applied Science and Laboratory Division is working to streamline and better communicate the processes for validating environmental organic and inorganic data. This ongoing effort is to clearly describe all data validation protocols and ensure training is conducted for staff.
- The Office of Mission Support (OMS) has been developing an Agency-wide Quality Assurance Enterprise Management System (QAEMS). This system will standardize and streamline the tracking and reporting of quality accomplishments and metrics across the Agency, as well as facilitate the exchange of information and best practices across the QA community.

- In FY 2019, OMS, in collaboration with Region 1 and the Office of Research and Development, issued a Citizen Science Quality Assurance & Documentation Handbook (EPA 206-B-18-001)[14] to assist citizen scientists in collecting and using quality data appropriate for intended uses. The Handbook contains instructions, templates and examples for developing Quality Assurance Project Plans for citizen science projects.

Training and Outreach

Training and outreach are two of the greatest tools to increase the impact and scope of Scientific Integrity efforts across the Agency. Training connects individuals with resources and contacts that help to ensure that scientific integrity standards are being met. Outreach efforts spread awareness across the Agency about the Scientific Integrity Policy and new Scientific Integrity initiatives.

- The Scientific Integrity Program continued to implement a program of management dialogues to promote a culture of scientific integrity at the Agency and a mandatory online training course about scientific integrity for all new EPA hires. The management dialogues and new hire training helps establish a personal commitment to scientific integrity, which will contribute to the overall culture of scientific integrity at EPA.
- ORD's National Health and Environmental Effects Research Laboratory held all-hands meetings to ensure that its scientists are aware of and fully understand scientific integrity procedures and policies.
- The Immediate Office of the ORD Assistant Administrator (IOAA) endorsed training for all ORD managers on Scientific Integrity and convened a special executive session on Scientific Integrity with Francesca Grifo at the February 6, 2019, Executive and Management Councils meeting in Research Triangle Park, North Carolina.
- In FY 2019, the Office of Chemical Safety and Pollution Prevention (OCSPP) began having weekly Senior Leadership meetings at which it provides a "Deep Dive" into certain topics, including one on Scientific Integrity to bring greater awareness to the top leadership. The OCSPP Assistant Administrator sent out an email expressing the importance of scientific integrity and encouraging staff to ask questions and report any concerns related to scientific integrity to the Scientific Integrity Official (SIO) or the OCSPP Deputy Scientific Integrity Official (DSIO). The office also initiated "office hours" for use by staff to privately raise questions or concerns about scientific integrity. In 2019, OCSPP hopes to expand on these efforts to provide scientists the opportunity to ask questions or express concerns.
- OCSPP's Office of Pesticide Programs (OPP) arranged for the SIO to hold office hours at its Arlington, Virginia, location to facilitate OPP access to the SIO. The SIO also held town hall meetings at that location to address staff's specific concerns.
- To support consistent, sound, science-based water quality standards development, Office of Water's (OW's) Office of Science and Technology offers the Water Quality Standards Academy (WQSA), which presents classroom-based and online courses, along with occasional webinars. Over 50 participants representing states, territories, tribes, environmental groups, industrial groups, municipalities, the academic community, federal

[14] https://www.epa.gov/sites/default/files/201903/documents/508_csqapphandbook_3_5_19_mmedits.pdf

agencies, watershed groups, and other interested parties attended five-day classroom courses in FY 2019.

Promoting a Culture of Scientific Integrity in Operations

While policies, procedures, training, outreach, technical and peer review are all vital to safeguarding scientific integrity across the Agency, leaders are taking additional steps to ensure a robust culture of scientific integrity in their program or regional offices. These efforts include leadership initiatives, hotlines, and anonymous suggestion boxes that are all intended to enhance the culture of scientific integrity in their offices.

- The Scientific Integrity Program proposed a new EPA National Honor Award for Scientific Integrity Achievements. The award will recognize employees or teams who have demonstrated exceptional resourcefulness, creativity, courage, and/or commitment to effectively implementing the Scientific Integrity Policy and to enhancing scientific integrity at EPA.
- In FY 2019, the OIG is conducting an audit of scientific integrity implementation across EPA and one of the goals of that project is to help further the awareness and culture of scientific integrity at EPA. The OIG plays a role in scientific integrity (research misconduct) and, as part of the audit, the OIG is looking internally at how to improve its coordination with the Scientific Integrity Official and internal hotline operations as they relate to scientific integrity.
- The Office of Regional Counsel management plans to raise awareness with its attorneys about scientific integrity and their role in supporting it. Legal sufficiency of regional counsel work products is a basic part of their job, but their efforts also further scientific integrity.

3. Opportunities for Improvement

In 2017, there were 22 total queries. In 2018, queries tripled to 62 and to 72 in 2019. Reports to the SIO have included instances of delay, suppression, interference, authorship disputes, and other alleged and substantiated violations of the Scientific Integrity Policy. The Policy came into effect in February 2012 and approximately half of all queries have come in the last two years (134 of 263)

Many of these issues were reflected in the Employee Viewpoint Survey (EVS) results. EPA positive responses decreased for 52 of the 71 core EVS Questions from 2017 to 2018. For example, only a little over a third of the EPA respondents in 2018 agreed with the statement “My organization’s senior leaders maintain high standards of honesty and integrity,” a 10% drop from the year before. In addition, there was a 6% drop in agreement with the statement “In our work culture, people feel free to raise dissenting opinions without it having a negative impact on their careers” with only 41% of the Agency respondents in agreement. These sentiments were further echoed in a series of structured interviews designed as part of our ongoing evaluation of the Scientific Integrity Policy, its implications, and impacts. These finding are summarized in Box 5.

Because of the focus on the large number of allegations and requests for advice in FY 2019, additional priority work was delayed. We hope to invest time and resources to update the Policy,

its implementation and the impacts of the Policy and our activities to implement it in FY 2020. Our written approaches to addressing differing scientific opinions is scheduled for completion in FY 2020. We plan to invest time and resources in FY 2020 to provide outreach and training regarding differing scientific opinions and these approaches.

Another place where improvement is warranted is in adjudication of allegations and the provision of assistance with advice. We received on average just under six queries each month. EPA will need to balance the need to address these queries with advancing other important initiatives.

Box 4: Themes from A Series of Structured Interviews with Senior Leaders

- **EPA's culture has been challengedover the past few years.**
- **The new Administration has instituted significant changes for thepurposes of increasing efficiency (p11).**
- **Senior leadership closing off optionsof working closely with career staff (p11).**
- **Career managers fear retaliationand retribution for protecting scientific integrity or raising concerns when the science is insufficient to support Agency decisions.**
- **Raised concerns about the types of studies they have been instructed touse.**
- **Concern about the tendency toexaggerate uncertainties and disagreements.**
- **Concerns about how science is integrated into policy decisions.**
- **Science Policy confusion.**
- **Imposition of timelines and deadlines on scientific products thatforce sacrifices in the quality and quantity of science used**

4. Areas for Future Investment

Several initiatives have been identified for FY 2020. They all have the goal of enhancing EPA's culture of scientific integrity either through increasing the visibility of scientific integrity, encouraging all of EPA to embrace and model scientific integrity, or protecting and maintaining scientific integrity at EPA. Specifically, in FY 2020 the Scientific Integrity Program will:

- Finalize the draft charter for the Scientific Integrity Committee.
- Work with the Office of Mission Support to improve our tracking for our mandatory onboarding training.
- Release our differing scientific opinions document and promote it widely across EPA.
- Continue management training and publish a quick guide for easy references for managers.
- Finalize and release draft procedures for addressing lapses in scientific integrity.
- Continue annual activities such as annual meeting, quarterly coordination with the OIG and OGC, and quarterly Scientific Integrity Committee meetings.
- Continue to devote large amounts of time and resources to advice requests and allegations of violations of the Scientific Integrity Policy.
- Respond to the audit by the OIG.

- Continue to pursue additional opportunities to increase the visibility of scientific integrity at EPA through the development of various outreach materials, publications and communications initiatives such as updated stand-up posters that are displayed in EPA headquarters lobbies further publicizing the SIO office hours and posters to inform employees of new policies and procedures.

FY2020 will also be the first full year of a re-organized Office of Research and Development. The Scientific Integrity work will move from the quasi-independent Office of the Science Advisor to the Office of the Science Advisor and Public Engagement located fully within the Office of Research and Development.

5. Conclusions

The increasing numbers of reports of violations of EPA's SI Policy to the SIO and DSIOs, the results of the structured interviews, and the EVS responses indicate EPA's culture of scientific integrity has continued to be challenged. It is important to note that in each conversation with a complainant, they typically report multiple incidents over time that they did not report that are therefore not reflected in these numbers. We will redouble our efforts to make all of EPA aware of the Policy and what they must do to enhance our culture of scientific integrity. Scientific Integrity at EPA is everyone's responsibility. Transparency and documentation continue to be critical to both preventing violations of the SI Policy, as well as allowing for the detection of such violations. The Scientific Integrity Official and her team, the Scientific Integrity Committee, and many others are here to assist everyone at EPA with reporting and resolving any concerns they might have. Implementing the Policy and fostering a culture of scientific integrity is most effective when all employees, contractors, grantees, and student volunteers understand the Policy and how they contribute to EPA's culture of scientific integrity. For seven years, implementation of the Policy has re-enforced the Agency's commitment to scientific integrity. In the upcoming years, the Program and Committee look forward to further assisting the Agency in ensuring that scientific integrity is embraced and modeled by all employees, contractors, grantees, and volunteers.

We will redouble our efforts to make all of EPA aware of the Policy and what they must do to enhance our culture of scientific integrity. Scientific Integrity at EPA is everyone's responsibility. The Scientific Integrity Official and her team, the Scientific Integrity Committee, and many others are here to assist everyone at EPA with reporting and resolving any concerns they might have.

Appendix I. The Annual Employee Conversation with the Scientific Integrity Official

Chair: Francesca Grifo, Ph.D., Scientific Integrity Official

June 6, 2019

Meeting Summary

Participants

Over 200 participants attended online or in person and represented several EPA program offices and regions.

Scientific Integrity at the EPA -- Annual Update

Dr. Francesca Grifo (the Scientific Integrity Official or SIO) opened the meeting with a scientific integrity overview. She explained that public trust depends on the integrity of our science. From research to problem formulation to assessing and managing risk and everything else that we do to protect public health and the environment, our Scientific Integrity Policy ("the Policy") shows us how to make our science unassailable and independent. Dr. Grifo then explained the distinction between science and policy. The Policy provides that scientific conclusions must not be influenced by their policy implications. According to the Policy, "...while Agency risk assessments are intended to address the needs of risk management, quantitative conclusions should not be influenced by possible risk management implications of the results." (§IV.A.1)

Dr. Grifo showed the participants the "Introduction to Scientific Integrity at EPA" whiteboard video.

Dr. Grifo updated the attendees on policies and procedures that implement the Policy and the role of the Scientific Integrity team, the Scientific Integrity Committee, and the Science Advisor. She also talked about the role of managers in upholding a culture of scientific integrity and mediating negative influences.

The Scientific Integrity Program ("the Program") writes and oversees policies and procedures on scientific integrity, conducts outreach and training, and listens to employees' concerns, giving advice and, when necessary, adjudicating allegations of a lapse in scientific integrity.

Dr. Vincent Cogliano summarized information on the number and types of queries (advice + allegations) that the Program has received since 2012, noting that this past year, there has been an uptick in the number of queries involving interference in science.

Dr. Grifo discussed the Differing Scientific Opinions Policy that the Program is developing.

Dr. Grifo provided information about the Whistleblower Protections Enhancement Act and EPA's Whistleblower Ombudsman, Steve Alderton.

Question and Answer Period

- A participant asked whether submitting a draft for review without correct attribution is plagiarism. Dr. Grifo recommended providing the proper attribution from the beginning. Also, if the supervisor requested that you provide the appropriate attribution early and you didn't, that would be an issue.

- A participant asked whether, if someone brings a scientific integrity issue to the OIG Hotline, would the Hotline forward it to the Scientific Integrity Program? Dr. Grifo responded that they would. She emphasized that, if you submit concerns to the Hotline or to the Program and you don't hear back, please follow up.

- A participant was confused about the different categories of queries. Dr. Cogliano had explained that the difference between interference and suppression/delay is that interference is trying to change the scientific conclusions versus suppression/delay, which is holding back products or not releasing a product at all. Dr. Grifo talked about a frequent question: when does "delay" become "suppression"? Suppression/delay is determined on a case-by-case basis. She said that we allow for a strategic window around the release of a product; but, for example, holding back the release of a product for five years would not be a strategic window and looks more like suppression and most definitely "delay".

- A participant asked what "averted" means in terms of status of "advice" cases. Dr. Cogliano explained that it means that the issue was resolved and did not proceed to an allegation.

- A participant asked when and how poor data quality analysis can compromise scientific integrity. Dr. Cogliano said that we want the best possible science to be done by EPA and that the last line of defense against poor scientific quality and analysis is peer review. He suggested that one way to improve a document before it goes to peer review is to include any differing scientific opinions.

- A participant asked about withdrawals of queries. Dr. Cogliano said that there are several reasons that a person might withdraw a concern: e.g., the issue has been resolved; the employee fears reprisal; the employee leaves the Agency.

- A participant asked when scientific data management plans (SDMPs) will be required for the whole Agency. Dr. Thomas Sinks replied that this is part of the public access plan and that anyone with questions about SDMPs could contact him.

- A participant asked whether ignoring scientific consensus on a regulatory decision would be considered a scientific integrity issue. Drs. Grifo and Cogliano replied. The statutes tell us how the science and policy play together. If the science is accurately represented in the deliberative documents and if the statute allows the decisionmaker to include other factors (e.g., cost, seasonality, community acceptance) in the decision, that would not be a scientific integrity issue. If the science were not accurately represented, then it could be.

- A participant asked whether we consider "science" to be only pure science or research articles. Dr. Grifo explained that we define "science" broadly.

- A participant commented that they appreciated being made aware of the Policy and its various provisions.

- A participant suggested that the pie charts on queries were too complicated and difficult to digest. Dr. Cogliano said that he would consider how they might be simplified.

- A participant asked for more examples of differing scientific opinions. Dr. Cogliano said that one example would be if you have different choices for the best studies to use, the models to use in your analysis, or how you might represent the results. Sometimes there are numerous studies, some positive and others negative. Different scientists can view a database and have different conclusions about the strength of the evidence. Some might say that this clearly demonstrates a hazard of this chemical in this environmental medium. Someone else might disagree -- there are these negative studies, also. That would be a differing scientific opinion about how you weigh the data, even if the Agency has guidelines.

  Another example: there may be different analytical methods that you could use to detect pollution in an environmental medium (e.g., how many parts per million of a chemical are present in drinking water). Some methods may be more sensitive than others. A report might include an analysis of the pollution in a water body, using a particular method. A differing scientific opinion might say that the researchers should have used a different method that would be more sensitive or that the level of pollution might vary by the time of day or the time of year. For example, if you are looking at how much ammonia is in runoff into a river and you look at it right after fertilizer is applied, it might be high. If you look one month before fertilizer is applied, it might be low. Whether the sampling plan is adequate or should improve, that is an area where there may be a differing scientific opinion.

  All employees are expected to welcome differing scientific opinions. It's not a matter of somebody being a naysayer or a troublemaker. It is someone being an expansive thinker. It's someone helping to protect you from a public comment that you might get that says that you have missed something. It might protect the Agency's action from litigation with a scientific argument that we did not think about internally.

  The type of culture that we want to encourage here is to have communities of different types of scientific disciplines across the Agency who can discuss scientific matters, improve each other's analysis, and strengthen the science that the Agency uses.

- A participant asked where the science ends and the policy begins. Dr. Cogliano replied that, we will all wrestle with where that line is. This is why it is important that you are able to talk with us and get advice, without fear of retaliation and with full confidentiality.

- A participant asked whether the Scientific Integrity Program was satisfied with the policies that were put in place after the incident of interference in Narragansett Bay. Dr. Cogliano explained that this happened when ORD and regional scientists were told not to participate in a meeting where they were scheduled to deliver some EPA research results. It resulted in a clear statement from the Administrator that this should not have happened and that, in

future, the office (of the scientist) would make the determination about who in that office gives scientific presentations.

- A participant asked whether an employee who disagrees with changes that their supervisor makes to a risk assessment could remove their name from that risk assessment. Dr. Grifo replied that it is sad to see someone who worked on a product remove their name from that product. It would be a decision made on an individual basis. But she would advise such a person that an option would be to write a differing scientific opinion, which would go along with the deliberative documents.

  Also, the employee might consider going to the supervisor to try to understand the context and reasons that the supervisor made those changes. Or, the employee could come talk to someone in the Scientific Integrity Program.

- A participant asked whether the Scientific Integrity Program would allow an allegation to be withdrawn if there were a significant concern about the science. Dr. Cogliano replied that, if there were an immediate danger to health and safety or the environment, it should be elevated immediately through your management chain. If the issue involves waste, fraud, or abuse, falsification or fabrication of science, or any criminal activity, that would go immediately to the Office of Inspector General Hotline.

- A participant asked when the next review of the Scientific Integrity Policy is scheduled. Dr. Grifo said that it would be in 2020.

The meeting was adjourned.

Appendix II. Full Accounts of EPA SI Accomplishments

Transparency and Public Access

Transparency and public access to scientific information and data are vital components to the creation of a healthy culture of scientific integrity across the Agency. Transparency helps to ensure accountability and adherence to a high standard of scientific integrity. Improving public access provides further safeguards for accountability and oversight, while increasing public engagement with Agency activities.

Office of the Administrator

The Office of Policy's National Center for Environmental Economics (NCEE) continues to participate in the agency's implementation plans for providing increased access to federally funded scientific research, which includes provisions to make economic data and related scientific information supporting peer-reviewed intramural research more accessible consistent with the Open Government Plan (v5.0) and policies being adopted by the agency. NCEE is participating in Phase 2 of the Plan to increase access to results of EPA-Funded scientific research, serving as a member of the Data Workgroup Implementation Plan and representing the perspectives of EPA's non-ORD intramural research and extramurally funded research in economics and other social sciences.

Box 5: Release of Scientific Information to the Public

The Scientific Integrity Policy fosters a culture of transparency regarding the results of research, scientific activities, and technical findings.

EPA encourages open communication that is free from political or other interference. The clear and timely release of science facilitates a free flow of information and increases public confidence in the Agency.

The Science Advisory Board Staff Office (SABSO) heavily utilizes a database for increasing transparency and the Agency's visibility to the public. By posting information "real-time," the public has access to the information the Board and Committees are working on and further increasing efficiency for SABSO staff and committee members.

Office of Research and Development

The National Center for Environmental Assessments (NCEA) continues to employ a variety of best practices to ensure the quality and integrity of scientific products. NCEA continues to integrate transparency into its process, releasing data and information to the public by updating its website regularly with announcements related to assessment development, public comment periods on draft products, and notification about public meetings, workshops and teleconferences on the Integrated Risk Information System (IRIS) Calendar.

NCEA has continued to expand its processes to ensure that the integrative review of evidence and development of scientific conclusions in its assessments is transparent. NCEA conducts numerous public meetings to facilitate discussion of scientific issues and provide opportunities for public and expert input into the assessment development program. In FY 2019, these meetings included National Academy of Science workshops on key issues for the IRIS assessment program such as systematic review and integration of scientific evidence, and peer input meetings for the development of draft Integrated Science Assessments.

During the past year, a focused effort was made by the National Exposure Research Laboratory's (NERL's) Computational Exposure Division to utilize ORD's ScienceHub as a means of making data that have been summarized in journal articles readily available to the public.

An integral aspect of the National Center for Computational Toxicology's (NCCT's) commitment to scientific integrity is providing public access to all chemical data, code, software, online tools, models and research publications. This aligns with the Agency's commitment to make its science and research results transparent and available for anyone to use to help inform decisions. All NCCT data, code, software, online tools, models and research publications are available on the EPA website through the File Transfer Protocol site, Git Hub and other online portals.

In FY 2019, NCCT continued to pilot an impact project to track the use of NCCT research products including publications, online tools and data. The information from this project are being used to determine which tools and publications are most used by clients which will help inform which areas of NCCT research should be emphasized. This information is available at http://comptox.ag.epa.gov/impact.

National Risk Management Research Laboratory staff routinely complete ScienceHub entries to provide public access to datasets used for publication which supports Scientific Integrity (100% (69 of 69) of FY 2018 and 92% (35 of 38) of to-date FY 2019 peer-reviewed journal articles published data sets in ScienceHub).

The ORD-managed ScienceHub was expanded for use by all EPA program offices and regions and is a system that is used to help manage EPA's research data throughout the life of a research project. Data and metadata are made publicly available in accordance with EPA's Public Access Plan, and better guarantees the transparency of and easy access to EPA's scientific data used in published articles and documents. In this way, ORD helped EPA to collaborate and meet data transparency requirements and the expectations of our external customers.

Office of Water

As a best practice in scientific integrity, the Office of Ground Water and Drinking Water (OGWDW) continues to demonstrate transparency regarding Unregulated Contaminant Monitoring Rule (UCMR) data collection. Under UCMR, EPA collects data for contaminants in drinking water that do not have regulatory standards under the Safe Drinking Water Act. Beginning in FY 2019, OGWDW began posting quarterly UCMR 4 data on the EPA website. Also, to increase transparency on the actions the EPA plans to take to address challenges with Per- and Polyfluoroalkyl Substance in the environment, in FY 2019 OGWDW published EPA's PFAS Action Plan.

The Office supported improved access to data, metadata and web-based reporting of results and findings from water quality assessments. The Office of Wetlands, Oceans and Watersheds expanded the use of interactive dashboards as a means of providing data for external exploration and transparency building from the successful launch of the National Lakes Assessment Interactive Dashboard to present the National Rivers and Streams Survey results in a similar format.

Region 1

In keeping with the Agency's Scientific Integrity Policy, EPA Region 1's Public Affairs Office ensures that knowledgeable and articulate spokespeople communicate research clearly, accurately and accessibly. The Region's press officers attend interviews with members of the media and work with

scientific staff to ensure that the Region is responsive to media inquiries. Likewise, the Region's intergovernmental staff ensure that scientific information is shared in a timely and accurate manner with congressional, state and municipal contacts.

Region 3

The Office of Communities, Tribes and Environmental Assessment (OCTEA) plays an integral role in communicating scientific and public health information to states, tribes, communities, and the public. OCTEA collaborates with Headquarters Office of Children's Health, Office of International and Tribal Affairs, Office of Research and Development, and Region 3 divisions and programs in utilizing data and scientific information to support public health programs efforts.

Technical and Peer Review

In addition to transparent and accountable action, the quality of the Agency's science relies on technical review and peer review of scientific reports, data and new products. These processes are facilitated by quality assurance plans, the development of new tools or technologies to aid in this review, internal and external review panels, and procedures and policies to standardize how these reviews are conducted.

Office of the Administrator

The Science Advisory Board Staff Office is providing comments and conducting review for documents including the proposed rule "Revised Definition of Waters of the United States;" the proposed rule "Mercury and Air Toxics Standards for Power Plants Residual Risk and Technology Review and Cost Review;" the proposed rule "Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy;" and the proposed rule "Strengthening Transparency in Regulatory Science" to specifically comment on the issues of providing secure access to confidential business information and personally identifiable information as specifically requested by the Administrator. SABSO is standing up subcommittees and panels to review the All Ages Lead Model, Scientific and Technological Achievement Awards (STAA) 2019 Nominations and provide recommendations to ORD, and complete a technical review of EPA's new computable general equilibrium (CGE) model late this summer/early fall.

Box 6: Peer Review and the Use of Federal Advisory Committees

Independent peer review is a necessary component of quality control in science and thus a crucial aspect of scientific integrity. EPA's review process is outlined in the Agency Peer Review Handbook. External federal advisory committees offer further opportunities for review of scientific activities and provide additional scientific expertise, presentations, media interviews, responses to Congressional inquiries, web postings and news releases.

Office of Chemical Safety and Pollution Prevention

The Risk Evaluation Process Rule requires that all draft risk evaluations undergo peer review, and OPPT uses the Agency's Peer Review Handbook and OMB guidance for this purpose. EPA's Science Advisory Committee on Chemicals (SACC) provides independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments (and certain other activities) for chemicals regulated under the Toxic Substances Control Act (TSCA). EPA's risk evaluation process ensures the integrity of scientific data used in actual risk evaluations by providing a rigorous framework of standards, guidance, peer review procedures, and other internal controls as out-

lined in the regulation and other publications described above. These controls are being put into practice during the risk evaluations now in progress.

During FY 2020, OPPT will receive the first peer review reports from its SACC committee on the first 10 risk evaluations. The office will then work to address these comments, along with those received by the public, to further refine and improve the risk evaluations before final release. OPPT is committed to transparency and continues to build processes that incorporate public comment and peer review into its work products.

Office of Enforcement Compliance and Assurance

The Office of Enforcement Compliance and Assurance's (OECA's) National Enforcement Investigations Center (NEIC) has had several internal and external assessments and audits of the integrated quality, safety and health, and environmental management systems. These audits identified a few non-conformities with ISO/IEC 17025 and other requirements. All non-conformities were addressed through NEIC's robust corrective/remedial action process. Additionally, identified areas of potential concern that do not reach the level of a non-conformity or potential quality-related improvements were also tracked and addressed, when possible, including those identified through the annual management system review. A few actions are still "in-process" as of June 2019; all others have been completed and the incorporated corrections are being actively tracked for their effectiveness. This is an indication of NEIC's mature management system programs and commitment to rigorous quality and scientific integrity.

Office of Mission Support

The Office of Mission Support (OMS) continues to collaborate with the Office of the Chief Financial Official (OCFO) and other EPA, state and tribal partners through the E-Enterprise Leadership Council to improve QAPP review and approval processes for QAPPs submitted to EPA by state and tribal grantees. The goal is to enhance the timeliness, transparency, and consistency of QAPP review and approval processes.

Office of Research and Development

Draft versions of journal articles undergo internal and external (as needed) peer reviews before being cleared and submitted for consideration by a scientific journal. When the articles are accepted for publication, final drafts are transmitted through ORD's STICS for public release via Science Inventory. While a focused effort has been made to try to ensure that all journal articles with EPA-supplied data can be accessed via ScienceHub, NERL continues to be challenged with delayed ScienceHub posting of data of a few journal articles that are principally authored by non-ORD scientists. To remedy this, administrative staff have been added as an additional level of review to ensure that ScienceHub is being populated with relevant data.

NERL incorporates appropriate levels of quality assurance (QA) to ensure that it is producing high-quality science. NERL has 324 active projects, 99% of which are operating under approved quality assurance project plans (QAPPs) or QAPPs under revision. During the reporting period, NERL conducted 134 QA reviews of products, 10 audits of data quality and four technical systems audits. All findings have been addressed with appropriate corrective actions. NERL also uses federal advisory committees and external peer reviews for independent reviews of its products.

Region 6

Established automated transfer of ORD's peer reviewed articles to PubMed Central and is assisting in the development and integration of eClearance with the National Institutes of Health Manuscript Submission (NIHMS) system and ScienceHub.

In coordination with the new Lab and Sciences Division, AR oversees the quality assurance and quality control conducted by the States, Local, and Tribal agencies who collect ambient air monitoring data in Region 6 for the national ambient air quality standards (NAAQS). The EPA works closely with the National offices to ensure the agencies provide compatible, comparable, and complete data. AR staff review annual network plans, 5-year monitoring plan reviews, oversee monitor audits and actively participates in workgroups to develop and review guidance and regulations.

Policy and Procedure

Office of Air and Radiation

The Office of Air Quality Planning and Standards initiated an office-wide effort to integrate all its SI related activities into a single process. The Office of Air Policy and Program Support lead the OAR-wide development of a flexible process for clearing staff-authored papers and complying with the Agency policy to increase public access to research publications and underlying data.

Office of Chemical Safety and Pollution Prevention

EPA is following procedures specified in the recently released Risk Evaluation Process Rule in all chemical risk evaluations being performed in FY 2019. OCSPP must act in accordance with the requirement that scientific standards for best available science are being met. OCSPP has also recently released the document, Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act, which describes the science standards, data quality considerations, and the steps of the risk evaluation process that external parties should follow when developing draft TSCA risk evaluations.

OPPT released for public comment the Application of Systematic Review in TSCA Risk Evaluation document, which describes the implementation of these scientific standards throughout the risk evaluation process. This document continues to guide the Agency's selection and review of studies and provides the public with transparency regarding how EPA plans to evaluate scientific information. The document will undergo peer review by the National Academies of Science, which will assist in refining and improving this document, as well as provide advice about incorporating public comments.

Office of Land and Emergency Management

The Office of Land and Emergency Management initiated a workgroup to develop an office policy for clearance of scientific products.

Office of Mission Support

The Office of Mission Support (OMS) has been developing an Agency-wide Quality Assurance Enterprise Management System (QAEMS) and is in the process of obtaining the Authority to Operate. This system will standardize and streamline the tracking and reporting of quality accomplishments and metrics across the Agency, as well as facilitate the exchange of information and best practices across the QA community.

In FY 2019, OMS, in collaboration with Region 1 and the Office of Research and Development, issued a Citizen Science Quality Assurance & Documentation Handbook (EPA 206-B-18-001) to assist citizen scientists in collecting and using quality data appropriate for intended uses. The Handbook contains instructions, templates and examples for developing QAPPs for citizen science projects.

Office of Research and Development

The National Center for Environmental Assessments (NCEA) utilizes the Scientific and Technical Information Clearance System (STICS) to conduct management review and clearance of all NCEA products. NCEA's robust clearance process includes up to seven approvers. NCEA management has included detailed descriptions of these processes in its employee handbook. Another oversight mechanism is NCEA's Quality System; NCEA adheres to its Quality Management Plan, which supports the collection and use of scientific data and information. The collection of practices noted above are evidence of a rigorous program implemented in NCEA.

As NERL continues to work on increasing the transparency of our research results, it adheres to the ORD Scientific Data Management Policy and expects to have all data sets associated with NERL journal articles published in FY 2019 entered into ScienceHub by the end of FY 2019.

NERL, led by its Systems Exposure Division, is also implementing a pilot LIMS to help develop better data management strategies. These systems are more efficient, less vulnerable to errors, and are routinely used for laboratory analysis by other federal and EPA laboratories.

The Office of the Science Advisor continues to develop the Agency Scientific Integrity program. A 2018 program review on the process for addressing and resolving violations of the Scientific Integrity Policy provided recommendations that were used to draft new procedures for addressing these allegations. The Scientific Integrity Committee reviewed and approved the draft procedures. The procedures will address timeliness, streamline the process, and more clearly define what types of concerns should be addressed through the process. Additionally, the SIO finalized language on the application of the Scientific Integrity Policy to EPA grantees; continued to work on language on scientific integrity for EPA contracts; and is developing an electronic system for the clearance of scientific products for EPA programs, offices, and regions to promote transparency, clarity, timeliness, predictability, and consistency in the clearance of documents.

OSIM sponsored an ORD-Wide ELMS event for Quality Assurance Project Planning. The ELMS event included a balanced team of researchers and QA Managers from across ORD who developed a proposal for migrating from 14 QAP templates to 1 common ORD template and leverage re-use of digitized information that is commonly shared across many research planning and implementation activities.

Office of Water

In FY 2020, the Office of Wetlands, Oceans and Watersheds (OWOW) plans to work collaboratively with other offices at the EPA (including ORD) and the US Army Corps of Engineers regarding an effort to advance the development of geospatial datasets of "waters of the United States." The agencies are planning to create a framework under which states, tribes, and Federal agencies could choose to develop datasets for approval for all, some, or none of the ''waters of the United States'' within their boundaries. This is a substantial effort that has been included in ORD's Strategic Research Action Plan. Outputs from this effort will promote greater regulatory certainty and improved access to data and enhance transparency regarding the jurisdictional determination process. As part of the 2020 effort,

OWOW plans to work collaboratively with the US Army Corps of Engineers to develop a geospatial dataset of previously determined Traditional Navigable Waters. This dataset will be made available to the public. All activities that occur under this effort will follow Agency protocols, including peer review policies as applicable, and will be guided by Quality Assurance Project Plans.

The Office of Science and Technology (OST) is continuously demonstrating its commitment to stakeholder engagement and transparency by developing user-centered websites to provide the public with tools and directions, such as N-Steps Online[15] , the BEACON(Beach Advisory and Closing Online Notification) database, the National Listing of Fish Advisories and the Industrial Wastewater Treatment Technologies (IWTT) web app.

Region 3

The Remedial Data Management Plan was finalized in June 2019 and implementation of the plan has begun. This plan describes how the Superfund Remedial Program will process and store all data acquired during the Superfund remedial process. This plan more clearly outlies the roles and responsibilities of those generating and working with environmental data.

As described in the last year's FY 2018 report, work has continued with the Applied Science and Laboratory Division to streamline and better communicate the processes for validating environmental organic and inorganic data. This ongoing effort is to clearly describe all data validation protocols and ensure training is conducted for staff. This project is anticipated to be completed in FY 2019.

Training and Outreach

Training and outreach are two of the greatest tools to increase the impact and scope of Scientific Integrity efforts across the Agency. Training connects individuals with resources and contacts that help to ensure that scientific integrity standards are being met. Outreach efforts spread awareness across the Agency about the Scientific Integrity Policy and new Scientific Integrity initiatives.

Box 7: Professional Development of Government Scientists and Engineers

EPA employees are encouraged to participate in professional development activities to fully en- gage with their scientific communities and be- come leaders in their fields. Professional development activities may include presenting at scientific meetings or conferences, participating in professional societies, or serving on editorial boards of peer-reviewed journals.

Office of the Administrator

The Office of Multimedia is collaborating with the Scientific Integrity team to create new whiteboard training videos on scientific integrity.

Office of Air and Radiation

To counter the inevitable impact of retirements on our radiation protection health physics knowledge expertise, OAR's Office of Radiation and Indoor Air extended its continuing education campaign, including hosting expert speakers both remotely and in person, sharing valuable on-demand training videos on a SharePoint site, and supporting staff enrollment in an intense Advanced Health Physics online university course.

[15] https://www.epa.gov/nutrient-policy-data/n-steps-program

Office of Chemical Safety and Pollution Prevention

The Office of Pesticide Programs (OPP) had the SIO hold office hours at Potomac Yard to facilitate OPP access to the SIO. OPP also had the SIO come to Potomac yard to hold town hall meetings to address staff's specific concerns.

In FY 2019, OPP began having weekly Senior Leadership meetings to provide a "Deep Dive" into certain topics. They had a "Deep Dive" at a Senior Leadership meeting on Scientific Integrity to bring greater awareness to the top leadership. The Assistant Administrator sent out an email expressing the importance of scientific integrity and encouraging staff to ask questions and re- port any concerns related to scientific integrity to the SIO or the OCSPP Deputy Scientific Integrity Official (DSIO). Leadership also initiated "office hours" for use by staff to privately raise questions or concerns about scientific integrity. In 2019, OPP expanded on these efforts to provide scientists an opportunity to ask questions or express concerns.

Office of Enforcement Compliance and Assurance

All new staff and management were trained on the National Enforcement Investigations Center (NEIC) and Agency level quality management systems, along with overviews of NEIC's two ISO/ IEC 17025 accreditations. NEIC's new field quality representative attended a thorough ISO/IEC 17025 accreditation .

training by NEIC's accrediting body, ANAB, which also included elements of internal auditing. Additionally, NEIC staff attended on-site direct training on scientific integrity by EPA's scientific integrity official, Dr. Grifo, on May 1, 2019. There was a robust question and answer session be- tween Dr. Grifo and NEIC staff.

Office of Land and Emergency Management

OLEM Managers participated in trainings on the principles of Scientific Integrity in FY 2019.

Office of Research and Development

In FY 2019, the immediate office of the ORD Assistant Administrator (IOAA) endorsed training for all ORD managers on Scientific Integrity and convened a special executive session on Scien- tific Integrity with Francesca Grifo at the February 6, 2019 Executive and Management Councils meeting in RTP, NC. IOAA also continues to meet regularly with the Agency Scientific Integrity Official to discuss issues of scientific integrity. The Office of the Science Advisor undertook measures to strengthen EPA's scientific integrity program including: quarterly meetings of the Scientific Integrity Committee with the SIO; the Annual Employee Conversation with the SIO; a meeting on scientific integrity with external stakeholders; quarterly meetings with the Office of General Counsel; and quarterly meetings with the Office of Inspector General. A systematic em- ployee training program was implemented with a program of management dialogues to pro- mote a culture of scientific integrity at the Agency and a mandatory online training course about scientific integrity for all new EPA hires. The management dialogues and new hire training helps establish a personal commitment to scientific integrity, which will contribute to the over- all culture of scientific integrity at EPA.

Additionally, staff meet with their Deputy Ethics Official regarding any external employment or appointments and take annual training regarding ethical standards which support Scientific Integrity. Scientists are aware of and fully understand scientific integrity procedures and policies through all-hands meetings, by asking questions of designated experts of staff, as part of annual performance review, and through QA and recordkeeping training before data are collected. NERL's QA Team has developed 12 QA training presentations and, during this reporting period, it offered 11 training sessions attended by 143 staff.

Office of Water

Eighty Office of Water managers attended the Scientific Integrity training by Francesca Grifo on February 12 or 13, 2019. All staff in the Office of Science and Technology (OST) are encouraged to participate in scientific meetings and trainings to support their professional development. To support consistent, sound science-based water quality standards development, OST offers the WQSA, which presents classroom-based and online courses, along with occasional webinars. Ove 50 participants representing states, territories, tribes, environmental groups, industrial groups, municipalities, the academic community, federal agencies, watershed groups, and other interest- ed parties attended 5-day classroom courses in FY 2019.

Furthermore, OST staff are encouraged to have an Individual Development Plan (IDP) and to dis- cuss their professional development goals with their manager at least twice per year. Currently, 98% of OST staff have an IDP (up from 77% in 2016), which has been reviewed within the last year.

The Office of Science and Technology also continues to emphasize the importance of professional development and IDPs for staff and managers, and to utilize the continuously updated IDP Share- Point site, which contains Frequently Asked Questions, competencies, training suggestions, sam- ple IDPs and other relevant resources. When implementing ELMS, OST included percentage of staff with a current IDP as one of the tracked performance measures for the Office, further high- lighting management's investment in professional development of staff.

Region 2

The Laboratory Services Applied Science Division Director and SI Manager communicated with the SIO to discuss region specific topics and agenda items for the October quarterly meeting and participated in quarterly National Scientific Integrity Committee meetings led by the EPA Scien- tific Integrity Officer to stay abreast of the current regional and national topics of interest and up- dates of activities. Staff participated in both the Annual Employee Conversation and the SI Stake- holder meeting. Staff also participated in the OIG Project on implementation of the EPA's Scien- tific Integrity Policy by announcing and reminding personnel about completion of the agency- wide SI survey and provided periodic SI and QA updates at LSASD All Managers and LSASD All employees meetings.

Met with Region 2 Tribal grantees to discuss QA & QAPP training needs, as well as a training workshop to be held in FY 2020. Prior to the meeting, the RQAM provided the grantees with a training needs questionnaire to complete.

Region 3

The SIO conducted management training in Region 3 to help illuminate connections between th Scientific Integrity Policy and leadership responsibilities, and to inform managers of scientific in- tegrit practices and processes.

Region 6

The Houston Environmental Laboratory continues to hold 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. Additionally, Region 6 hosted Management Dialogue Meetings with SIO Dr. Grifo at a monthly Business Review meeting and a special session of the Management Improvement Team.

Region 10

To strengthen SI in the Region, Region 10 hosted conversations between the EPA's SIO Dr. Grifo and the Region's Executive Team, supervisors, Laboratory staff, and the Science Steering Council. Region 10 also provided an opportunity for staff to discuss any SI concerns with the SIO in person or via conference call during her regional visit, as well as to the DSIO.

Promoting a Culture of Scientific Integrity in Operations

While policies, procedures, training, outreach, technical and peer review are all vital to safeguarding scientific integrity across the Agency, leaders are taking additional steps to ensure a robust culture of scientific integrity in their program or regional offices. These efforts include leadership initiatives, hotlines and anonymous suggestion boxes that are all intended to enhance the culture of scientific integrity in their offices.

Office of General Counsel

Managers plan to raise awareness with our attorneys about scientific integrity and our role in supporting it. Attorneys view ensuring legal sufficiency of their work product as a basic part of their job; However, they may not consciously realize that their efforts also further scientific integrity.

Office of the Inspector General

This year, the OIG is conducting an audit of scientific integrity implementation across the EPA and one of the goals of that project is to help further the awareness and culture of scientific integrity at EPA. The OIG plays a role in scientific integrity (research misconduct) and, as part of the audit, the OIG is looking internally on how to improve our coordination with SIO and internal hotline operations as they relate to scientific integrity.

Box 8: Promoting a Culture of Scientific Integrity

The Scientific Integrity Policy establishes an expectation that the Agency will foster honest investigation, open discussion, refined understanding and a firm commitment to evidence, and scientific research that is generated in a timely manner, characterized appropriately for Agency policy-making, and communicated clearly to the public. All EPA employees are explicitly forbidden from suppressing, manipulating or otherwise altering scientific data. This assures that EPA decisions are informed by the best science that the Agency, its contractors, grantees and collaborators can offer. A culture of scientific integrity is also one that protects employees who report allegations of suspected violations of the policy. Similarly, employees who express differing scientific opinions should neither fear nor experience retaliation.

Office of Research and Development

The Office of the Science Advisor (OSA) is home to EPA's Science Integrity Program. The Program helps to implement the Scientific Integrity Policy, which provides a framework to promote scientific integrity across the Agency. In FY 2019, the Scientific Integrity Program drafted a proposed new EPA National Honor Award for Scientific Integrity Achievements. The award will recognize employees or teams who have demonstrated exceptional resourcefulness, creativity, courage, and/or commitment to effectively implementing the Scientific Integrity Policy and to enhancing scientific integrity at EPA.

Staff are expected to promote scientific and ethical standards, including quality standards; communications with the public; the use of peer review and advisory committees; and professional development. Additionally, staff are encouraged to bring any questionable practices or results to management's attention.

All ORD publications adhere to scientific integrity principles (see STICS/Science Inventory for examples) and all staff receive relevant scientific integrity training. Additionally, there are multiple mechanisms (Branch Chief, Division Director, Union, anonymous suggestion box) in place to report scientific integrity related issues.

The senior leadership team set aside time annually to refresh ourselves on the principles and policy of scientific integrity. Management has communicated to staff about the Scientific Integrity Official's open office hours.

Appendix III.

EPA Scientific Integrity Committee

Francesca T. Grifo, Ph.D., EPA Scientific Integrity Official and Committee Chair

EPA Office/Region	Deputy Scientific Integrity Official
Office of the Administrator	Wes Carpenter
Office of Air and Radiation	Betsy Shaw
Office of Chemical Safety and Pollution Prevention	Carol Ann Siciliano
Office of the Chief Financial Officer	David Bloom
OA/Office of Childrens Health Protection	Jeanne Briskin
Office of Enforcement Compliance Assurance	Erica Canzler
Office of General Counsel	Jim Payne
Office of International and Tribal Affairs	Martin Dieu
Office of Land and Emergency Management	Barry Breen
Office of Mission Support	Lynnann Hitchens
OA/Office of Policy	Al McGartland
OA/Science Advisory Board	Tom Brennan
Office of Research and Development	Bruce Rodan
Office of Water	Benita Best-Wong
Region 1	Johanna Hunter
Region 2	Anahita Williamson/ Linda Mauel
Region 3	Bill Jenkins
Region 4	Dawn Taylor
Region 5	Carole Braverman
Region 6	David (Wes) McQuiddy
Region 7	Cecilia Tapia
Region 8	Debra Thomas
Region 9	Duane James
Region 10	Linda Anderson-Carnahan

For Additional Information or to report an allegation:

Scientific Integrity Official

Francesca T. Grifo, PhD

Grifo.francesca@epa.gov

(202) 564-1687

To report fraud, waste or abuse,

Email: EOIG_Hotline@epa.gov

Phone: 1-888-546-8740

Fax: 202-566-2599

Online: http://www.epa.gov/oig/hotline.htm

Write:

EPA Inspector General Hotline

1200 Pennsylvania Avenue NW

Mail code 2431T

Washington, DC 20460

https://www.epa.gov/scientific-integrity