Comprehensive list of Scientific Integrity Activities

I. FY 2020 Agencywide Meeting

EPA AGENCYWIDE MEETING ON SCIENTIFIC INTEGRITY

June 17, 2020

Virtual Meeting

MEETING SUMMARY

Participants

Over 1,000 participants attended the virtual meeting and represented every EPA program office and region.

Introductory Remarks

Doug Benevento, Associate Deputy Administrator of the U.S. Environmental Protection Agency (EPA), welcomed participants to the meeting and congratulated EPA staff for their work protecting human health and the environment for the past 50 years. He credited EPA's success to its strong culture of scientific integrity but noted that such integrity still can be improved.

Jennifer Orme-Zavaleta, EPA's Acting Science Advisor and Office of Research and Development Principal Deputy Assistant Administrator, thanked everyone for their part in improving the scientific integrity of EPA. She noted that scientific integrity, scientific quality, the peer-review process, and quality assurance all improve the scientific foundation of EPA and foster public confidence in EPA's work. Maintaining this strong culture of scientific integrity will require EPA to remain informed about the Agency's accomplishments in scientific integrity; the different initiatives of the scientific integrity program; and the scientific integrity contributions of different EPA employees, contractors, grantees, fellows, and interns.

Scientific Integrity 2019 Highlights

Francesca Grifo, Scientific Integrity Official at EPA, introduced EPA's scientific integrity program and updated the attendees on the program's progress. The implementation of scientific integrity at EPA ensures objectivity, clarity, reproducibility, and utility of

scientific results by providing insulation from bias, fabrication, falsification, plagiarism, interference, and censorship. Having scientific integrity means that individuals must adhere to professional values and practices when conducting, communicating, supervising, and utilizing scientific information. EPA follows practices that ensure high scientific and research integrity involving quality-control methods, the validation of protocols, the accreditation of facilities, clearance procedures, and a robust peer-review practice. Scientific integrity also is applied once research data are acquired when those data are communicated and used for decision-making. EPA's Scientific Integrity Policy (Policy) supports the Agency's culture of scientific integrity, enhances transparency, and assures protections of government science. Information regarding and resources surrounding the Policy can be found on EPA's website.

Francesca Grifo introduced the scientific integrity team members and Scientific Integrity Committee. The scientific integrity team writes and oversees policies, performs scientific integrity training, listens to concerns about EPA's scientific integrity, and provides outreach efforts. The team also generates an annual report, establishes language for grant agreements and requirements for upholding scientific integrity, and determines best practices for authorship and clearance. The team develops a charter for the Scientific Integrity Committee, drafts procedures for addressing concerns, finds solutions to resolve scientific conflicts, and specifies roles and responsibilities for upholding scientific integrity for managers and supervisors at EPA. Finally, the team presents on scientific integrity, provides advice concerning scientific integrity, and adjudicates violations of the Policy.

Francesca Grifo presented an update on the scientific integrity team's work. The Office of the Inspector General (OIG) released a report on scientific integrity that included results of a 2018 survey. The 2018 survey indicated that EPA staff had increased awareness of several Scientific Integrity Policy components since the previous survey was taken in 2016: 93 percent of staff were aware of the Policy, 68 percent of staff were familiar with the contents of the Policy, 50 percent of staff knew how to report scientific integrity allegations, 69 percent of staff agreed that they could freely express scientific views provided they specify that they are not speaking on behalf of EPA, and 34 percent of staff indicated that their clearance procedures are consistent within their office. Francesca Grifo noted that the scientific integrity team is actively working to standardize clearance procedures.

The survey also revealed some areas of decreased awareness since the previous survey that were in need of improvement: 47 percent of staff stated that their management chain consistently stands behind staff who put forth scientifically defensible positions that may be controversial; 52 percent of staff stated that, within EPA, they can openly express scientific opinions about the Agency's scientific work without fear of retaliation; 51 percent of staff stated that they have the right to review,

correct, and approve the scientific content of an Agency document that identifies them as an author or represents their scientific opinion before public release; and 29 percent of staff stated that scientific and technical products they contributed to are released in a timely fashion. EPA is working to address this decreased awareness.

Francesca Grifo discussed the status of scientific integrity allegations and advice. From February 2012 through mid-June 2020, EPA received 78 allegations and 178 requests for advice. Allegation submissions covered the following topics: data quality, authorship, delay/suppression, interference, plagiarism, other science integrity topics, and topics not related to scientific integrity. Allegations were submitted from program offices, regions, external sources, and unknown sources. Allegations were directed at program offices, the Office of the Administrator, regions, and other areas. Of the submitted allegations, 28 percent are not substantiated, 22 percent are substantiated, 15 percent are withdrawn, 11 percent are not related to scientific integrity, 7 percent were transferred to OIG, and 17 percent are active. Advice submissions covered the following topics: peer review, retaliation, authorship, clearance, delay/suppression, interference, topics not related to scientific integrity, data quality, differing scientific opinions, general advice, and other topics. Advice was submitted from program offices, regions, external sources, and unknown sources. Advice was directed at program offices, the Office of the Administrator, regions, and other areas. Of the submitted advice requests, 25 percent were averted; 2 percent were closed; 3 percent have been moved to allegations; 7 percent were not related to scientific integrity; 3 percent were transferred to OIG; and 3 percent were withdrawn. As of this report, 56 percent have no current allegation, and 1 percent are on hold.

Because EPA is both a research and regulatory agency, maintaining scientific integrity is uniquely challenging. Tensions exist between science and policy, and these tensions must be mediated effectively. Transparency and documentation facilitate mediation by providing evidence to guide actions made in response to allegations and advice requests.

EPA Whistleblower Protections

Lori Ruk, EPA's Whistleblower Protection Coordinator (WPC), OIG, presented on whistleblower protections. The Inspector General Act of 1978 requires each inspector general to designate an individual within their office to serve as a WPC. WPCs must educate Agency employees about prohibitions on retaliation for whistleblowing, as well as employee rights and remedies if an employee is subjected to retaliation for making a protected disclosure. WPCs also provide information about the role of OIG, the Office of Special Counsel, and the Merit Systems Protection Board, as well as the timeliness of cases, the availability of alternative dispute mechanisms and avenues for potential relief. WPCs cannot provide legal advice or act as legal representatives.

Disclosures from whistleblowers help WPCs prevent and detect waste, fraud, and abuse. Agency employees can contact the WPC program via email, phone, or the contact information on the OIG website. Employees who contact WPCs are provided with confidentiality.

Lori Ruk highlighted the protected disclosures that are related to scientific integrity. The Whistleblower Protection Enhancement Act of 2012 clarified that protected disclosures include those made by federal employees revealing censorship related to scientific research, analysis, or technical information if the censorship causes or will cause any gross mismanagement; violation of law, rule, or regulation; gross waste of funds; abuse of authority; or substantial and specific danger to public health or safety. Similarly, it is illegal for a subcontractor, employee of a federal contractor, grantee, sub-grantee, or personal services contractor to be discharged, demoted, or otherwise discriminated against as a reprisal for making a protected disclosure if the disclosure is related to a federal contract or grant and filed within 3 years of the alleged reprisal.

Further information on this process can be found on the OIG website. Lori Ruk concluded by emphasizing the critical service whistleblowers provide for the public and EPA.

Getting Assistance with Scientific Integrity Concerns

Francesca Grifo thanked Lori Ruk for her presentation and, with Kevin Collins, EPA National Hotline Manager, OIG, discussed the process of requesting assistance for scientific integrity concerns. She recommended that individuals seek help early, and she provided her contact information and a schedule of office hours reserved for this purpose.

In addition, Francesca Grifo encouraged individuals to seek out their Deputy Scientific Integrity Official, who are listed online. Three main entities receive allegations and requests for advice: Francesca Grifo, Deputy Scientific Integrity Officials and the OIG Hotline. Information from reports is shared by these entities on a need-to-know basis. It is helpful for the process when the reporter provides information on which policies are being violated. It also is helpful when managers support reporters and carefully listen to concerns without interrupting.

II. Listing of FY 2020 Scientific Integrity Activities

Office of Air and Radiation

- The Office of Air and Radiation's (OAR) Office of Atmospheric Program (OAP) completed and is now implementing an EPA's Lean Management System (ELMS) Project called the "OAP Journal Publication and Data Transparency Process." The project focuses on improving the system by which staff, who author a journal

publication, can comply with the requirements for public access to data. The development of this ELMS project coincided with the Agency's recent implementation of these publication and data transparency and accessibility processes.

- OAP sought opportunities to communicate science externally with the public through participation in scientific conferences, federal interagency work-products, international technical and scientific collaboration, and invitational presentations in classroom settings. Fiscal year (FY) 2020 examples include OAP's support for the U.S. Global Change Research Program's federal climate change indicators platform by providing scientifically sound and externally peer reviewed indicators to this initiative.

- OAR also responded regularly to inquiries and requests from Congress, public officials, and program stakeholders by providing clear scientific and technical scientific findings, along with a discussion of underlying assumptions and associated uncertainties.

- Products are reviewed both internally and through the peer review process. Scientific findings are disseminated in a timely manner through posting on the web, publishing in peer-reviewed journals, hosting and presenting at conferences and symposiums, and through answering inquiries. OAR has also continued efforts to make progress in establishing procedures and practices which facilitate compliance with the key elements of the policy.

- In the past year, OAR's Office of Radiation and Indoor Air (ORIA) initiated an ELMS project to evaluate the review and approval process for ORIA scientific and technical products. By mapping out the process and tracking the flow of product review, they have been able to decrease the time it takes for scientific and technical products to go through the internal review process.

- Professional Development/Training Professional development in OAR is strongly encouraged and accomplished through training, mentoring, and participation in scientific conferences and workshops.

- The Office of Radiation and Indoor Air (ORIA) is continuing its comprehensive staff education campaign, which had begun in 2017, to counter the impact of staff retirement on its internal radiation expertise. In 2020, they focused on several different concurrent approaches: hosting expert speakers and brown-bag lunches remotely and in person; sharing valuable on-demand training videos on a SharePoint site; and facilitating an intense Advanced Health Physics course using an online university course. This education campaign has been successful in increasing the depth of radiation protection knowledge in ORIA.

- The Office of Atmospheric Programs (OAP) also encourages scientists to obtain specialized or advanced training, including in methods to effectively communicate

scientific results. In FY 2020, several OAP scientists engaged in advanced geographic information system training and opportunities to improve the visualization of data through data modernization systems. OAR supports professional development opportunities including participation in annual meetings of professional scientific organizations.

- OAR programs continue to integrate scientific integrity procedures and practices into their overall operations so that scientific integrity-related activities are integral, rather than an add-on, to current practices. For example, OAR's Office of Air Quality Planning and Standards (OAQPS) has developed a procedure for conducting formal review and approval of staff proposals to conduct research and analysis for publication in scientific journals as part of the normal workflow. The requirements are such that all work conducted using Agency resources is approved and authorized before the work is initiated. Additionally, an electronic flow board was implemented to track the review of proposals for research and analytical activities and manuscripts throughout the entire clearance process. This allows staff to view the status of review of their proposals and manuscripts in relation to defined timelines and facilitates the approval of proposals and manuscripts in a systematic and consistent manner. OAR programs are also utilizing the ELMS to evaluate and improve SI and related activities.

Office of Enforcement and Compliance Assurance/National Enforcement Investigations Center

- 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 International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) 17025 accreditations.

- NEIC conducted internal audits of the quality management system. 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. This is an indication of NEIC's mature management system programs and commitment to rigorous quality and scientific integrity.

Office of Research and Development

- The Office of Research and Development (ORD)'s Office of Science Information Management (OSIM) continued to work with other Assessable Units to meet ORD Scientific Data Management (SDM) policy requirements. The OSIM-managed Science Hub is used 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, OSIM helps

EPA to collaborate and meet data transparency requirements as well as meet the expectations of our external customers. See the SDM website, including information on ScienceHub, at: https://intranet.ord.epa.gov/science/scientific-data-management

- The Great Lakes Toxicology and Ecology Division uses the Scientific and Technical Information Clearance System and Science Hub to control and review products that are produced for internal use or released external to the agency (public view). This creates records that are available for Freedom of Information Action (FOIA) and give public access to publication data. This emphasizes the critical need for a researcher to apply their knowledge and practice of high-level scientific integrity to their gathering of research data, documenting study methods and following Quality Assurance Project Plans prior to developing and releasing their products internal to the EPA and externally to the public.

- An integral aspect of the Center for Computational Toxicology and Exposure (CCTE)'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. Publicly releasing CCTE research also helps communicate the research for stakeholders outside EPA and to solicit feedback regarding advances in computational toxicology research; this can be used to accelerate the pace of chemical testing. All CCTE data, code, software, online tools, models, and research publications are available on the EPA website through the FTP site, Git Hub, and other online portals. Downloadable data: https://www.epa.gov/chemical-research/downloadable-computational-toxicology-data, Online tools: https://comptox.epa.gov and code: https://github.com/search?q=org%3AUSEPA+comptox&unscoped_q=comptox

- Staff routinely complete Science Hub entries to provide public access to datasets used for publication of peer-reviewed journal articles which supports Scientific Integrity. As of April 24, 2020, 100% of FY2020 through FY 2016 peer-reviewed journal articles have published datasets. (Total number: fiscal year 2020(20), fiscal year 2019(72), fiscal year 2018(63), fiscal year 2017(78), and fiscal year 2016(92)).

- All research products and outputs, except for internal reports that are provided to the ORD National Research Programs, are externally peer reviewed.

- The Office of Research and Development's Immediate Office of the Assistant Administrator (IOAA) encouraged all managers, who had not previously taken Scientific Integrity training, to participate and work with the Agency Scientific Integrity Official to coordinate Scientific Integrity training to all staff in major facilities of Washington DC, Cincinnati, and Research Triangle Park.

- In fiscal year 2020, IOAA supported the Office of Science Advisor, Policy and Engagement (OSAPE) and the Scientific Integrity Official in recruiting additional Scientific Integrity staff to replace retirements.

- OSAPE: The program continues to build a culture of scientific integrity at EPA by holding quarterly meetings of the Scientific Integrity Committee with the Scientific Integrity Official (SIO); an Annual Employee Conversation with the SIO; quarterly meetings with the Office of General Counsel; and quarterly meetings with the Office of Inspector General (OIG).

- In addition to independently led external triennial assessments conducted at each of CEMM's five locations, the Center's Quality Assurance (QA) team conducts internal assessments to ensure its research projects comply with quality system requirements. These assessments may include, but are not limited to, Technical Systems Audits, Audits of Data Quality, Data Quality Assessments, and field audits. Currently, CEMM has 372 identified projects requiring Quality Assurance Project Plans (QAPPs) with 88% of these operating under approved QAPPs, 1% in development, 4% in review by QA staff, and 7% in revision by technical leads. From 1st quarter through 2nd quarter of fiscal year 2020, the CEMM QA team conducted 55 QAPP reviews, 28 extramural package reviews, 173 product reviews, 1 technical systems audit, 5 audits of data quality, 1 data quality assessment, and 2 field audits. All findings from audits/assessments have been addressed with appropriate corrective actions. To facilitate continued competency with organizational quality requirements during the reorganization transition, the CEMM QA Team has conducted four (4) Center-wide training sessions in FY 2020 Q1 and Q2, which resulted in high rates of participation. Topics covered during the training sessions included research notebooks, QAPP development, and laboratory practices. Providing expeditious public access to CEMM scientific and technical information is a high priority for the Center. To that end final drafts of peer-reviewed articles are transmitted via ORD's Scientific and Technical Information System (STICS) for public release as soon as they are accepted for publication in scientific journals. Additional administrative resources (eg, contractors) have been installed to remedy delays in posting data that support such articles for public access when necessary (eg, articles principally authored by non-ORD scientists). The report from an external peer review panel's evaluation of CEMM's Community Multiscale Air Quality (CMAQ) modeling site, conducted during the summer of 2019, is posted for public view on the CMAQ website (www.epa.gov/cmaq/cmaq-publications-and-peer-review).

Office of Water

- Data quality is essential to the development of products we use to support regulations, guidance, and major policy decisions. As such, EPA continues to address challenges with Per- and Polyfluoroalkyl Substance (PFAS) in the environment. In fiscal year (FY) 2019 the Office of Water (OW) published EPA's PFAS Action Plan (https://www.epa.gov/pfas/epas-pfas-action-plan). As part of the 2019 Action Plan, EPA proposed in February 2020 to regulate Perfluorooctane Sulfonate and Perfluorooctanoic Acid. As part of this action, EPA requested information and data on other PFAS substances as well as sought comments on potential monitoring requirements and regulatory approaches EPA is considering for

PFAS chemicals. https://www.epa.gov/newsreleases/epa-announces-proposed-decision-regulate-pfoa-and-pfos-drinking-water .

- In FY 2020, the OW posted quarterly occurrence data obtained as part of the Unregulated Contaminant Monitoring Rule (UCMR 4) on EPA website at, https://www.epa.gov/dwucmr/occurrence-data-unregulated-contaminant-monitoring-rule#4. Monitoring and data collection began under the UCMR 4 in 2018, which involves gathering data on 30 contaminants of emerging concern from all large public water systems (PWSs) and a representative set of small PWSs.

- OW invested in improved access to data, metadata, and web-based reporting of results and findings from National Aquatic Resource Surveys (NARS) water quality assessments. The OW has also made strides in making data and information more transparent through How's My Waterway. How's My Waterway allows users to navigate the wealth of data contained within OW, and this increased transparency continues to improve the data.

- In FY 2020, our scientists represented EPA and promoted OW's mission at conferences held by the following professional organizations: Society of Toxicology, The Toxicology Forum, Society of Environmental Toxicology and Chemistry, American Public Health Association, National Association of Black Geoscientists, American Society of Civil Engineers, Pittcon Conference, American Council of Independent Laboratories, and the Great Lakes Beach Association. In addition, staff participated in meetings held by a number of stakeholder associations and organizations: Association of Clean Water Administrators, Association of State Drinking Water Administrators, American Waters Works Association, Massachusetts Bay National Estuary Program, Interstate Shellfish Sanitation Conference, New England Interstate Water Pollution Control Commission, Delaware's Department of Natural Resources and Environmental Control National Association of Clean Water Agencies, National Rural Water Association, and International Water Association. Staff also attended meetings with states and other stakeholders on program implementation and on technical topics such as nutrients, harmful algal blooms, recreational criteria/swimming advisories, coliphage (viral indicator), perfluorinated compounds, water quality benefits assessments, emerging contaminants, and effluent guidelines. Finally, to support water quality standards development, OW offers the Water Quality Standards Academy, which presents classroom-based and online courses, along with occasional webinars.

- OW is responsible for developing and implementing the nation's drinking water regulations. The Safe Drinking Water Act requires the Administrator to use the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices as well as data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). [SDWA Section 1412(b)(3)(A)]

- The Office of Water continued to adhere to the Information Quality Control and Peer Review guidance for reports and products. The Office of Water implemented Quality Assurance Project Plans for both contract work and Agency work for EPA/State National Aquatic Resource Surveys.

- The Permitting and Water Quality Branch hired and trained (2) new staff in water quality standards as well as (1) in wetlands programs; hosted a virtual Program Manager's meeting with state agencies on National Pollutant Discharge Elimination System permitting, oversight, and water quality standards June 2020; and conducted a Review of a state's Department of Environmental Quality and Department of Agriculture, Food, and Forestry implementation of authorized program in August 2020.

- Office of Water staff are encouraged to have an Individual Development Plan (IDP) and to discuss their professional development goals with their manager at least twice per year. Ninety eight percent of Office of Science and Technology staff have an IDP, which has been reviewed within the last year.

- The Office of Water expanded the use of electronic field data applications for tablet devices, enabling NARS field crews to collect data electronically and submit it directly (or as soon as they have internet access). The use of the tablets and field application is designed to enhance the quality of data and speed input of data into the NARS database.

- The Office of Water continues to support monitoring and adaptive management development for restoration work in the Gulf of Mexico, as a Deepwater Horizon (DWH) Trustee and member of the Trustee Council (NOAA, DOI, EPA, USDA, and Gulf states). The DWH Trustees have recognized the need for robust monitoring and adaptive management to support restoration planning and implementation, given the unprecedented temporal, spatial, and funding scales associated with the DWH oil spill restoration effort. Monitoring provides feedback to inform decision-making through adaptive management. Adaptive management is a science-based approach to decision-making. It is iterative and involves monitoring and the use of improved scientific understanding to repeatedly fine-tune restoration projects for improved results.

Office of Chemical Safety and Pollution Prevention

- The Office of Chemical Safety and Pollution Prevention (OCSPP) continues to ensure that the scientific information we use in the implementation of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016), the Pollution Prevention Act and the Toxics Release Inventory is of high quality for its intended use.

- In 2017, EPA finalized the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (Risk Evaluation Rule) (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-

evaluations-chemicals-under-tsca) and Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act (Prioritization Process Rule) (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/federal-register-notice-procedures-prioritization). EPA is required to meet the scientific standards in TSCA for best available science, utilizing a weight-of-scientific evidence approach when conducting risk evaluations. The Risk Evaluation Process Rule defines "best available science" as science that is reliable and unbiased and involves the use of supporting studies conducted using sound and objective science practices, including peer reviewed studies when available and data collected using accepted or best available methods. The definition also states that EPA will consider, as applicable, the extent to which the scientific information is reasonable for and consistent with the intended use of the information and is relevant for making a decision about a chemical substance or mixture, the degree to which clarity and completeness are documented, the extent to which variability and uncertainty are characterized, and the extent of independent verification or peer review. The rule further describes the process EPA will use to evaluate hazard and exposure, exclude consideration of costs and other non-risk factors, use scientific information and approaches in a manner that are consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence. EPA is following these procedures in all chemical risk evaluations being performed in FY 2020.

- OPPT also released Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-assist-interested-persons-developing-and-0). This guidance 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.

- In June 2018, 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 (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/application-systematic-review-tsca-risk-evaluations). 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. This document expands upon EPA's initial work on systematic review as described in the supplemental files for each TSCA scope document, which include the Strategy for Conducting Literature Searches and the Bibliography for each chemical. An example of this document can be found at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-asbestos-0#scope. During FY2020, OPPT has implemented innovations to literature searching and screening through the use of new, automated techniques to identify studies for use in risk evaluation. Additionally, screening tools and the use of active-learning techniques have been used to enhance and speed the process of screening studies. OPPT has also developed additional criteria and workflows to strengthen TSCA's systematic review process.

- EPA has held up its commitment to have the systematic review procedures peer reviewed by the National Academies of Science, Engineering, and Medicine (NASEM). An ad hoc committee of the NASEM is currently evaluating and before the end of 2020 will provide recommendations to EPA on its application of systematic review for TSCA risk evaluations, focusing on whether it is comprehensive, workable, objective and transparent. EPA has presented to committee twice in 2020 and has an additional two meetings to share information on innovations in searching and screening.

- The Risk Evaluation 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) (https://www.epa.gov/tsca-peer-review), a FACA committee established under authority of the Lautenberg Act, 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 TSCA. The SACC is comprised of experts in toxicology, environmental risk assessment, exposure assessment and related scientific disciplines. In 2019 and 2020, EPA convened public meetings of the SACC to obtain independent review of the science underlying its draft risk evaluations for all of the first ten initial risk evaluations, The agency has, and will continue use the input from the committee, along with public comments, to inform the final risk evaluations for these chemicals. EPA's risk evaluation process thus ensures the integrity of scientific data used in actual risk evaluations by providing a rigorous framework of standards, guidances, peer review procedures, and other internal controls as outlined in the regulation and other publications described above. These controls are being put into practice in the course of the risk evaluations now in progress.

- OPPT often uses data with Confidential Business Information (CBI) claims. OPPT has implemented all procedures and strict internal controls to ensure the security of these data while conducting assessments of these chemicals. To further enhance transparency, OPPT has been working to implement the provisions of TSCA Section 14, which requires EPA to review and make determinations on many claims, including those made for health and safety data submissions. OPPT has also updated websites and performed outreach to stakeholders to describe the processes for the use of CBI in the evaluation of new chemical submissions, and the prioritization of chemicals, and risk evaluation of existing chemicals.

- OPPT continues to be in compliance with the Agency's Quality Policy and with the office's own Quality Management Plan and related quality documentation. In FY20, OPPT planned to conduct a QA Audit in compliance with the OPPT-wide QMP. In FY 2020, OPPT seamlessly transitioned from one QAM to another, the new QAM would oversee the FY 2020 QA audit.

- OPPT's New Chemical Review Program employs a number of practices to ensure scientific integrity of chemical data. Each pre-manufacture notice submitted by a

chemical manufacturer is reviewed by a multidisciplinary team of experts trained in standard review protocols. The agency has published an extensive set of guidance to help manufacturers develop submissions that will meet EPA standards for data sufficiency and quality, and thereby facilitate effective chemical review. The agency has developed standard assessment methods, databases and predictive models to ensure consistency in the new chemical review process. Information is available in the use of these models.

- The following are examples of key activities the TRI Program uses to help ensure the scientific integrity of its data:
    - Pursuant to National Program Managers (NPM) Guidance, the Toxics Release Inventory (TRI) Program Division (TRIPD) completes at least 600 data quality checks annually as part of various ongoing data quality activities intended to optimize the quality of TRI data submitted by industrial facilities and federal facilities.
    - The TRI Program uses an innovative electronic TRI reporting software called Toxics Release Inventory – Made Easy Web (TRI-MEweb) that numerous data field-level and batch-level data quality checks and enables facilities to file a paperless TRI report, all of which

- The Office of Program Management Operations (OPMO) mission is to use customer-focused approaches in leading, coordinating and resolving program management and administrative matters that help OCSPP achieve its broader mission of protecting the American public and the environment from potential risks from pesticides and toxic chemicals. Specific to scientific integrity, OPMO's role is to raise awareness of and compliance with EPA's scientific integrity policies and practices. As just one example of implementing this role, OPMO is using its bi-weekly "Musings" newsletter, which is electrically distributed to all OCSPP, to bring attention to scientific integrity. For example, the June 8 issue introduced CarolAnn Siciliano as OCSPP's Deputy Scientific Integrity Official, pointed to the EPA Scientific Integrity policy, promoted the upcoming Agency-wide scientific integrity meeting, and shared contact information for EPA's Scientific Integrity Official Francesca Grifo. As a reoccurring feature in these newsletters, scientific integrity was also highlighted in the June 22 issue that conveyed some highlights from the Agency's training and provided a link to the Whiteboard Video produced by EPA's Office of Scientific Integrity. At OPMO's suggestion, the Scientific Integrity Official addressed OCSPP senior leadership and reiterated key aspects of the Scientific Integrity Policy. The Deputy Scientific Integrity Official has also established Office Hours, publicized in the biweekly newsletter, and has adopted as her A3 project streamlining clearance of scientific products.

- Office of Pesticides Program (OPP) has a robust internal peer review system that helps ensure both the quality and scientific integrity of our scientific work products. OPP managers determine and are accountable for the level of peer review required for each risk assessment case and the scope of that review.

- In the Health Effects Division (HED) there are two main types of cross-divisional internal peer review panels which are consulted during the preparation of disciplinary chapters and human health risk assessments to provide technical advice and to confirm certain scientific decisions. Each type is described as follows:

- Science Assessment Review Committees (SARCs) are used by the division to ensure that scientific decisions are sound, and that current risk assessment policies and procedures are consistently applied. Each SARC has a standard operating procedure for its operation, and all decisions and documents are available to all staff members.

- Science Advisory Councils (SACs) and other scientific review committees/teams are consulted for specific disciplinary questions and to conduct quality assessments of major disciplinary assessments. There is a SAC for each of the following disciplines: residue/product chemistry, dietary exposure evaluation, toxicology, and occupational and residential exposure. In addition, HED has Residues of Concern Knowledge-based Subcommittee and a Dose Adequacy Review Team. All disciplinary scientists are encouraged to attend the meetings. This structure ensures that disciplinary policy decisions are disseminated rapidly throughout the division and that disciplinary policies are applied consistently across the division. Each SAC has a standard operating procedure for its operation, and all decisions and documents are available to all staff members.

  After a staff member has prepared a draft document, it is subjected to an internal peer review, also known as a secondary review. Each branch has its own procedures for the internal peer review, and the extent of the peer review is task specific. Generally, disciplinary assessments or reviews are subjected to a secondary review by one or more scientists within that discipline, while a risk assessment is reviewed by the team responsible for preparing the individual elements used in its preparation. If a branch does not have sufficient depth to conduct a secondary review, it will call upon other resources in the division to ensure an adequate secondary review is performed. The Branch Chief and/or a designated senior scientist review and approves all scientific documents.
- Before any work product is finalized by the branch, it must be reviewed by a primary or group of disciplinary experts that are designated by the Branch Chief. The disciplinary expert/senior scientist signs-off on branch products (there may be more than one disciplinary expert selected for branch product review in each branch). The disciplinary expert/senior scientist may consult with other disciplinary experts within the branch or division before approving any document under their purview.

- OSCP conducted an ELMS project titled: OCSPP Technical Product Clearance
  - Improves current process across OCSPP which includes the scientific integrity review procedures
  - Designing workflow for clearance

Office of Land and Emergency Management

- The Superfund program (Program) collaborated with regional staff to develop technically sound plans for investigating/assessing environmental contamination and reducing over time exposures to chemical contaminants arising from environmental contamination. The Program has endeavored to communicate scientific information with honesty, integrity, and transparency, both within and outside the Agency and to dispassionately review the quality and scientific soundness of scientific information prior to use or dissemination. The Program continues to periodically facilitate/arrange training and information-sharing sessions for interested EPA staff, led by practitioners or experts, about human health risk assessment, environmental processes, radiation, vapor intrusion, and other matters. The Program endeavors to keep abreast of technical developments and research pertaining to environmental processes, risk assessment, and environmental remediation methods; to collaborate with EPA researchers in these areas; and to be cognizant of and understand and appropriately communicate the specific programmatic statutes that guide our branch's work.

- Each Brownfields Assessment, Cleanup, Multipurpose and Revolving Loan Fund (RLF) cooperative agreement has an approved Quality Assurance Project Plan (QAPP) that is unique to the project(s) and helps both Brownfields grantees and environmental consulting firms understand what is required and expected while collecting and using environmental data. In addition to EPA regional project officers working with grant recipients, the Office of Land and Emergency Management (OLEM)'s EPA funded technical assistance providers also help communities to develop or prepare their sampling and analysis plans and their QAPP in accordance with their specific projects, when requested. Additionally, OLEM has completed revisions to a final report on the environmental benefits of brownfields redevelopment. This report was reviewed by ORD and OLEM experts and their comments were incorporated. The report will not be published in peer-reviewed literature, so OBLR sought internal Agency peer review**.**

- OLEM's Federal Facility Restoration and Reuse Office (FFRRO) continues to meet with other Federal Agencies to promote the use of the Uniform Federal Policy for Quality Project Plans (UFP-QAAP). FFRRO is also working with DOD to review the Army and Air Force Sampling Project Plans for PFAS PA/SI investigations.

- The Office of Underground Storage Tanks (OUST) strives for a fair, balanced, and peer-reviewed research when organizing studies and developing technical materials. OUST assigned staff to act as the OUST's Peer Review Coordinator, Data Quality Manager, and a member of the OLEM's Clearance Policy Workgroup. The Workgroup is currently drafting OLEM's Policy for Clearance of Scientific Products.

- OLEM's Office of Emergency Management (OEM) completed the following actions in FY20:

  Wide-Area Biological Decontamination and Restoration Projects

The Analysis for Coastal Operational Resiliency (AnCOR) is a collaborative EPA, DHS, USCG, and DTRA field demonstration project, which originated from gaps identified by EPA and the National Laboratories during the DHS Underground Transport Restoration (UTR) Project from FY'15 – FY'17. Specifically, the UTR Project identified the connectivity between the underground transit systems and many of aboveground outdoor areas (including coastal environs). As a result, the US Coast Guard is proactively trying to determine methods for data management, sample characterization, fate and transport, decontamination options (including vegetation, vessels, critical infrastructure), waste management and clearance sampling for above ground coastal areas. Specific accomplishments include the following.

- EPA is developing for AnCOR a Category B Quality Assurance Project Plan (QAPP) prior to the collection of any data. The QAPP will be followed throughout the test and a Quality Assurance Manager will be present during much of the testing to note any observations and relevant findings.
- AnCOR includes an entire segment of this research effort that is dedicated to data management (methods, procedures, innovative solutions, etc.) and information sharing to facilitate scientific discussion. To ensure the integrity of the data, it will be stored on an EPA server where only the project team has access. The collected data and final report will undergo review for scientific accuracy by the inter-Office and inter-Agency project team as well as the Quality Assurance staff.

Fixed and Mobile Chemical Labs

The OEM fixed and mobile chemical laboratories (known as the Portable High-Throughput Integrated Laboratory Identification System or PHILIS) provide the emergency response community with ability to rapidly analyze large numbers of environmental samples to identify hazardous chemicals, including chemical warfare agents. Scientific integrity is integral to their successful operation. Specific accomplishments include the following.

- OEM fixed labs and PHILIS must undergo routine audits under the National Environmental Laboratory Accreditation Program (NELAP) to maintain accreditation. This allows the labs to fulfill one of their primary missions by generating confirmatory analytical data for the EPA's regions, program offices, stakeholders, and other outside agencies. EPA conducts these audits at least annually, in accordance with NELAP accreditation requirements.
- All OEM fixed and mobile chemical laboratories maintain and update all laboratory standard operating procedures, Quality Management Plans, Data Management Plans, and Chemical Hygiene Plans. We make this a requirement in our support contract based on the requirements under the NELAP accreditation program (http://www.nelac-institute.org/).
- The PHILIS laboratories are part of the EPA's Environmental Response Laboratory Network (ERLN) which promotes uniformity in operational SOPS, QA/QC criteria as well as data integrity, and uniformity and sharing (https://www.epa.gov/emergency-response/environmental-response-laboratory-network). The ERLN itself is part of the Interagency Consortium of

Laboratory Networks (ICLN), which acts to provide analytical support, and support data uniformity, sharing and integrity and cooperation amongst several federal laboratory networks (https://www.icln.org/).

Publication in Open Sources
OEM actively supports scientific discourse through the publication of our research in public sources. Almost all of these research projects and publications are a result of inter-Office, if not inter-Agency/Department efforts. Integral to these collaborations is the support of differing scientific opinions and results-driven, scientific objectivity. These publications undergo review and open discussion through both OEM/EPA review processes as well as by the open-source journal. One example is provided below.

- *Evaluating the Environmental Persistence and Inactivation of MS2 Bacteriophage and the Presumed Ebola Virus Surrogate Phi6 Using Low Concentration Hydrogen Peroxide Vapor*, Wood et all, American Chemical Society, February 19, 2020.

Office of the Administrator/Office of Public Affairs

- As the Agency's communications arm, the Office of the Administrator/Office of Public Affairs (OA/OPA) supports ORD and the Scientific Integrity Office in communicating the importance of their efforts. OA/OPA worked with the Office of Inspector General to publicize their survey on scientific integrity.

- Outreach to staff and managers was provided across EPA on new Agency standard operating procedures for staff participating in private sector standards development activities. This standard operating procedure includes a section on scientific integrity considerations for standards participation and was developed in consultation with EPA's Scientific Integrity Official.

- OA/OPA supported program offices in the creation of multimedia content for outreach purposes.

Office of Mission Support

- EPA Core Products: in fiscal year 2020, the Office of Enterprise Information Programs reduced the backlog of overdue Quality Management Plans (QMPs) approvals and Quality System Assessment (QSA) reports by 100%. This improved customer satisfaction, regained customer trust in the Agency’s Quality Program, and increased business productivity.

Region 1

- The Region's Public Affairs Director ensures that press officers and intergovernmental staff work closely with scientists to ensure that science is plainly and clearly communicated, and that scientific findings and results are never altered or changed. In keeping with the Agency's Scientific Integrity Policy, Region 1’s Office of Public Affairs (OPA) ensures that knowledgeable and articulate spokespeople

communicate research clearly, accurately, and accessibly. Region 1'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.

- Examples include:
    - Organized press conference regarding release of EPA's PFAS Action Plan and was hosted by the Office of Chemical Safety and Pollution Prevention's Assistant Administrator, Alex Dunn, February 2019: https://www.epa.gov/newsreleases/epa-announce-first-ever-comprehensive-nation-wide-pfas-action-plan
    - Provided critical support in the development of EPA's Handbook for Citizen Science Quality Assurance and Documentation, which was released in March 2019: https://www.epa.gov/citizen-science/quality-assurance-handbook-and-guidance-documents-citizen-science-projects
    - Region 1 worked with the MSD Scientific Integrity Coordinator, the Deputy Scientific Integrity Official, the Regional Science Council communications committee, the Regional Science Liaison, regional programs, and the Agency's Scientific Integrity Official to develop regional clearance procedures for scientific products.

Region 2

- Region 2 staff reviewed and provided comments on a draft orientation guide to EPA's Quality Assurance handbook for citizen science for the Science and Technology Policy Council Citizen Science Workgroup.

- Region 2 staff participated in the fiscal year (FY) 2019 EPA Peer Review report to the Office of Management and Budget

- Region 2 hosted a visit by Francesca Grifo who held the following: Scientific Integrity Management Dialogues that were attended by 54 EPA Program and Regional Managers involved with science; Open Houses for managers and supervisors to continue discussions or ask questions; Scientific Integrity Overviews with open sessions attended by 47 staff; a meeting with the Regional Science Council; and open office hours.

- Region 2 participated in an OIG Project on the implementation of the EPA's Scientific Integrity Policy kick-off meeting and reviewed the OIG's draft report on the implementation of the EPA's Scientific Integrity Policy.

- Region 2 personnel participated in the FY 2020 Agency-wide Annual Meeting.

- Region 2 staff followed up with Region 2 employees who had not completed their mandatory Scientific Integrity onboarding training within six months of their start date (this training only applies to new hires).

Region 3

- In fiscal year 2020, the Office of Public Affairs (OPA) worked closely with the Air and Radiation Division (ARD) in developing a communications plan and public messaging intended to help inform communities living near high priority Ethylene Oxide (EtO)-emitting facilities. In Region 3, those facilities are in Pennsylvania, Delaware, and West Virginia. This work is based on the results of a National Air Toxics Assessment identifying EtO as a potential health concern that may contribute to potential elevated cancer risks in certain census tracts.
    - Participating in monthly EPA national EtO planning calls
    - Educating local-elected officials and community leaders about EtO and EPA's actions to better understand and regulate EtO
    - Educating the media (reporters) on EtO and EPA's actions to address the air toxic.

- The Superfund and Emergency Management Division (SEMD) continues to hold regional cross-program meetings on the emerging PFAS contaminants, now held at a monthly interval. Participants include SEMD personnel along with the Water Division, the Office of Regional Council, Office of Public Affairs, a representative from the Office of Research and Development and the Agency for Toxic Substances and Disease Registry. This meeting allows for specific site information to be shared along with updates on policy and technical information. In the Division, a process has been implemented to evaluate which sites should be targeted for PFAS sampling. In addition, SEMD participates in weekly briefings with the Deputy Regional Administrator to ensure awareness of site activities and policy updates regarding PFAS.

- Within the Water Division, the Underground Injection Control (UIC) program created a webpage to share UIC permits and operator reports. This website has reduced the number of FOIAs, and citizen inquires that historically took staff time to answer. The program can direct requesters to the website for more information. https://www.epa.gov/uic/underground-injection-control-epa-region-3-de-dc-md-pa-va-and-wv

- ARD has updated its 105 Grant Commitment database to enhance the tracking and monitoring of State and Local Agency section 105 grant commitments. Auto-generated email reminders are now being sent by GRANTTRAX to remind EPA contacts (ARD staff) of approaching deliverable due dates for their Section 105 grant commitments, allowing the tracking of all state quality assurance plans and project plans to ensure the plans are current.

- The work of the Science, Analysis, and Implementation Brach (SAIB) of the U.S. EPA Chesapeake Bay Program Office uses fact- and evidence-based environmental

monitoring and assessments of the Chesapeake Watershed and Tidal Bay. The monitoring and assessments are thoroughly vetted and reviewed in technical workgroups and committees of the Chesapeake Bay Program partnership by Federal, State, university, and other professional members. Major projects are peer reviewed under the EPA SAIB guidelines.

- The Laboratory and Technical Services Branch (LTSB) conducts Annual Laboratory Ethics Training for all laboratory employees. Additionally, an "Achieving and Maintaining Data with Integrity" Webinar is provided for all laboratory employees by LTSB.

Region 4

- In fiscal year 2020, the ARD continued its efforts to promote scientific integrity by adherence to professional values and practices when conducting and applying the results of science and scholarship. Continuing areas of emphasis are ARD's work with headquarters (HQ) and their state/local air agencies to assess pollutant emissions and the quality of monitoring/modeling data for evaluating and making decisions about air permitting and planning in the Southeast. The division provided guidance and technical support to state, local, and tribal partners to ensure environmental data used for decision-making was of known and documented quality. To continually improve the division's work products and assist state and local agencies, the division works both internally and externally to promote informed, scientifically sound decision-making. The Division continues to evaluate and review the quality management processes to ensure information and data quality, as well as integrity are maintained. ARD, in collaboration with OAQPS, the Region 4 Laboratory Services and Applied Science Division, and several states, was able to quickly stand up a program to evaluate Ethylene Oxide (EtO) emissions at the local level. There have been numerous concerns and challenges from the public balancing the need for sterilization services with exposures resulting from residual emissions from sterilizer facilities. The collaboration has resulted in improved understanding of atmospheric concentrations of this chemical, emission sources, mitigation approaches, and analytical techniques. The Division will continue to work with stakeholders to ensure that quality assurance and procedures conducted in the region follow EPA's guidance and standard operating procedures.

- In order to continue to cultivate an environment where science is the backbone of all decision making and provide the necessary technical support to our states, Region 4 staff from the Enforcement and Compliance Assurance Division and the Office of Regional Counsel formed a multidisciplinary workgroup to provide technical and legal support to one of our states in developing an interim enforcement order for PFAS-related violations. Staff with expertise in the Resource Conservation and Recovery Act, Safe Drinking Water Act, Clean Water Act, and the Toxic Substances Control Act participated and provided technical expertise/peer review for PFAS enforcement, which is an emerging area for each of these programs. Concurrently,

the multidisciplinary PFAS team is working closely with HQ to develop global company-wide settlements for two large PFAS manufacturers. These global settlements will have lasting impact of identification of PFAS contaminants, legacy contaminants, and future cleanup of PFAS compounds in contaminated media. Regional staff, in close communication with HQ and the Office of Research and Development, regularly provide up-to-date information on PFAS enforcement policy and scientific reviews to all state partners.

- The Region 4 SEMD Scientific Support Section has developed and issued a comprehensively updated Supplemental Guidance to Ecological Risk Assessment Guidance for Superfund (ERAGS). The Region 4 Ecological Risk Assessment document provides detailed regional guidance for the implementation of the ERAGS by practitioners and the regulated community. The Region 4 Supplemental Guidance offers more detailed and site-specific considerations for Ecological Risk Assessment performance or review than the overarching national guidance. Among other significant contributions, the Guidance includes a substantial set of up-to-date scientific screening values for use in screening water, soil, and sediment data for potential ecological risk that are not available elsewhere.

Region 6

- The Underground Storage Tank program continues to implement Peer Review procedures which have been in place in the region and utilized by the inspector throughout the decision-making process.

- 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.

- The Land, Chemical and Redevelopment Division (LCRD) has two branches which have demonstrated the use of scientific integrity. The LCRD staff completed technical/scientific training within their core disciplines to maintain their respective certification. Resource Conservation and Recovery Act (RCRA), Brownfields, and Solid Waste Branch. Technical teams in the RCRA Corrective Action program are utilized to evaluate scientific data and conclusions to ensure scientific integrity in the Corrective Action process.

- The Pesticides Program has worked directly with Tribal Communities to support their development of Community Oriented Integrated Pest Management (IPM) Plans. These IPM Plans formalize the various aspects of integrated pest management to incorporate good-housekeeping, effective timeframes, and appropriate tools for the specific targeted pests are all given proper consideration. Additionally, the Pesticide Program contributes on a variety of workgroups that address 1) pest management

and its relationship to improved health, 2) emerging issues in agriculture, and 3) preventing illegal pesticides from entering the marketplace.

Region 7

- In fiscal year 2020, to promote the understanding of the Scientific Integrity Policy, Region 7 worked to ensure that all new employees took the Scientific Integrity training. To remind Region 7 employees, several Local Area Network (LAN) Bulletin board postings were conducted as a reminder. Region 7 advertised/posted and emailed all technical Divisions to attend the Annual Conversation with the Scientific Integrity Official.

Region 8

- The Region continued to support staff with PubMed Central and Science Hub to ensure that the public has access to peer reviewed publications that include EPA authors.

- Six new members were selected for the Region 8 Science Council in fiscal year 2020, expanding the Council's reach in building a culture of science and scientific integrity. New members were briefed on the importance of scientific integrity. Two Council members were selected for management positions in fiscal year 2020, further expanding the reach of the Council and advancing the importance of scientific integrity. Positions filled by Council members included the Water Quality Section Chief and the Deputy Division Director for the Laboratory Services and Applied Sciences Divisions.

- The Council held an all-day retreat in March 2020. At this annual event, Council leadership reemphasized the importance of scientific integrity to the culture in Region 8; especially embracing diversity of thought and opinion.

- The Region 8 Science Council organized and led a cross-regional science council meeting. Leadership from each regional council shared information about their structure and function. Possibilities for future collaboration were also identified. Prior to this meeting, there was very little interaction among regional science councils. This meeting opened the door for future collaboration, including future discussions on scientific integrity.

- The Region 8 Science Council continued seminar series/trainings to advance professional development. The Council formed a new Industry Education Committee to advance professional development. The intent was to provide more in-depth learning opportunities.

- The Region 8 Science Council met in-person with Jennifer Orme-Zavaleta and Chris Robbins to discuss science and scientific integrity.

- Region 8 completed the annual process to identify the highest priority regional science needs. This included input from both staff and leadership and relied heavily upon the combined knowledge of scientists on the R8 Science Council to ensure that the region identified the highest priority needs.

Region 9

- Francesca Grifo provided Scientific Integrity training to managers in November 2019 and held office hours for staff and managers.