U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Fostering Quality Science at EPA

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Good afternoon Chairman Harris, Ranking Member Miller, and Members of the Subcommittee. I am Arthur Elkins, Jr., Inspector General at the U.S. Environmental Protection Agency (EPA). I also serve as the Inspector General of the U.S. Chemical Safety and Hazard Investigation Board. I am pleased to appear before you today for the first time since becoming Inspector General in June 2010 to discuss recent work conducted by my office related to EPA's Office of Research and Development (ORD). As the scientific research arm of EPA, ORD conducts research on ways to prevent pollution, protect human health and the environment, and reduce risk. ORD's role is critical given that EPA relies on sound science to safeguard human health and the environment.

Under the Inspector General Act of 1978, as amended, Inspectors General are tasked with promoting economy and efficiency, and identifying fraud, waste and abuse within their respective agencies. In recent years, the Office of Inspector General (OIG) has increased its focus on ORD's operations and activities. My testimony today highlights the results of this work from 10 selected reports issued since 2009 in the following areas: ORD controls, performance measures and resources; and ORD's role in providing research for decision-making in selected program areas.

ORD Controls, Performance Measures and Resources

OIG work has identified areas for improvement regarding ORD peer review panels, internal controls to address scientific integrity and research misconduct, performance measures, and how EPA manages its workforce and workload that have implications for ORD.

Peer Review Panels

Peer review is a process for enhancing a scientific or technical work product so that the decision or position taken by EPA, based on that product, has a sound, credible basis. The former EPA Deputy Administrator requested we review EPA's peer review process in response to concerns about EPA's handling of allegations of impartiality on one of its peer review panels. Our review focused on EPA's National Center for Environmental Assessment (NCEA) peer review process. Specifically, our objectives were to determine whether: 1) current laws, regulations, guidance, and other relevant requirements for such panels are adequate to produce objective scientific reviews; and 2) the current system of populating and managing such expert panels could be improved.

In our April 2009 report, we noted that NCEA's peer review panel selection process did not differ in many aspects when compared to the processes of four other science-based organizations. One noteworthy difference impacting panel selection was that Federal Advisory Committee Act (FACA) panels, such as the National Academy of Sciences and EPA's Science Advisory Board, attempt to achieve consensus among panelists, and concerns about impartiality of panel members can be mitigated by balancing the panel with varying viewpoints. Since NCEA peer review panels are not designed to obtain consensus, NCEA strives to select "impartial" panelists. However, we found that this concept was vaguely defined in Office of Management and Budget (OMB) and EPA guidance and was not explained in any NCEA-specific operating guidance. Further, NCEA did not have procedures for addressing conflicts of interest or potential biases impacting a panelist's impartiality that became known after a panel had completed its deliberations. Finally, there was no clear documentation of authority and responsibility for

making final determinations regarding panel selection or how potential conflicts of interest were resolved.

We made several recommendations to ORD to improve the peer review process. Among them were: 1) define the concept of "impartiality" and maintain records of all management decisions pertaining to the selection of peer reviewers, particularly resolution of potential conflicts of interest; 2) in cases where panelists with potential conflicts or biases are accepted on the panel, the records should include a memorandum of decision explaining the suitability and rationale for including or excluding each panelist, which is signed off on by an EPA official; and 3) develop guidance to address conflict of interest issues that arise after panel formulation and amend contracts for external peer review services to require that panelists re-certify their conflict of interest status prior to the panel convening. ORD agreed to all of our recommendations and provided an acceptable corrective action plan. EPA certified that these corrective actions were completed in December 2009.

Scientific Integrity

Since EPA decision-making relies on science, it is critical that EPA's scientific and technical activities be of the highest quality and credibility. Since 2000, a number of federal and EPA policies on ensuring the integrity of government science have been issued. EPA Order 3120.5 implements the federal policy on research misconduct, and ORD and others formulated the "Principles of Scientific Integrity" and the Principles of Scientific Integrity E-Training to further highlight professional ethics for EPA scientists. We looked at whether ORD has controls to address scientific integrity and research misconduct and how effective those controls are.

We reported in July 2011 that ORD has internal controls that include policies, procedures, training, and peer review. However, ORD should improve how it evaluates the effectiveness of its policies and procedures for scientific integrity and research misconduct. Currently, ORD does not test its policies and procedures because ORD asserts that few reported instances of misconduct means that it generally does not occur. However, few identified instances of research misconduct could signal that staff lacks awareness of key criteria and reporting requirements necessary to identify and report misconduct.

We issued an electronic survey to over 1,300 ORD science staff on their awareness of EPA's scientific integrity and research misconduct policies and procedures. We found that 65 percent of respondents were unaware of EPA Order 3120.5, and 32 percent were unaware of EPA's Principles of Scientific Integrity. We also found that ORD has not updated the Principles of Scientific Integrity E-Training since June 2005. The existing e-training is not mandatory for ORD staff and does not include actual examples to aid understanding by training participants. Sixty-five percent of our survey respondents indicated they had not completed the e-training. Those who have not completed the training may be unaware of key criteria regarding scientific integrity.

We made three recommendations to ORD. First, periodically test the effectiveness of controls in place to address scientific integrity and research misconduct. Second, work across EPA offices to initiate outreach on EPA Order 3120.5 to raise awareness on roles/responsibilities and reporting steps, and to identify EPA staff and managers who should complete the Principles of Scientific Integrity E-Training. Finally, continue to work with unions to update and implement E-training. Without these additional internal control efforts, ORD risks having its science called

into question, potentially lessening the credibility of its work. ORD agreed with our recommendations and subsequently followed up with a corrective action plan addressing our recommendations. ORD plans to complete all corrective actions by September 2012.

ORD Performance Measures

In 2010, ORD had twelve national research programs that provided science to support EPA's goals in its strategic plan. One research program, the Land Research Program (LRP), provided the science and technology needed to preserve land, restore contaminated properties, and protect public health from environmental contaminants. The LRP spent $186.2 million on land-related research between fiscal years (FYs) 2005 and 2009. We conducted a review to determine whether the LRP had appropriate performance measures for assessing the effectiveness of its research products.

The difficulty of measuring research performance has been recognized by the National Research Council of the National Academies (NRC) and other authoritative sources. No single measure can adequately capture all elements of research performance. LRP employed a variety of methods to assess its research performance, such as: 1) OMB Program Assessment Rating Tool (PART) measures; 2) client feedback; and 3) peer reviews by EPA's Board of Scientific Counselors (BOSC) who provides advice, information, and recommendations on ORD's research programs.

In our August 2010 report, we noted that improvements were needed in each area to better enable ORD to assess the effectiveness of LRP research products. Key findings included: LRP did not have measures that assessed progress toward short-term outcomes; LRP's citation analysis PART measures were not meaningful to ORD program managers and were not linked to LRP's goals and objectives; ORD's survey of LRP clients did not provide a meaningful measure of customer feedback because ORD's client survey was not reliable; LRP lacked some key measures that would aid BOSC in conducting its LRP program reviews; and ORD had not clearly defined elements of its long-term goal rating guidance for BOSC reviews.

Several underlying issues impacted ORD's development of LRP performance measures. These included the inherently difficult nature of establishing outcome-oriented research measures and ORD's decision not to tailor its measures to each research program. As a result, ORD had invested resources in performance measures and tools that had not effectively measured key aspects of LRP performance. The measures did not provide LRP with the data to assess program progress towards goals, identify areas for program improvement, or track the short-term outcomes of its research.

We made several recommendations to ORD to improve LRP's research measures, including that ORD: 1) develop measures linked to short-term outcomes in LRP's Multi-Year Plan; 2) augment LRP's citation analysis with measures meaningful to ORD program managers and linked to LRP's goals and objectives; 3) develop an implementation plan for the client survey to ensure that the program has a reliable method for assessing relevance (or develop a reliable alternative customer feedback mechanism); 4) provide appropriate performance measurement data to BOSC prior to full program reviews; and 5) revise its long term goal rating guidance to BOSC for program reviews. ORD generally agreed with our recommendations and provided an acceptable plan of action to address our recommendations.

EPA Workload and Workforce

Over the last five years, EPA has averaged over 17,000 positions in its organizational structure with annual payroll costs of approximately $2 billion. ORD's enacted budget for FY 2011 was $582.1 million with an authorizing level of 1907.2 full-time staff. For any organization to operate efficiently and effectively, it must know what its workload is. While there is no one exact definition of workload, it is commonly thought to be the amount of work assigned to, or expected to be completed by, a worker in a specified time period. Workload that is set too high or too low can negatively affect overall performance. The main objectives of assessing and predicting workload are to achieve an evenly distributed, manageable workload and to accurately determine the resource levels needed to carry out the work. The OIG has issued three reports since 2010 examining how EPA manages its workload and workforce levels. While not specifically focused on ORD, our findings and recommendations are applicable to ORD since they span across EPA programs and offices.

We found that EPA has not collected comprehensive workload data or conducted workload analyses across EPA in about 20 years. EPA does not require program offices to collect and maintain workload data, and the programs do not have databases or cost accounting systems in place to collect data on time spent on specific mission-related outputs. OMB guidance states that agencies should identify their workloads to help determine the proper workforce size, and federal accounting standards require that agencies establish cost accounting systems to allow them to determine resources consumed for work performed. Without sufficient workload data, program offices are limited in their ability to analyze their workloads and accurately estimate resource needs, and EPA's Office of Budget must base budget decisions primarily on subjective justifications at a time when budgets continue to tighten and data-driven decisions are needed.

We also found that EPA's policies and procedures do not include a process for determining resource levels based on workload as prescribed by OMB. Further, EPA does not determine the number of positions needed per mission-critical occupation using workforce analysis as required by the Office of Personnel Management. These conditions occurred because EPA has not developed a workload assessment methodology and has not developed policies and procedures that require workload analysis as part of the budget formulation process. As a result, EPA cannot demonstrate that it has the right number of resources to accomplish its mission.

Finally, we found that EPA does not have a coherent program for position management to assure the efficient and effective use of its workforce. Position management provides the operational link between human capital goals and the placement of qualified individuals into authorized positions. While some organizational components have independently established programs to control their resources, there is no Agency-wide effort to ensure that personnel are put to the best use. Without an Agency-wide position management program, EPA leadership lacks reasonable assurance that it is using personnel in an effective and efficient manner to achieve mission results.

We made several recommendations to address these findings including that EPA: 1) conduct a pilot project requiring EPA offices to collect and analyze workload data on key project activities; 2) amend guidance to require that EPA complete a workload analysis for all critical functions to support its budget request; and 3) establish an Agency-wide workforce program that includes controls to ensure regular reviews of positions for efficiency, effectiveness, and mission

accomplishment. EPA has not committed to a specific course of action with milestone dates for completion for many of our recommendations, therefore they remain open pending completion.

ORD Role in Providing Research for Decision-Making in Selected Program Areas

OIG work has also raised concerns about ORD's limited role in chemical risk programs such as the children's chemical evaluation and endocrine disruptor programs, and about the processes and procedures for climate change research and greenhouse gases endangerment finding.

Voluntary Children's Chemical Evaluation Program

EPA utilizes voluntary partnership programs to help it address a wide array of environmental issues by collaborating with companies, organizations and communities. EPA often relies on scientific data provided by its partners and self-certifications rather than independently validate such data. The result is that ORD often plays a limited role in these partnership programs. One example is the Voluntary Children's Chemical Evaluation Program (VCCEP), a pilot program administered by EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and designed to assess the possible risks from 23 chemicals. EPA asked the manufacturers and importers of these chemicals to volunteer to provide data sufficient for EPA to evaluate the risks of these chemicals to children's health.

In a July 2011 report, we reviewed the VCCEP to determine the outcomes of the program. Overall, we found that poor program design and EPA's failure to use its regulatory authorities under the Toxic Substances Control Act to compel data collection from industry partners resulted in the failure of the VCCEP as an effective children-specific chemical management program. ORD did not have a lead role in any aspect of the program. ORD activities were limited mainly to participating as a stakeholder during the program's design phase, and placing an ORD scientist on the Peer Consultation Panel. The panel, comprised of experts in toxicity testing and exposure evaluations, independently analyzed the submitted data to determine whether additional data was necessary to adequately characterize the risks the chemical may pose to children. An independent third party was used to manage this peer consultation process rather than ORD.

Endocrine Disruptor Screening Program

In our May 2011 report, we reviewed whether EPA has planned and conducted the requisite research and testing to evaluate and regulate endocrine-disrupting chemicals. We specifically focused on EPA's Endocrine Disruptor Screening Program (EDSP), which is administered by OCSPP with support from ORD. The Food Quality Protection Act, passed in 1996, gave EPA the authority to screen and test substances that may have an effect in humans similar to that of a naturally occurring estrogen, or such other endocrine effects as the EPA Administrator may designate. Congress also passed the Safe Drinking Water Act amendments in 1996, which provided EPA additional discretionary authority to test substances. In 1998, EPA established the EDSP, which uses a two-tiered screening and testing approach to assess endocrine effects.

We found that EPA has not adequately addressed the emerging issue of endocrine disruptors. The program has made little progress in identifying endocrine-disrupting chemicals.

While we acknowledge that EDSP encountered difficulties and delays, its lack of progress is also due to EPA's lack of management control over the program. EDSP has not developed a management plan laying out the program's goals and priorities or established outcome performance measures to track program results. EDSP has not finalized specific procedures to evaluate testing results. Finally, EDSP has not clearly defined the universe of chemicals it plans to evaluate over time. Developing a management plan would ensure that the program's goals and priorities are transparent so EPA's leadership and Congress can assess whether the goals of the program are being achieved within reasonable cost and schedule.

ORD provides support for EDSP. EPA established the Endocrine Disruptor Research Program in 1995, which conducts both basic and applied research to develop the fundamental scientific principles used by EPA program and regional offices in making risk assessment decisions. ORD also conducted the underlying research to develop many assays for chemical testing. ORD identified endocrine disruptors as one of its top six research priorities and since 1998, ORD has issued a research plan and two multiyear plans concerning endocrine disruptors. Within the multiyear plans, ORD specifically identified the support of EDSP as one of its three long-term goals. However, ORD stated in its draft Multiyear Plan for Endocrine Disruptors for FY 2007-2013 that the long-term goal of supporting EPA's EDSP will not be carried forward beyond 2011. According to the plan, all future work would be under a different long-term goal. It is unclear what impact, if any, this will have on the program.

Climate Change Research

Since the enactment of the Global Change Research Act of 1990, EPA's research on climate change – also known as global warming – has been part of a national and international framework. EPA is 1 of 13 federal agencies that make up the U.S. Global Change Research Program, which is a multi-agency effort focused on improving our understanding of the science of climate change and its potential impacts. Part of EPA's role is to understand the regional consequences of global change. ORD manages EPA's climate change research function through its Global Change Research Program. EPA's Office of Air and Radiation conducts activities related to mitigating greenhouse gases.

In a February 2009 report we looked at how well EPA policies, procedures, and plans help ensure that its climate change research fulfills its role in climate change. We found that EPA did not have an overall plan to ensure developing consistent, compatible climate change strategies across the Agency. We surveyed EPA regions and offices and found they needed more information on a variety of climate change topics. They needed technical climate change research and tools as well as other climate change policy guidance and direction. We learned that, in the absence of an overall Agency plan, EPA's Office of Water and several regional offices had independently developed, or were developing, their own individual climate change strategies and plans. The lack of an overall climate change policy can result in duplication, inconsistent approaches, and wasted resources among EPA's regions and offices.

At the time of our report, EPA's plan for future climate change research did not address the full range of emerging information needs. Specifically, the projected time of completion or the scope of some research projects did not match the timing or the scope of regions' needs. ORD did not have a central repository of its climate change research for its internal users, nor did it effectively communicate the results of its climate change research to EPA's internal users. While ORD collected research requirements from regions and program offices, the selection

criteria for research topics were not transparent to the regions. Finally, ORD did not have a system to track research requests through completion, or a formal mechanism to obtain feedback from its users.

We made several recommendations to ORD to establish various management controls to ensure EPA fulfills its emerging climate change role and related information needs. Among our recommendations was that ORD must continue to routinely update the Science Inventory to include the latest information from its laboratories and centers; establish a formal mechanism to track regional research needs from research project selection to completion; and establish a formal method for coordinating research work with regions and program offices, communicating research results, and collecting feedback on research products. ORD agreed with our recommendations and has certified that all corrective actions have been completed.

Greenhouse Gases Endangerment Finding

In September 2011, we reported on our review of the process EPA used to make and support its greenhouse gases endangerment finding based on a congressional request. Our objective was to determine whether EPA followed key federal and EPA regulations and policies in obtaining, developing, and reviewing the technical data used to make and support its greenhouse gases endangerment finding. Our review examined the data quality procedures EPA used in developing the endangerment finding. We made no determination regarding the impact that EPA's information quality control systems may have had on the scientific information used to support the finding. We did not test the validity of the scientific or technical information used to support the endangerment finding, nor did we evaluate the merit of EPA's conclusions or analyses.

We found that EPA met statutory requirements for rulemaking and generally followed requirements and guidance related to ensuring the quality of the supporting technical information. However, EPA's peer review of the technical support document (TSD) for the endangerment finding did not meet all OMB requirements for peer review of a highly influential scientific assessment primarily because the review results and EPA's response were not publicly reported, and because 1 of the 12 reviewers was an EPA employee. In our opinion, the TSD was a highly influential scientific assessment because EPA weighed the strength of the available science by its choices of information, data, studies, and conclusions included in and excluded from the TSD. EPA officials told us they did not consider the TSD a highly influential scientific assessment. We also found that no contemporaneous supporting documentation was available to show what analyses EPA conducted prior to disseminating information from other agencies in support of its greenhouse gases endangerment finding.

We recommended that ORD: 1) revise its Peer Review Handbook to accurately reflect OMB requirements for peer review of highly influential scientific assessments; 2) instruct program offices to state in proposed and final rules whether the action is supported by influential scientific information or a highly influential scientific assessment; and 3) revise its assessment factors guidance to establish minimum review and documentation requirements for assessing and accepting data from other organizations. EPA stated that its response to the final report will address our recommendations. We consider our recommendations unresolved pending our receipt and analysis of EPA's response to our final report, which is due at the end of December 2011.

Unimplemented ORD Recommendations

The Subcommittee expressed an interest in OIG recommendations that ORD has not implemented. Unimplemented recommendations refer to recommendations from prior OIG reports on which corrective actions have not been completed. The OIG is mandated by the Inspector General Act to identify unimplemented recommendations in our semiannual reports to Congress. We prepare a Compendium of Unimplemented Recommendations to satisfy this requirement. Our Compendium highlights for EPA management those significant recommendations from previous semiannual reports to Congress that have remained unimplemented past the date agreed upon by EPA and the OIG. It also provides a listing of all of the other significant recommendations with future completion dates.

In our most recent Compendium, we identified one unimplemented recommendation by ORD that is past due from a 2009 report that reviewed actions EPA has taken to mitigate health risks from chemical vapor intrusion at contaminated sites. We specifically recommended that ORD finalize toxicity values for Trichloroethylene and Perchloroethylene in the Integrated Risk Information System database. The agreed-to completion date was September 30, 2011. We also identified eight unimplemented recommendations with future planned completion dates from four reports. Corrective actions are set to be completed by ORD on these recommendations ranging from December 2011 out to 2015.

Planned and Ongoing Work on ORD Activities

In addition to the completed work discussed above, the OIG is currently conducting reviews of other ORD activities that may be of interest to the Subcommittee. One area we are reviewing is ORD's management of Science to Achieve Results (STAR) grants, which fund research grants and graduate fellowships in numerous environmental science and engineering disciplines through a competitive solicitation process and independent peer review. For FYs 2008 through 2010, this program received over $90 million in funding. We are planning a review of the actions EPA takes before awarding a STAR grant and during its monitoring of a grant to ensure no research misconduct occurs. We expect to start this work during the current FY. We have also started an evaluation of ORD's review process for proposals submitted for one particular STAR grant competition. Specifically, our objectives are to determine whether ORD followed applicable federal and EPA policies and procedures in managing the technical peer review panel process, and communicated with grant applicants in an accurate, timely, appropriate, and transparent manner regarding the status of their proposals. We expect to complete this work by April 2012.

Another area we are currently examining is EPA's approach to nanomaterials, which has become an emerging issue. Nanomaterials are particles so tiny they cannot be detected by conventional microscopes. These miniscule materials are being widely used in consumer products because of their unique properties and potential benefits, but the health and environmental implications associated with their use have not been fully determined. We have started a review to determine how effectively EPA is managing the human health and environmental risks of nanomaterials. We expect to complete this work by January 2012.

Conclusion

OIG work has identified areas where ORD can improve its operations and activities so it can better provide the solid underpinning of science and technology necessary for EPA regulatory decision-making. I believe the OIG has been a positive agent of change through the many recommendations we have made to ORD in those areas. To their credit, ORD has been receptive to many of our recommendations. We will continue to work with ORD to identify additional areas needing attention.

Thank you for the opportunity to testify before you today. I would be pleased to answer any questions the Subcommittee may have.