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Introduction

Good afternoon Mr. Chairman and members of the Subcommittee. Thank you for the opportunity to appear before this Subcommittee to discuss the use of scientific peer review at the Environmental Protection Agency. EPA has in place a strong and extensive program for peer reviewing our scientific and technical work products, and it is my pleasure to discuss that program with you today.

Context: EPA's System for Ensuring Scientific Quality

Our peer review policy fits within the context of a larger, Agency-wide quality system. EPA's quality system is the means by which we manage our scientific information in a systematic, organized manner. It provides a framework for planning, implementing, and assessing scientific work performed by EPA and for carrying out quality assurance and quality control activities. Each EPA organization is to develop a quality management plan that describes its quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and necessary interfaces for the planning, implementing, documenting, and assessing of all activities conducted. At the individual project level, we develop quality assurance project plans that describe the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The goals of the Agency-wide Quality System are to ensure that environmental programs and decisions are supported by data of the type and quality needed and expected for their intended use, and that decisions involving environmental technology are supported by appropriate quality-assured engineering standards and practices.

During the last twenty years there have been numerous independent evaluations of the role of science at EPA, including the Agency's use of peer review. These evaluations have been prepared by diverse groups such as the General Accounting Office, the National Research Council, Resources for the Future, the Harvard Center for Risk Analysis, the Agency's own Science Advisory Board and the writings of independent scholars. Many of these evaluations have suggested improvements in the ways that the Agency strives to bring quality science to its mission-oriented programs.

EPA recognizes that OMB's new Information Quality (IQ) Guidelines, together with our own IQ Guidelines issued in October 2002, are an important step forward in the quest for quality. The OMB guidelines call for all Federal agencies to develop quality performance goals, including procedures to assure quality before information is disseminated. In response to these guidelines, EPA has established a new system for addressing complaints about the quality of information that the Agency has disseminated. OMB guidelines identify peer review as a device to establish the presumption of objectivity for the Agency's information products.

Consistent Agency-wide application of peer review has been an EPA priority for many years. Since issuing our peer review policy in 1993, we have taken several major steps to support and strengthen the policy. But proof of a policy's value lies in its implementation, and here also EPA has been very active to ensure that our peer review policy is not only understood across the Agency, but is *applied* rigorously across EPA's program and regional offices. In a moment, I will provide an overview of our approach to the peer review of major scientific and/or technical work products, and then will follow with a description of how we have implemented the peer review policy across EPA. However, before I do, I would like to share a couple examples of how EPA relies on peer review in its broader sense to ensure that the Agency is "doing the right science" and "doing the science right."

One example is the external peer review of EPA's research strategies and plans by the Agency's Science Advisory Board (or "SAB," a FACA committee established to provide EPA with independent, external advice on scientific issues) and others. These reviews provide critical, early input to the Agency at the planning stage as it establishes its research priorities. A second example is the external peer review of EPA's research efforts by the National Research Council, the EPA Office of Research and Development's (ORD's) Board of Scientific Counselors and others. Indeed, this week the Human Studies Division of EPA's National Health and Environmental Effects Research Laboratory (NHEERL) is undergoing a three-day peer review of its epidemiologic and clinical research. Each of NHEERL's nine divisions conducts such a detailed review every four years, with a mid-cycle review after two years. Also, all the grants awarded by ORD's Science to Achieve Results (STAR) program are selected through a rigorous peer review process, whereby panels of independent researchers review all the proposals for their scientific quality. STAR research is funded through Requests for Applications (RFA) that are derived from the ORD Strategic Plan and from research plans for specific topics developed by ORD. RFAs are prepared in cooperation with other parts of the Agency and concentrate on areas of special significance to the EPA mission.

What Peer Review Is and What It Is Not

Peer review is a documented critical review of a specific scientific or technical work product, conducted by qualified individuals (or organizations) who are independent of those who performed the work (that is, at a minimum from a different office), but who are collectively equivalent in technical expertise (i.e., peers). It is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established quality requirements. Peer review is usually characterized by a one-time interaction or a limited number of interactions by independent peer

reviewers, and can occur during the early stages of the project or methods selection, or as typically used, as part of the culmination of the work product, ensuring that the final product is technically sound.

Peer review provides an independent scientific perspective on the basis for, and the conclusions reached in, EPA's scientific and technical work products. It also provides an opinion from experts that is helpful in resolving issues. However, the recommendations resulting from peer review are not issue resolution in and of itself. It is still up to EPA decision makers to weigh the peer reviewers' recommendations against other information, to determine how the work product should be modified and used to best inform Agency decision making. The disposition of peer reviewers' comments – which provides a clear explanation of what comments were accepted, which were not, and what changes were made based on the peer review – is documented in the peer review record for that product. Interested parties may contact the peer review manager for questions on the disposition of reviewers' comments.

EPA's Approach to Peer Review

EPA's approach to peer review is articulated in our policy, *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency*. The peer review policy was first issued in January 1993, and was reissued in 1994. In addition to the policy, EPA has published a handbook that provides detailed guidance for implementing the policy. The *Peer Review Handbook* is attached, and we request that it be included in the record of this testimony. We believe this is one of the most advanced treatments of peer review for intramural research and scientific/technical analysis of any Federal agency.

At EPA, we peer review major scientific and technical work products that support Agency decisions. A scientific or technical work product that supports a regulatory program or policy position and meets one or more of the following criteria is considered "major" and is therefore a candidate for peer review:

- Establishes a significant precedent, model, or methodology
- Addresses significant controversial issues
- Focuses on significant emerging issues
- Has significant cross-EPA/inter-agency implications
- Involves a significant investment of agency resources
- Considers an innovative approach for a previously defined problem/process/methodology
- Satisfies a statutory or other legal mandate for peer review.

EPA also considers economic analyses and reports to be potential candidates for peer review. The following economic work products will normally be classified as major and will be candidates for peer review:

- Internal EPA guidance for conducting economic and financial analysis

- New economic and financial methodologies that will serve as principal methods or protocols for conducting economic analyses within a program
- Unique or novel applications of existing economic and financial methodologies, particularly those that are recognized to be outside of mainstream economic practices
- Broad-scale economic assessments of regulatory programs, such as those required by Congressional mandates (e.g., the Clean Air Act reports to Congress on benefits and costs)
- New stated preference (e.g., contingent valuation) and revealed preference surveys (e.g., recreational travel cost surveys) developed to assist in the economic analysis of a regulation or program
- New national surveys of costs and expenditures for environmental protection (e.g., financial needs surveys, pollution abatement expenditures surveys)
- Economic research plans developed to assess and advance the state of the science in economic theory, methodologies, or modeling (in particular, the technical feasibility of the plan's components)
- New meta-analyses that re-analyze existing published literature and supporting data on the measurement of economic benefits, costs, and impacts.

However, if a work product applies, in a straightforward manner, previously peer-reviewed methods that are accepted by the scientific community, generally it would not be subject to peer review. This principle holds true for *any* repetitive or routine action – economic or otherwise – such as pre-manufacturing notices, National Pollutant Discharge Elimination System (NPDES) permitting, and routine monitoring reports.

Economic studies prepared to support major or economically significant regulations typically do not utilize innovative or untried economic methods, and we generally do not conduct peer reviews of straightforward applications or transfers of accepted, previously peer reviewed economic methods or analyses. Economic assessments prepared to support the regulatory development process routinely make use of previously published, peer-reviewed literature and adopt tools that allow for the transfer or adaptation of these techniques and information. The procedures used to transfer or adapt this work will generally be established by separate economic guidance documents that have been peer reviewed. Therefore, economic documents that are developed using these procedures will not normally receive additional peer review, even those prepared in support of major and economically significant rules. Even so, EPA's National Center for Environmental Economics performs an internal review of all EPA economic analyses, even if they apply routine methods and previously peer-reviewed techniques. This review ensures the analyses conform with mainstream economics and EPA's guidelines for preparing economic analyses.

Every day, we at EPA make regulatory and other decisions that necessarily involve many different considerations. Our peer review policy applies to major work products that are primarily scientific and technical in nature and may contribute to the basis for those policy or regulatory decisions. By contrast, this policy does not apply to non-major or nontechnical matters that EPA managers consider as they make decisions. Similarly, this policy does not apply to these ultimate decisions.

EPA managers in our program and regional offices determine, and are accountable for, the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made consistent with program goals and priorities, resource constraints, and statutory or court-ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice. For other work products, internal peer review is an acceptable alternative to external peer review. Ultimately, EPA's Assistant and Regional Administrators are responsible for the decision of whether and how to peer review the scientific and technical work products developed in their offices.

Peer review is not restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial. For example, our Science Policy Council sent EPA's *Framework on Cumulative Risk Assessment* to the SAB as an early consultative step in our progress toward developing Agency guidance on cumulative risk assessment. Early in the development of a product, we frequently seek consultations or advisories with the SAB and other advisory bodies, to make sure that we are starting out in the right direction and if not, to make any necessary corrections. Expert review and advice received early in the development of our scientific documents can help us make direct our efforts toward providing the most relevant and highest-quality science to inform Agency decisions.

Implementing Peer Review at EPA

Policy and Guidance

The 1992 report *Safeguarding the Future: Credible Science, Credible Decisions* focused on the state of science at EPA. The panel of experts who prepared the report emphasized the importance of peer review, especially external peer review, and the need for broader and more systematic use of it at EPA to evaluate scientific and technical work products. Their specific recommendation regarding peer review reads as follows:

"Quality assurance and peer review should be applied to the planning and results of all scientific and technical efforts to obtain data used for guidance and decisions at EPA, including such efforts in the program and regional offices. Such a requirement is essential if EPA is to be perceived as a credible, unbiased source of environmental and health information, both in the United States and throughout the world."

In response to this recommendation, EPA developed an Agency-wide policy statement in January 1993. This policy recognizes that effective use of peer review is indispensable for fulfilling

EPA's mission and therefore deserves high-priority attention from program managers and scientists across the Agency.

In 1994, the central role of peer review at EPA was reaffirmed in an Agency-wide implementation program. From 1994 to 1998, our program and regional offices wrote and used their own standard operating procedures for peer review. In 1998, the *Peer Review Handbook* was issued as a single, centralized implementation guidance for EPA staff and managers. The *Peer Review Handbook* was reissued as a second edition in December 2000.

The peer review policy provides for both external and internal reviews of the Agency's work products. It also recognizes the role of publishing articles in refereed scientific journals, although journal review alone generally is not adequate for scientific papers that are used in the Agency's decision-making process. External peer review typically is conducted for work products used to inform decisions that EPA considers to be major. Based in part on the guidance in the *Peer Review Handbook* for identifying major scientific/technical products, we send our highest-priority scientific products needing external peer review to the SAB and, for pesticides, to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) and similar bodies. For the next-tier products (*i.e.*, major products not selected for SAB or SAP review), we use other independent bodies, as well as ad-hoc panels selected and convened by private contractors. For even lower-tier cases, we may use letter (rather than panel) external reviews. In all cases, irrespective of which external organization provides the peer review, it is EPA's role and responsibility to decide how the reviewers' comments and recommendations will be considered and addressed in the Agency's decision-making process.

Any decision to use an internal peer review mechanism for such work products would be the exception rather than the rule. Of the more than 800 products listed in our database as either having undergone peer review in 2002 or needing peer review in the next few years, approximately 450 were slated for external peer review; 67 for internal review; 225 for refereed journal review; and for the balance, the review mechanism has not yet been determined (which is typical when products are a few years from completion).

Implementation

To know the extent to which peer review is conducted across EPA, we need to understand the universe of scientific and technical work products generated in our program and regional offices as well as in our research laboratories and centers. We rely on our Peer Review Coordinators and the Office of Research and Development's Office of Science Policy to provide this information.

Each EPA program and regional office has a Peer Review Coordinator who organizes an annual review of all scientific and technical work products in their organizations, and submits this information to the Office of Science Policy (OSP). OSP reviews summary information on each scientific and technical work product to determine if the office's decision on whether to subject the

product to peer review is consistent with EPA policy. If the organization proposes to peer review the product, then OSP evaluates whether the proposed peer review mechanism (for instance, external review panel) is appropriate.

This product-specific summary information is tracked in a database maintained by ORD. When the database was created in 1995, EPA's program and regional offices submitted to the database information on 112 products; by 1999, that number had risen to 1,062 product summaries created or updated in the database. For 2002, the Programs and Regions submitted 859 product summaries for OSP's review.

Let's look a little more closely at the 859 work products reviewed by OSP in 2002. Of that total, 113 had peer reviews completed in the past year; 273 products were designated as needing peer review sometime in the future (usually within the next 1 - 3 years, depending on where the product is in its development); 362 were scientific articles, or compilations of several articles, to be submitted to refereed scientific journals; and 111 were products that were deemed, usually because of their repetitive or routine nature, not to be candidates for peer review. Dividing 111 "peer review not needed" products by the 859 sum, we see that nearly 90 percent of our scientific and technical work products receive internal or external peer review.

Regular training helps reinforce adherence to the policy. The Peer Review Coordinators are responsible for training the staff in their organizations on implementation of the peer review policy. ORD periodically provides training to the Peer Review Coordinators, based on turnover among the coordinators and changes to the peer review policy. During the first several years of populating the peer review database and implementing the 1998 *Peer Review Handbook*, ORD and OEI held annual training meetings of the Peer Review Coordinators. This year, because the Coordinators have been meeting monthly to address peer review issues, we will not hold a training meeting. For 2003, we are investigating options for web-based training, so that we can better meet the needs of our staff the regional offices.

EPA's Peer Review Coordinators meet regularly to discuss issues related to implementing the peer review policy. Significant unresolved issues are raised to EPA's Science Policy Council (SPC), chaired by the Agency's Science Advisor, for resolution. The SPC, on behalf of the Deputy Administrator, oversees implementation of the peer review policy.

The Quality Staff in EPA's Office of Environmental Information (OEI) has played a key role in implementing our peer review policy. In 1996, EPA was concerned about the effectiveness of peer review. The Quality Staff, then part of ORD, was asked to assess implementation of the peer review policy across the Agency. This review found that implementation of the peer review policy was inconsistent and that many people who had responsibility for peer review activities were not aware of their responsibilities. These findings were in part responsible for the development of the *Peer Review Handbook*. In addition to creating the peer review database, the Quality Staff also developed training

for the Agency's Peer Review Coordinators, and made site visits to each organization to evaluate their documentation and record keeping practices for peer review. In 2001, OEI reassessed implementation of the peer review policy and concluded that the Agency had made significant progress.

Conflict of Interest

The concerns in a 1999 EPA Inspector General (IG) report focused on *potential* financial conflict-of-interest concerns about peer reviewer candidates, although the IG found no case of actual conflict of interest. The IG recommended that ORD issue supplemental guidance directing contractors and peer review leaders to inquire whether a potential reviewer has or had a financial relationship with the Agency. The IG agreed with EPA that issuing supplemental guidance, rather than revising the *Peer Review Handbook*, would be an effective way to address the IG's concerns.

As described below, EPA has taken several steps to address the conflict-of-interest issue, in particular regarding peer reviewers' disclosure to the Agency of prior technical or policy positions they may have taken on the issues at hand, and the expectation that reviewers disclose their sources of personal and institutional private- or public-sector funding. The *Peer Review Handbook* provides several considerations to evaluate conflict of interest in relation to the employment, financial interests (including those with the Agency itself), and professional affiliations of the peer reviewer(s). It also provides for public disclosure of any previous involvement with the issue under peer review consideration.

In response to the 2001 General Accounting Office (GAO) report entitled *EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance*, the SAB has taken several steps to address potential conflict-of-interest concerns. These include internal procedural actions within EPA's SAB Staff Office, as well as the new conflict-of-interest form developed by the SAB (and approved by the Office of Government Ethics) that is required to be submitted by all prospective panel members; this same, new conflict-of-interest form is now being used by EPA's other review bodies that utilize Special Government Employees, such as the SAP. It is also our intent to extend these new conflict-of-interest procedures to all extramural peer reviews managed by contracts.

Internal conflict of interest – making sure that those EPA employees who manage the peer review process are not inappropriately influenced by Agency decision makers who will determine how the work product informs the decision – is also an issue we have considered and addressed. In its December 2000 2nd edition of the *Peer Review Handbook*, EPA included supplemental guidance to address this issue. The revised handbook, among other things, clarifies the importance of strictly separating the management of scientific work products from the management of the peer review of those work products.

Impact: Does Peer Review Matter?

In 2001, the SAB's Research Strategies Advisory Committee (RSAC) thoroughly reviewed three major EPA documents and concluded that, in all three cases, peer reviews had substantial impacts on the final products. The RSAC chose the three documents from a list of ten documents proposed by the Agency; the RSAC's selections were based on, among other things, its view that the three documents related to EPA activities that set precedents for the use of science in developing Agency policy. While the number of products that the RSAC examined is small, we believe the Committee's findings demonstrate the value that peer review provides to all our scientific and technical work products. That is why, even though the peer review of our major scientific and technical work products – the risk assessments, technical documents, and the like that are critical to informing Agency decisions – costs us time and resources, we are committed to expending the effort, spending the money, and taking the time to maintain peer review as an integral part of how we do business here at EPA.

In July 2002, the EPA IG issued a draft report, *Science to Support Rulemaking*, stating that “critical science supporting the rules often was not independently peer reviewed.” The IG's report may be an accurate reflection of the past, but it does not represent the state of peer review at EPA today. The IG's report looked at 15 Agency decisions as far back as 1990. (In the report, the IG did not describe its criteria for selecting these 15 decisions.) However, even rules issued in the late 1990s would have used scientific products developed before our peer review guidance was completed in 1998. Only one 1 of the 15 “significant rules finalized” reviewed by the IG were promulgated after 1998, when we issued the *Peer Review Handbook* as guidance to the Agency on how to implement our peer review policy. In that one case, the IG did not provide any specific criticisms of how the Agency managed the peer review process.

Conclusion – Building on Our Progress

By consistent and rigorous monitoring of the use of peer review across the Agency, led by ORD's annual evaluation of offices' peer review plans, the value of scientific peer review in ensuring the quality of EPA's scientific and technical products is now widely understood and accepted across the Agency. Conscientious use of peer review is essential to the credibility of EPA's decisions, and we must ensure that the process always works as designed. For this reason, we submit the peer review process to regular evaluation, with an eye toward continuous improvement.

We are confident enough in the strength of our peer review program that we made it a cornerstone of the Information Quality Guidelines we issued last October. Since issuing our policy ten years ago, peer review has become a part of EPA's culture and its use is widespread across the Agency. Our challenge for the future is to continue the significant progress we have achieved to date and, not being content with the status quo, to look for ways to enhance the use of peer review as a tool for ensuring that EPA's decisions are supported by a firm foundation of scientific and technical information.

While we feel that our existing peer review policy and procedures provide the necessary framework for our peer review program, we look forward to working with the Subcommittee to

identify ways to build on our successes to further strengthen peer review at EPA. Thank you for the opportunity to speak with you today.