



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

THE ADMINISTRATOR

June 7, 1994

**MEMORANDUM**

**SUBJECT:** Peer Review Program

**TO:** Assistant Administrators  
General Counsel  
Inspector General  
Associate Administrators  
Regional Administrators  
Staff Office Directors

Today, I am reaffirming the central role of peer review in our efforts to ensure that EPA policy decisions rest on sound, credible science and data (see attached policy statement). Toward that end, as its first major task, EPA's Science Policy Council (SPC) is instituting a program to expand and improve peer review in all EPA offices. This memorandum gives an overview of current practices and outlines the new program.

**Peer Review Practices and Policy**

Peer review at EPA takes several different forms, ranging from informal consultations with Agency colleagues who were not involved in developing the product to the formal, public processes of the Science Advisory Board (SAB) and the FIFRA Scientific Advisory Panel (SAP). In any form, peer review assists the Agency's work by bringing independent expert experience and judgment to bear on issues before the Agency to the benefit of the final product.

EPA's peer review policy, which responds in part to recommendations in the "Credible Science, Credible Decisions" report, outlines general principles for peer review at EPA. Different EPA offices have undertaken various implementing activities, including an Agency-wide information and planning workshop, internal guideline development, and numerous specific peer reviews. Even with these activities, however, I am concerned that EPA does not yet have a comprehensive Agency-wide program for implementing its peer review policy. I therefore welcome the SPC initiative toward effective, efficient implementation of the policy in all the program areas to which it applies.

**Expanding and Improving Peer Review**

The Science Policy Council and its Steering Committee have outlined a dual-track implementation program of planning and assistance for all Agency offices. The first track has three major milestones.

First, during the next few weeks, Steering Committee members will consult with senior management in each office to exchange information on current peer review activities, assistance needed, possible obstacles to implementation, and implementation planning.

Second, using information and materials developed during the first stage, peer review task groups in each office will develop standard operating procedures (SOPs) for use in each office, based in part on generic guidance to be issued by the SPC and in part on peer review needs and capabilities specific to each office. The resulting SOPs will delineate as appropriate the scope of application of peer review with

respect to various types of scientific and technical work products such as reports of original research, risk assessments, and analytical methods of economic analysis. OARM and OGC staff will assist each office as needed on legal, budget and administrative matters. Each AA and RA will submit draft SOPs for Steering Committee review by July 15.

Third, the SPC review group will work with each office to complete each plan by September 15.

In parallel with the above, consistent with the peer review policy, the Science Policy Council will work with each AA and RA to identify "major scientific and technical work products" as peer review candidates for the coming year. This process will consider existing and new plans for internal reviews and for SAB, FIFRA SAP, and other external reviews. The two-fold objective is to plan reviews for technical products covered by the peer review policy and to gain experience with options and obstacles. We will use this experience to review and revise the SOPs as needed. Also, to establish a baseline for comparison, each AA and RA will identify the "major technical products" completed within his/her program during the past 12 months.

The Science Policy Council has sent additional information to each office offering guidance on the procedures that you are asked to develop and the schedule for these activities. Please note, however, that because the policy is effective immediately, current peer review planning should continue on present schedules in parallel with developing the formal SOPs.

To begin this process, I have asked each Assistant Administrator and Regional Administrator to designate a Peer Review Coordinator to work with the Steering Committee on implementation activities specific to each office. I am very pleased that the Science Policy Council is taking this important step. A comprehensive peer review program is essential to maintaining and improving the quality of the analyses that underlie Agency actions. I look forward to working with you and your staff on this important activity.

/s/

Carol M. Browner

Attachment

cc: Science Policy Council

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<http://www.epa.gov/ORD/spc/memo0607.htm>

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## **PEER REVIEW AND PEER INVOLVEMENT AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY**

This document establishes the policy of the United States Environmental Protection Agency (EPA) for peer review of scientifically and technically based work products that are intended to support Agency decisions. Peer review is presented in the context of the broader concept, peer involvement.

### **BACKGROUND**

The report "Safeguarding the Future: Credible Science, Credible Decisions"<sup>1</sup> 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, then-Administrator Reilly directed staff to develop an EPA-wide policy statement, which he issued in January, 1993. The paragraphs below preserve the core of that earlier statement while updating it to specify the role of the Science Policy Council in guiding further implementation of the policy. Effective use of peer review is indispensable for fulfilling the EPA mission and therefore deserves high-priority attention from program managers and scientists within all pertinent Headquarters and Regional Offices.

### **PEER INVOLVEMENT AND PEER REVIEW**

EPA strives to ensure that the scientific and technical underpinnings of its decisions meet two important criteria: they should be based upon the best current knowledge from science, engineering, and other domains of technical expertise; and they should be judged credible by those who deal with the Agency. EPA staff therefore frequently rely upon peer involvement -- that is, they augment their capabilities by inviting relevant subject-matter experts from outside the program to become involved in one or more aspects of the development of the work products that support policies and actions.

One particularly important type of peer involvement occurs when scientifically and technically based work products undergo peer review -- that is, when they are evaluated by relevant experts from outside the program who are peers of the program staff, consultants, and/or contractor personnel who prepared the product. Properly applied, peer review not only enriches the quality of work products but also adds a degree of credibility that cannot be achieved in any other way. Further, peer review early in the development of work products in some cases may conserve future resources by steering the development along the most efficacious course.

Peer review generally takes one of two forms. The review team may consist primarily of relevant experts from within EPA, albeit individuals who have no other involvement with respect to the work product that is to be evaluated (internal peer review). Or the review team may consist primarily of independent experts from outside EPA (external peer review).

### **POLICY STATEMENT**

Major scientifically and technically based work products related to Agency decisions normally should be peer-reviewed. Agency managers within Headquarters, Regions, laboratories, and field components 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 in conformance 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. 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.

## SCOPE

Agency managers routinely make regulatory and other decisions that necessarily involve many different considerations. This policy applies to major work products that are primarily scientific and technical in nature and may contribute to the basis for policy or regulatory decisions. By contrast, this policy does not apply to nonmajor or nontechnical matters that Agency managers consider as they make decisions. Similarly, this policy does not apply to these ultimate decisions.

This policy applies where appropriate, as determined by the National and Regional Program Managers, to major scientifically and technically based work products initiated subsequent to the date of issuance. Peer review should be employed to the extent reasonable to relevant work products that currently are under development. This policy does not apply to the bases for past decisions, unless and until the relevant scientific and technical issues are considered anew in the Agency's decision-making processes.

Except where it is required by law, formal peer review (as distinguished from the Agency's normal internal review procedures) should be conducted in a manner that will not cause EPA to miss or need extension of a statutory or court-ordered deadline. Agency managers still may undertake peer review if it can be conducted concurrently with necessary rulemaking steps.

## LEGAL EFFECT

This policy statement does not establish or affect legal rights or obligations. Rather, it confirms the importance of peer review where appropriate, outlines relevant principles, and identifies factors Agency staff should consider in implementing the policy. On a continuing basis, Agency management is expected to evaluate the policy as well as the results of its application throughout the Agency and undertake revisions as necessary. Therefore, the policy does not stand alone; nor does it establish a binding norm that is finally determinative of the issues addressed. Minor variations in its application from one instance to another are appropriate and expected; they thus are not a legitimate basis for delaying or complicating action on otherwise satisfactory scientific, technical, and regulatory products.

Except where provided otherwise by law, peer review is not a formal part of or substitute for notice and comment rulemaking or adjudicative procedures. EPA's decision whether to conduct peer review in any particular case is wholly within the Agency's discretion. Similarly, nothing in this policy creates a legal requirement that EPA respond to peer reviewers. However, to the extent that EPA decisions rely on scientific and technical work products that have been subjected to peer review, the remarks of peer reviewers should be included in the record for that decision.

## IMPLEMENTATION

The Science Policy Council is responsible for overseeing Agency-wide implementation. Its responsibilities include promoting consistent interpretation, assessing Agency-wide progress, and developing recommendations for revisions of the policy as necessary.

The Science Policy Council will oversee a peer-review work group, which will include representatives from program units throughout EPA to effect a consistent, workable implementation of the policy. The work group will assist the programs in (1) formulating and, as necessary, revising standard operating procedures (SOPs) for peer review consistent with this policy; (2) identifying work products that are subject to review; and (3) for each major work product, selecting an appropriate level and timing of peer review.

In assisting the programs, the work group will take into account statutory and court deadlines, resource implications, and availability of disinterested peer reviewers. The group will work closely with Headquarters offices and the Regional Offices toward ensuring effective, efficient uses of peer review in

supporting their mission objectives. However, the Assistant Administrators and Regional Administrators remain ultimately responsible for developing SOPs, identifying work products subject to peer review, determining the type and timing of such review, documenting the process and outcome of each peer review, and otherwise implementing the policy within their organizational units.

Because peer review can be time-consuming and expensive, Agency managers within Headquarters, Regions, laboratories, and field components are expected to plan carefully with respect to its use -- taking account of program priorities, resource considerations, and any other relevant constraints as well as the policy goal of achieving high-quality, credible underpinnings for decisions. External peer reviewers should be chosen carefully to ensure an independent and objective evaluation. The affiliations of peer reviewers should be identified on the public record, so as to avoid undercutting the credibility of the peer-review process by conflicts of interest.

The policy is effective immediately. The peer-review work group mentioned above will identify the focal point to whom comments and questions should be addressed and, from time to time, will provide further information about implementation activities.

APPROVED: \_\_\_\_\_/s/ \_\_\_\_\_ DATE: JUN 7 1994

CAROL M. BROWNER, ADMINISTRATOR

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1 EPA/600/9-91/050, March 1992.

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