

EPA AN SAB REPORT: REVIEW OF THE PEER REVIEW PROGRAM OF THE ENVIRONMENTAL PROTECTION AGENCY

**A REVIEW BY THE RESEARCH
STRATEGIES ADVISORY
COMMITTEE (RSAC) OF THE
SCIENCE ADVISORY BOARD**

November 22, 1999

EPA-SAB-RSAC-00-002

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Subject: An SAB Report: Review of the Peer Review Program of the
Environmental Protection Agency

Dear Ms. Browner:

The review conducted by the Research Strategies Advisory Committee (RSAC) on September 23-24, 1999 focused on whether or not key components of sound peer review process are in place at the EPA, whether appropriate tools and training are available, and whether management commitment exists to carry out EPA directives for peer review. The Committee was pleased to see the Agency's diligence with respect to Peer Review. From the materials presented to RSAC, EPA's Peer Review Process is well articulated and appears to be fundamentally sound and, with a few exceptions, working as intended. Future RSAC reviews are planned to evaluate the extent, adequacy and timeliness to which peer review is carried out by various program offices, Regions and EPA laboratories.

The RSAC found that peer review processes appear to be well established at the EPA. In addition, these processes are continuing to improve through a mechanism of continued internal examination, led by the Office of Research and Development, and process changes carried out by Decision-makers at the direction of the Science Policy Council. The driver for the Peer Review Program has been established by EPA management leadership. This high level management commitment to peer review major EPA Technical and Scientific products was manifested in such actions as the 1994 Peer Review Policy statement, the establishment of the Science Policy Council, the Peer Review Handbook, and most recently the establishment of a policy that all rules planning and analytic blueprints must specifically address and include consideration of peer review. The continued success of the Peer Review process at EPA will only be ensured with continual commitment on the part of Senior managers to the Peer Review process in all appropriate aspects of the Agency's endeavors. At the same time, RSAC recommends that EPA take the necessary steps to keep the process from becoming inappropriately bureaucratic.

The RSAC has made several suggestions to strengthen the peer review process. A key

suggestion is expanding the scope to the evaluation of interagency and international products considered important to environmental decision-making. Peer review should also be extended to the up-front review of scientific and technical planning products such as strategic plans, analytic blueprints, research plans, and environmental goals documents. In addition to major science and technology products, social science research products can and should be subjected to the peer review process in a manner similar to natural science products. Products that are policy analytic, in that they are not purely science-based but involve the application of policy and values, should also be peer reviewed to ensure that appropriate methods and procedures have been used, including an explicit treatment of assumptions and value judgments, adequate sensitivity analysis, and adequate treatment of uncertainty. Thus, the explicit need to review major social science products (in addition to economic products), and policy analytic products should be added to the Peer Review Handbook. Finally there should be a requirement for completion of training before a person can be designated as a Peer Review Leader.

We appreciate the opportunity to review and provide advice on the Agency's Peer Review process. The Research Strategies Advisory Committee would be pleased to expand on any of the findings in the attached report, and we look forward to your response.

Sincerely,

Dr. Joan M. Daisey, Chair
Science Advisory Board

Dr. William Randall Seeker, Chair
Research Strategies Advisory Committee
Science Advisory Board

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ABSTRACT

On September 23 and 24, 1999 the RSAC met to review the Agency's peer review program. The Committee responded to five charge questions. The RSAC found that the Peer Review processes appear to be well established at the EPA. The Science Policy Council Peer Review Handbook is an excellent guidance document and provides definitive criteria for deciding what to peer review. Some concerns still remain regarding the process leading to the decision to peer review or not because of the funding available and/or because of pressure to complete the work product before peer review due to timing constraints. Consistent with the intent of the policy, the practice of peer review should not be limited to final products but should also be extended to the up-front review of significant scientific and technical planning products such as strategic plans, analytic blueprints, research plans, and goals documents. In general, the Handbook contains good guidance on issues related to conflict of interest for the peer reviewers. However, there is concern with respect to conflict of interest of the Peer Review Leader. The Handbook states that the Peer Review Leader could be the Decision-maker, but Decision-makers often have a professional interest in the outcome of the review. The RSAC suggests that EPA include interagency and international products that are used in support of environmental decision-making in the US under the peer review policy. The evaluation of EPA's peer review process is expected to be conducted over two to three years. Therefore, RSAC could not fully address the charge questions "Are the reviews and resulting advice timely" and "Do the peer reviews make a difference?" during this first review. Data need to be collected and case studies developed to help the RSAC address these questions.

Keywords: Peer review

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1.0 EXECUTIVE SUMMARY

On September 23 and 24, 1999, the Research Strategies Advisory Committee (RSAC) of the Science Advisory Board (SAB) reviewed the Agency's peer review program. RSAC was pleased to see the attention given to the RSAC review by senior EPA personnel.

As part of the review process, the RSAC responded to five charge questions:

- a) Is EPA peer reviewing the right products?
- b) Are the peer reviews conducted appropriately?
- c) Do the peer reviews make a difference?
- d) Does EPA peer review all the science it uses (e.g., data submitted from parties outside the Agency)?
- e) Does the RSAC have additional comments/guidance for EPA?

The credibility of science used by EPA to support its decisions has been called into question over the last several years as more controversial issues and more subtle health and ecological effects have been investigated. The Committee thinks that independent peer review of scientific products makes it much more difficult to question the quality of the Agency's science base. Independent peer review, as defined in section 1.4.8 of the Peer Review handbook, is one of the central elements that ensure the quality and improves the credibility of the Agency's scientific and technical products. Thus, a comprehensive peer review mechanism is a necessary component for the Agency's decision-making process and must be rigorously imposed by Agency managers and scientists.

Peer Review processes appear to be well established at the EPA. In addition, these processes are continuing to improve through a mechanism of continued internal examination led by the Office of Research and Development and process changes carried out by Decision-makers at the direction of the Science Policy Council. A key to success in implementing the peer review process has been the involvement of the Office of Research and Development in the oversight role. ORD scientists have an understanding of the importance of peer review in developing good scientific and technical products. ORD has provided effective support to the establishment of the Peer Review process within EPA through development and implementation of training, collection of data on products and their review status, and also by bench marking EPA's peer review efforts against reviews at other organizations.

The Science Policy Council Peer Review Handbook is an excellent guidance document and provides definitive criteria for deciding what to peer review. While the guidance is clear, some concern still remains regarding present mechanisms leading to the decision to peer review or not based on funding available and/or pressure to complete the work product before peer review

due to timing constraints. There will always be some difficult decisions, but these are areas where the Agency could focus its attention on in the future. Every effort should be made to ensure that all major scientific and technical products are appropriately peer reviewed.

The focus of the “Peer Review Handbook” developed by the Agency’s Science Policy Council is the peer review of major scientific and technical products. The review of major products is obviously important to ensure that they are of acceptable quality. The Handbook clearly defines and articulates the nature of the products that should be peer reviewed, and it is an excellent guide to help managers select both the products for peer review and the proper mechanisms for performing the review.

However, the focus of the peer review should not be limited to the end products of the scientific endeavor. Peer review should also be extended to the up-front review of scientific and technical planning products such as major strategic plans, analytic blueprints, research plans, and goals documents. The Office of Research and Development follows this practice by peer reviewing its strategic plans and research strategies. While the Handbook does discuss peer input it does not explicitly address the importance of peer review in the planning of products and documents.

In general, Section 3.4 of the Handbook contains good guidance on issues related to conflict of interest for the peer reviewers. However, there is concern with respect to conflict of interest of the Peer Review Leader. The Handbook states that the Peer Review Leader could be the Decision-maker (Section 1.4.4). The Decision-maker will often have a professional interest in the outcome of the review. An essential part of peer review as defined by the EPA is independence of the review from the person (or persons) who has developed the product or overseen the development of the product. In addition, the role of sign-off upon completion of the review by the peer review leader is not defined. Comparing peer review to quality assurance (QA), one of the important aspects of the QA officer’s responsibilities is to stop activity if there is a serious problem with implementation of the QA/QC program. Currently only the Decision-maker signs off when the peer review is complete. It should be the Peer Review Leader’s responsibility to determine if changes to the product have been satisfactorily made and to stop the product from moving forward until that determination can be made.

The RSAC has made several other suggestions to strengthen the peer review process. A key suggestion is expanding the scope to the evaluation of interagency and international products considered important to environmental decision-making. Peer review should also be extended to the up-front review of scientific and technical planning products such as strategic plans, analytic blueprints, research plans, and environmental goals documents. Products that are policy analytic, in that they are not purely science-based but involve the application of policy and values, should also be peer reviewed to ensure that appropriate methods and procedures have been used, including an explicit treatment of assumptions and value judgments, adequate sensitivity analysis, and adequate treatment of uncertainty. For example, flawed decision-making on the implementation of environmental control technologies (which may include considerations and approaches that are nested in the social science framework) can result in a poor program even if

the technological options are intrinsically effective. Thus, in addition to major science and technology products, social science research products, and policy analytic products, can and should be subjected to the peer review process. The explicit need to review major social science products (in addition to economic products) should be added to the Peer Review Handbook. Finally, there should be a requirement for completion of training before a person can be designated as a Peer Review Leader.

The RSAC review of EPA's peer review process is expected to be conducted by the SAB over two to three years. This report is the product of the first meeting in a multi-year process. It was not possible to fully address the charge questions concerning the timeliness of peer reviews and resulting advice (i.e., "Are the reviews and resulting advice timely?") and the effectiveness of peer review in improving Agency decision-making (i.e., "Do the peer reviews make a difference?"). Data need to be collected and case studies developed to help the RSAC evaluate these issues.

2.0 INTRODUCTION

On June 7, 1994, the EPA Administrator issued a Peer Review Policy requiring that all major scientifically and technically based work products related to Agency decisions should be peer reviewed. This Peer Review Policy was re-emphasized in the subsequent memos issued by the senior management in the Agency and by the release of the Peer Review Handbook in 1998. The Deputy Administrator also initiated an audit by the National Center for Environmental Research and Quality Assurance within ORD to evaluate the extent to which the Agency offices and regions were complying with the peer review procedures. The General Accounting Office has completed at least two independent evaluations of the Peer Review Program at EPA. Recently, the National Research Council issued its Blue Ribbon panel report on Evaluating Federal Research Programs (NAS, 1999).

The Research Strategies Advisory Committee (RSAC) of the Science Advisory Board was requested to conduct a review of the overall process and the Agency's initial efforts to develop and implement the peer review policy and guidance. RSAC decided to conduct this review in two phases. The first phase, which is the subject of this report, focuses on EPA's Peer Review Processes and Policies. The second phase will focus on the implementation of the processes and policies, and the impact of the Peer Review Policy on the Agency's decision-making.

EPA's charge to the RSAC was:

- a) Is EPA peer reviewing the right products?
 - (i) Are there sufficient criteria for deciding what to peer review?
 - (ii) Is the information collected about projects sufficient to apply the criteria and to judge whether and where the peer review should take place?
 - (iii) What information should be gathered on individual work products for managers of the peer review process to determine how best to conduct the peer review?
 - (iv) Are the right products being peer reviewed?
 - (v) Do the products go to the right place for peer review?
- b) Are the peer reviews conducted appropriately?
 - (i) Does the process take the right steps to minimize conflicts of interest?
 - (ii) Does the process give proper attention to controversial and polar positions?
 - (iii) Are the reviews set up appropriately to address the needs of the Agency?
 - (iv) Are the reviews and the resulting advice timely?
- c) Do the peer reviews make a difference?
 - (i) To what extent are the review comments responded to and acted on by the Program Office/Region?

- d) Does EPA peer review all the science it uses (e.g., data submitted from parties outside the Agency)? How well does EPA capture which scientific components were peer reviewed and which were not?
- e) Does the RSAC have additional comments/guidance for EPA?

On September 23 and 24, 1999, the RSAC met to conduct the review and prepare its report to the Administrator. This RSAC review was limited to an overall evaluation of the peer-review process gleaned from the Peer Review Handbook (1998), several GAO reports, and a number of letters and memos from senior management in the Agency. This RSAC review was further aided by presentations from and interactions with Agency staff during the September 23-24 1999 public meeting. RSAC has planned to conduct a subsequent in-depth analysis to fully examine trends in the use of peer review in EPA, the impacts of the peer reviews, and additional opportunities for enhancing the benefits from peer review in the form of quality, credibility, relevance and Agency leadership position. The following subset of the charge questions, from the list shown above, will be addressed in the subsequent RSAC review.

- a) Are the reviews and resulting advice timely?
- b) Do the peer reviews make a difference?
- c) To what extent are the review comments responded to and acted on by the Program Offices and Regions?

The RSAC based its review on briefings by Agency staff during the meeting and the reference documents provided by the Agency. These documents are listed in the reference section at the end of this report.

3.0 OVERVIEW OBSERVATIONS AND COMMENTS

The Office of Research and Development has had a peer review policy in place since 1982. However, the process was not standardized and documented except for those reviews carried out through the SAB. Thus, in general, there was no way to determine the effectiveness of the ORD-organized peer reviews in improving the science work products that were reviewed. Thus, the implementation of a formal process with central collection of information regarding the review is an important step in providing greater confidence in the scientific quality of the Agency's major science work products.

On September 23 and 24, 1999 the Research Strategies Advisory Committee (RSAC) of the Science Advisory Board (SAB) met to review the Peer Review Program of the US Environmental Protection Agency (EPA). The review meeting was conducted in public session under the provisions of the Federal Advisory Committee Act (FACA). The Committee was provided with background documents supplied by the Agency, supplemented by briefings from Agency senior managers during the meeting.

The Committee was pleased to see the Agency's diligence with respect to Peer Review. From the materials presented to RSAC, EPA's Peer Review Process is well articulated and appears to be fundamentally sound and, with a few exceptions, working as intended. The materials provided before the meeting were very comprehensive and useful in preparing for the review. Overall, it seems that EPA has been responsive to the SAB, GAO and other organizations' recommendations regarding peer review. The process currently in place covers many facets of peer review requirements.

The RSAC found that peer review processes appear to be well established at the EPA. In addition these processes are continuing to improve through a mechanism of continued internal examination led by the Office of Research and Development and process changes carried out by Decision-makers at the direction of the Science Policy Council. The driver for the Peer Review Program has been established by EPA management leadership. This high level management commitment to Peer Review of major EPA Technical and Scientific products was manifested in such actions as the 1994 Peer Review Policy statement, the establishment of the Science Policy Council, the release of the Peer Review Handbook, and, most recently, in the policy requiring that all rules, planning, and analytic blueprints must specifically address and include consideration of peer review (Robertson, 1999). The continued success of the Peer Review process at EPA will only be ensured with continual commitment on the part of Senior managers to the Peer Review process in all appropriate aspects of the Agency's endeavors.

Another key to success in implementing the peer review process has been the involvement of the Office of Research and Development in the oversight role. ORD scientists have a good understanding of the importance of peer review in developing good scientific and technical products. ORD has provided effective support to the emergence of the Peer Review process within EPA through development and implementation of training, collection of data on products

and their review status, and evaluations of the appropriate level of reviews at other organizations. The development of the Peer Review Data Base can become a powerful tool to allow the continual assessment of whether all major EPA generated Science and Technology (S&T) and economics products are being reviewed by the proper mechanisms. In addition, it will be critically important for the Agency to continue audits of different offices to ensure that the peer reviews are being properly done on the variety of products generated by the Agency.

4.0 RESPONSE TO THE CHARGE

4.1 Is EPA peer reviewing the right products?

4.1.1 Are there sufficient criteria for deciding what to peer review?

Yes. The Science Policy Council Peer Review Handbook is an excellent guidance document and provides definitive criteria for deciding what to peer review. The rule of thumb is that all major scientific and technical work products which affect major Agency decisions must be peer reviewed, and when there is doubt the work product should be listed for peer review. Interpretative guidance is provided on what is and what is not a major product. Adequate descriptive criteria for each category are provided.

While the guidance is clear, some concern still remains regarding the process leading to the decision to peer review or not based on funding available and/or pressure to complete the work product due to timing constraints. There will always be some difficult decisions, but these are areas where the Agency must focus its attention in the future so that no major products escape an appropriate peer review. Every effort should be made to ensure that all major scientific and technical products are appropriately peer reviewed.

4.1.2 Is the information collected about projects sufficient to apply the criteria and to judge whether and where the peer review should take place?

To answer this question in the next phase of our review, RSAC would like to see representative examples of the forms or other procedures used to describe work products being considered for peer review, from more than one organization if they differ from organization to organization. RSAC would also like to review a sample of completed forms along with the justification for placing the candidate product on list B (products to be peer reviewed) or list C (products deemed minor or peer review is infeasible). RSAC notes that the criteria are sufficiently clear and simple so that every EPA organization should be able to apply them without an elaborate information-gathering process.

4.1.3 What information should be gathered on individual work products for managers of the peer review process [to] use to determine how best to conduct the peer review?

The most important tasks for the peer review managers are to write an appropriate charge and to select peer reviewers with proper expertise and independence (as described in section 1.4.8 of the Peer Review Handbook), either individually or through another agent such as the SAB or a peer review contractor. To do so, the managers must understand the scientific content of the product and what areas of the science are most likely to be weak or controversial. Such determinations will be easier the closer the product is to completion as a draft work product, but in most cases the peer review should be planned early in the process of work product

development. Because the peer review managers are located within the organizations developing the work products, they should already possess a relatively good understanding of the scientific, technical or economic issues addressed by the work product and the decisions they are intended to inform. To be sufficiently independent to manage the peer review effectively, however, they may not be (at least initially) fully familiar with the content of the work and may need to interview the product team to enhance their understanding. It may also be prudent to seek advice from outside the performing organization on who should be leading the effort and on who might be peer review panel candidates for the more important work products.

Specific types of information that might be valuable for organizing the peer review include:

- a) information on purpose of the project;
- b) information on the potential for regulatory use or rule making;
- c) information on the potential for the project to be used as a foundation for additional research or to be directly utilized;
- d) information on key scientific and technical findings.

4.1.4 Are the right products being peer reviewed?

The focus of the Peer Review Handbook developed by the Agency's Science Policy Council is to provide detailed guidance on conducting peer review of major scientific and technical products. The review of products is obviously important to ensure that the products are of acceptable quality. The handbook clearly defines and articulates the types of products that should be peer reviewed, and is an excellent guide to help managers select completed products for peer review and the appropriate peer review mechanisms.

However, the focus should not be limited to just end products of the scientific endeavor. Peer review should also be extended to the up-front review of scientific and technical planning products such as strategic plans, analytic blueprints, research plans, and goals documents. This is a practice followed by the Office of Research and Development as seen in the peer review of strategic plans and research strategies. While the Handbook does discuss peer input, it does not explicitly address the importance of peer review in the planning products and documents. This is an important omission in the handbook. An up-front peer review of these planning products will allow peer input prior to the conduct of the research and scientific undertaking and, therefore, can have a significant impact on the direction of the effort and the quality of the final product. It is in the planning process where changes can more easily be made as opposed to the peer review of the final products where there is more resistance to change, as well as more pressure to use the available information for timely decision making. RSAC recommends that future supplements and updates of the Handbook include the importance of conducting peer review of planning products and documents.

The following documents were provided by the Agency upon request from the Committee:

- a) Appendix C- June 1996 List. Products Peer Reviewed since 1991;
- b) Appendix D- June 1996 List. Candidate Products for Future Peer Review;
- c) Appendix C- June 1997 List. Products Peer Reviewed from 6/96 Through 5/97;
- d) Appendix D-1- June 1997 List. Candidate for Future Peer Review;
- e) Products Considered and Not Selected for Peer Review. Appendix D2 - Historical Data to be converted to List C.

They contain information on the product; region; program office; peer review leader; date of product completion; review mechanism; dates of initial entry, initiation and completion of the peer review, and receipt of comments; and comments relevant to the outcome of the process, including the rationale for proceeding or not with the peer review. The latter should contain the information needed to address this question of the charge by the RSAC. However, inclusion of the rationale for the eventual decision about peer review is not consistent.

Based on the titles of products, and the rationale (when included), it appears that the right products are being peer reviewed. However the determination of those products deemed minor or where peer review is infeasible (list C) is harder to judge. The information provided in these documents needs to be more complete in order for the Committee to fully answer this question. It is also important to the Agency that the process of decision about peer review be transparent both internally and externally. It is recommended that the Agency develop a list of categories based on those presented in Chapter 2 of the Peer Review Handbook (expanded, if needed), so that the rationale is clearly and systematically presented across all products. A code could be attached to each category. This would allow for direct referral to the Handbook, and can also facilitate and expedite the peer review decision process.

While all products listed as peer reviewed were appropriately designated, it is not clear if some of the products classified as “not for peer review” should have been peer reviewed. The RSAC cannot evaluate this issue at this time, but will revisit it during the next round of this review. Specific but representative case studies should be selected and evaluated in more detail as discussed in section 5 relative to the next phase of this review.

4.1.5 Do the products go to the right place for peer review?

Based on the documentation provided (see charge question 4.1.4) it appears that the products are directed to the right regions/offices/programs and to the appropriate type of peer review. Further clarification is needed about which specific entity at EPA takes the lead for peer review about products that cross multiple offices and programs.

4.2 Are the peer reviews conducted appropriately?

4.2.1 Does the process take the right steps to minimize conflicts of interest?

In general, Section 3.4 of the Handbook contains good guidance on issues related to conflict of interest for the peer reviewers. As indicated in that section of the Handbook, eliminating all conflicts of interest may be practically impossible and, further, may not be in the best interest of the Agency for obtaining a peer review of the best possible quality. RSAC notes that direct economic interest in the actions that might be taken on the basis of the product is not the only type of interest that could cause conflicts; most qualified candidates for peer review responsibilities will have taken some prior position that could be perceived to be a conflict. The RSAC therefore agrees with the Handbook that the important goal is achieving balance in the spectrum of biases represented in the review group. As with any other such endeavor, balance will remain to some extent in the eye of the beholder, and the peer review managers must strive to eliminate their own individual or organizational opinions from unduly influencing the judgment. Although the RSAC is not planning to investigate the overall balance in the selection of reviewers, it has no reason to suspect that EPA is not pursuing a prudent course.

There is concern with respect to conflict of interest with the Peer Review Leader. The Handbook states that the Peer Review Leader could be the Decision-maker (Section 1.4.4). The Decision-maker will often have a professional interest in the outcome of the review. An essential part of peer review as defined by the EPA is independence of the review from the person who has developed the product or overseen the development of the product. For example, journal publications are given great weight because the editorial review process is perceived to be independent. The person who is to use the product or someone who is subordinate to the Decision-maker is not clearly independent and has an intellectual stake in the product. Thus, although they may do an appropriate job of managing the peer review, there is the perception of possible conflict of interest that could potentially undermine the credibility of the process.

The role of sign-off upon completion of the review by the Peer Review Leader is not defined. Comparing peer review to quality assurance, one of the important aspects of the QA officer's responsibilities is to stop activity if there is a serious problem with implementation of the QA/QC program. Currently only the Decision-maker signs off at the end to indicate that the peer review is complete. It should be the Peer Review Leader's responsibility to determine if changes to the product have been satisfactorily addressed and to stop the product from moving forward if necessary. An independent review process has not been completed if there is not this possible outcome. It may be that the Decision-maker has to utilize the product without the Peer Review Leader sign-off, but then it should be acknowledged that the product has not been peer reviewed.

4.2.2 Does the process give proper attention to controversial and polar positions?

The Handbook adopts the general philosophy that people who have publically expressed specific views on an issue should be avoided. Depending on the issue, it may be better to utilize the approach generally used by the National Research Council and SAB to obtain balanced views.

The objective of a peer review is not necessarily to achieve consensus, but to determine if the scientific content in the product is credible. Obtaining disparate views may provide better insights into the criticisms that the product will face once it becomes public. The Handbook may be too conservative in its recommendations of avoiding controversy in the reviews, but such diversity may be useful in assessing if the product is completely addressing the relevant issues. Agreement on the scientific content provides more weight to the subsequent decisions based on the product, but if there are differences in understanding or interpretation of the scientific data, it is best to acknowledge them and provide a clear rationale for making particular choices. The product does not have to agree with all of the peer review comments. Peer reviewers can be wrong. The task of the Peer Review Leader is to make a professional judgement on what changes do or do not need to be made to the product. A diversity of views can be helpful in making such judgments.

4.2.3 Are the reviews set up appropriately to address the needs of the Agency?

The most recent changes in the Agency's peer review process were instituted because of persistent criticisms (e.g., in the NAS and GAO reports) that EPA's science was not sufficiently peer reviewed and therefore of questionable quality. The new process appears to be well suited to improve both EPA's scientific activities and the external world's perception of those activities. It should help in making the scientific products and the decisions based on them more credible and truly effective. Although the Agency cannot expect criticisms of its science to completely disappear, it probably will be better prepared to address such criticisms.

In a different sense, the flexibility of the guidelines in the Handbook is appropriate to address the need of the Agency to trade off multiple considerations (budgets, statutory or judicial deadlines, quality and credibility of the science) in deciding how much peer review to undertake and by whom.

The extent to which an individual product meets the Agency's needs can be made more explicit in the review process by including a charge question which addresses the product's ability to meet a well-defined Agency need.

4.3 Does EPA peer review all the science it uses (e.g., data submitted from parties outside the Agency)? How well does EPA capture which scientific components were peer reviewed and which were not?

RSAC has not yet been provided with documentation that would allow an "audit" of the products on lists A (peer review complete), B (candidate products to be peer reviewed) , and C (products to not be peer reviewed) against all the EPA activities that might be appropriate for peer review. Section 2.2 of the Peer Review Handbook is rather inclusive in its definitions of what products should be considered for peer review; if it is being followed, few scientific products should escape peer review. From anecdotal evidence, some of the program offices may not look very closely at the peer review status of science done for them under contracts and grants or submitted by interested parties (either regulated entities or the environmental community). It is

also not clear to what extent peer review is being applied to non-economic social science (e.g., risk communication studies) products.

The EPA should use peer-reviewed science as the basis for all actions and decisions. However, all non-EPA science cannot possibly be peer reviewed by the Agency. EPA must systematically determine if the science used by the Agency has been peer-reviewed. Science published in peer-reviewed journals is reviewed by the journal's reviewers. Science provided by other agencies/laboratories may have been subjected to peer review by that agency/laboratory. Section 2.4.5 (page 35) of the Peer Review Handbook requires EPA to conduct its own peer review even if the material being used has been previously peer reviewed. This is a very conservative requirement most appropriate in cases where EPA's application is novel or marginal to the purpose of the research product. In the instance of confident recognition of high-quality, non-Agency peer review, direct relevance of peer-reviewed science to EPA's needs, and/or non-controversial or relatively low significance decisions, the requirement to conduct additional EPA peer review should be placed on the Peer Review Manager. EPA should strive to determine if the science they are using has been peer reviewed. If it has not, the importance and significance of the science and/or the issue may be used to determine whether or not EPA should conduct its own peer review.

In addition to major science and technology products, social science research products can and should be subjected to the peer review process in a manner similar to natural science products. In addition, some products are policy analytic, in that they are not purely natural and social science-based but involve the application of policy and values. Peer review ensures that appropriate methods and procedures have been used, including an explicit treatment of assumptions and value judgments, adequate sensitivity analysis, and adequate treatment of uncertainty. For example, flawed decision-making on the implementation of environmental control technologies (which may include considerations and approaches that are nested in the social science framework) can result in a poor program even if the technological options are intrinsically effective. Thus, the explicit need to review major social science products (in addition to economic products), and policy analytic products should be added to the Peer Review Handbook.

4.4 Does the RSAC have additional comments/guidance for EPA?

The RSAC has several suggestions for strengthening the peer review process in the future. These involve expanding the scope of peer review to further enhance the Agency's scientific credibility and effectiveness at developing policies based on sound science.

The peer review process currently focuses on review of individual EPA products. RSAC encourages EPA to include evaluation of interagency and international products that are considered in support of environmental policy making in the US. Such work can be very valuable to EPA policy making, provided that it has been reviewed in the context of its use in support of EPA's decision-making.

Although the guidance provided (specifically, the Science Policy Council Handbook on Peer Review) emphasizes flexibility, it is highly structured and has some potential for becoming a bureaucratic hindrance to scientific activities at the Agency. Care must be taken to preserve flexibility and to avoid reviews that consume resources but do not necessarily contribute to the overall credibility of EPA policy making.

One way to help insure that peer review is as effective as possible is through periodic evaluation of how well activities under review are helping EPA achieve its goals and how well EPA is responding to peer review recommendations. This level of continued regular review of the overall peer review process and its impact could provide the opportunity to modify the review process to better meet Agency goals.

Credibility also will be enhanced by peer evaluation of the Agency as a leader in international as well as national scientific research and its application to policy making. This evaluation can assess current status of the Agency in this regard and the extent to which EPA is building leadership through programs that encourage high quality science and increased cooperation between EPA and scientists in other Agencies and around the world on important global issues.

Peer Review works best when both the reviewers and the reviewees are convinced that the goal and outcome of peer review activities will be better products and decisions. Unless the reviewees feel that their work will be well received and more effective, they will have little incentive to make the most of a peer review. Unless the peer reviewers feel that their advice will be considered and used as much as possible, they will be reluctant to spend the time and effort needed for a constructive review.

The peer review process described in the Peer Review Handbook is non-adversarial. RSAC agrees with this approach; the peer review process should not be viewed as punitive by the peer reviewers. If they perceive that peer review is a largely bureaucratic process that will consume their energies and delay the completion of their work without much real benefit, it will not likely be very effective. For the most part, the Handbook is consistent with a positive approach by both parties. However, RSAC sees some seeds of bureaucracy that could germinate and grow. Having the process managed by the Office of Research and Development could be perceived as an application of power rather than a collegial association. Emphasis on the documentation of the peer review process could grow into a form-driven bureaucratic and inefficient process. Section 3.6 of the Handbook seems to focus excessively on rules for the acquisition of peer review services, not on ways to ease the acquisition of those services. RSAC recommends that EPA take the necessary steps to keep the process from becoming inappropriately bureaucratic.

The RSAC also recommends that charges for peer reviews not become overly elaborate. The WTI charge seen in Appendix B, pages B-2 to B-10, appears to fall in that category. We have also seen charges that ask only very selected questions, sometimes dodging the crucial scientific issues. Every charge should have a final open-ended question similar to this one (#5).

The Handbook provides guidance requiring the reviewer to agree not to disclose draft work products to the public. While RSAC understands the evils that can come from release of a draft that might well change substantially, we note that any review by a FACA committee such as the SAB means that the draft being reviewed is accessible to the public. Some resolution of this conflict, or at least a discussion thereof, is needed.

There should be a requirement of completion of training before a person can be designated as a Peer Review Leader. Under current practice, EPA personnel cannot be project monitors without training. Peer review of the major science products is an important function within the Agency and should be recognized as such by requiring appropriate training before taking on such tasks.

RSAC concluded that all Agency documents should contain an information statement indicating whether or not the science in the document has been reviewed along with some description of the peer review processes used. The Peer Review Handbook does require documentation of the peer review processes and responses but there is not an explicit requirement for the information to be placed in the actual document that presents the results of the study. It is equally important to allow the reader of the document know if the information in report was not peer reviewed as well as the rationale for the decision not to peer review. The Agency should explore the implications for having a policy requiring all documents to include an information statement on the status of the peer review process for the product.

Past reviews of the EPA peer review process by outside groups (GAO, NAS) have indicated a few reoccurring problems: lack of understanding of what peer review is; uneven application of the guidance policy across the Agency in conducting peer reviews; inconsistent oversight mechanisms including the role of QA review; criteria used to opt out of peer review; tracking of all peer review projects; peer review of directed research; inconsistency in who selects and approves reviewers. The Science Policy Council Peer Review Handbook and associated EPA policies are aimed at correcting all of these deficiencies. Implementation is still a work-in-progress.

The Peer Review Data Base can become a very useful tool for assisting in the evaluation of the status and trends of the Agency's programs. As EPA develops additional data bases on those same programs, it should consider adding linkages to the Peer Review Database that would permit cross-referencing among multiple databases.

Looking ahead some additional emphasis could be given to the following issues;

- a) Training programs could further emphasize the need to consider peer review a part of the over-all process of conducting and completing research and science and technology products;
- b) Further consideration should be given to consistency in training across the Agency;

- c) Feedback on projects which were not peer reviewed could be enhanced.

5.0 NEXT STEPS

The review of EPA's peer review process is expected to be conducted over two to three years. This report is the product of the first meeting that launched the process. Thus, it was not possible to fully address all of the charge questions at this time. This section contains the charge questions for which further examination and review will be required. It is anticipated that a series of case studies will be developed laying out how selected Agency programs and products were developed; what the planning was for peer review; how the peer review was conducted; and how the Agency used the peer review advice.

5.1 Are the reviews and resulting advice timely?

RSAC was not provided with sufficient information to evaluate this question in depth during this review. Clearly, peer review will always add to the time needed to complete any work product, and the Agency has expressed concerns about the timeliness of certain SAB or NAS reviews in the past. Especially for external reviews, the timeliness of the review will always be, to some extent, in the hands of the reviewers themselves. RSAC does applaud the Handbook's call for an explicit review schedule that reflects a compromise between the Agency's need for closure and the reviewers' need for adequate time to deliberate.

In order to evaluate this charge question, data should be collected on the time required for the various peer review steps. In addition, the EPA groups affected by the product and its peer review need to provide an assessment of timeliness. Such a formal evaluation and reporting of timeliness provides data to help evaluate the overall value of the review process in the future.

5.2 Do the peer reviews make a difference?

The Peer Review Policy established on June 7, 1994 requires scientifically- and technically-based work products related to EPA decisions to be peer reviewed. For those work products intended to support the Agency's most important decisions, peer review is the procedure of choice. Therefore, to evaluate the impact of the peer review process, RSAC requests information on:

- a) The scientific and technical character of the work products;
- b) The scope and depth of the peer review to be conducted;
- c) The peer review results/recommendations generated;
- d) The use of peer review results in Agency decisions (e.g., how did peer review result in better decisions?).

RSAC needs to carefully examine several completed peer reviewed products, interview Agency Decision-makers and establish what types of products and peer reviews improved Agency decisions, which ones did not and why.

The Committee also needs information on completeness and comprehensiveness of the peer review. For example, if there were to be a risk assessment and EPA decision on the need for regulations of a solid waste stream, the questions to ask would be:

- a) Was peer review conducted for the quality, adequacy and completeness of the data developed and obtained from the literature for the risk assessments and Agency decisions?
- b) When was the peer review conducted?
- c) Did the peer reviewers have adequate time to conduct an in-depth review?
- d) How were the peer review results utilized to improve EPA 's decision?

In principle, peer reviews should be making a difference in the sense that more sound science is being and will be used in policy making as a result of the peer review process. However, in order to be able to answer this question, the EPA needs a mechanism for monitoring the effectiveness of its peer review program.

5.3 To what extent are the review comments responded to and acted on by the Program Office/Region?

The SAB always requests feedback on how its findings and recommendations were incorporated into the work product, and many of the Program Offices are quite conscientious about providing such feedback. Sometimes, however, SAB is still left without much sense of how its review made a difference. This limitation is likely to extend to other types of peer review. Whether the reviews are being ignored or being heeded without sufficient documentation is not certain. Case studies will be used in the next phase of this review so that the impacts of the Agency peer review processes can be evaluated. The focus will be on assessing the response and actions of the program offices/regions to the peer review process. Information on the case studies will be needed on what peer review comments were made and how the Agency responded to these comments.

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