

MEMORANDUM

SUBJECT: EPA's Selection of Peer Reviewers
Report 1999-P-217

FROM: Elissa R. Karpf
Deputy Assistant Inspector General
for External Audits

TO: Assistant Administrators
Regional Administrators

The attached report describes our review of the policies and procedures for ensuring the independence of those who review EPA scientific and/or technical work products. We found that the policy and procedures of the Science Advisory Board and Science Advisory Panel were effective and being followed. However, our sample identified instances where peer review leaders in Agency program offices and contractors did not effectively attempt to determine whether conditions existed which may preclude an independent review. This report contains recommendations we believe will strengthen the Agency's selection process.

The findings and corrective actions described in this report represent the opinion of the Office of Inspector General. Final determinations on matters discussed in this report will be made by EPA managers in accordance with established audit resolution procedures. Accordingly, the findings in this report are not binding upon EPA in any enforcement proceedings brought by EPA or the Department of Justice.

ACTION REQUIRED

In responding to the draft report on behalf of the Assistant and Regional Administrators, the Assistant Administrator for Research and Development described corrective actions with specific milestones for each of our recommendations. Accordingly, we have closed this report on issuance and no further response is necessary.

We wish to thank all those involved for their cooperation and assistance.

Should you or your staff have any questions, please contact John T. Walsh, Divisional Inspector General for Audit, Headquarters Audit Division, on (202) 260-4959, or Cathy Jenson, of my staff, on (202) 260-8207.

Attachment

BACKGROUND

Peer review is a documented critical review of an Agency's major scientific and/or technical work product conducted by qualified individuals (or organizations) who are independent of those who performed the work, but who are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. More specifically, the peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to a specific major scientific and/or technical work product and of the supporting documentation.

In June 1994, the Administrator reaffirmed the central role of peer review, and instituted an Agency-wide implementation program. However, the General Accounting Office (GAO) reported in September 1996 that although EPA had made progress, program implementation remained uneven. The GAO attributed the unevenness to: (1) confusion among Agency staff and management about what a peer review is, what its significance and benefits are, and how and when it should be conducted, and (2) inadequate accountability and oversight mechanisms to ensure that all relevant products are properly peer reviewed. In response, the Administrator issued the Agency's Peer Review Handbook (Handbook) in February 1998. The Handbook complements the 1994 Policy and provides a format that offers all users a focused reference on peer review issues. As a point of reference, the Handbook assists the Agency in meeting its goals of enhancing the quality and credibility of Agency decisions through peer review of the underlying scientific and technical work products. To assist in implementing the Handbook, ORD, in August 1998, supplied the peer review coordinators in program offices with training materials to instruct management and peer review leaders in the Handbook's policies and procedures. Program offices and Regions provided Handbook training to staff and managers from fall 1998 through summer 1999.

EPA performs the administrative task of selecting peer reviewers in three basic ways: (1) via a contract, by either a work assignment under an existing contract or awarding a new contract, (2) by Federal advisory committees such as EPA's Science Advisory Board (SAB) and Science Advisory Panel (SAP), or (3) by peer review leaders from program offices.

OBJECTIVES, SCOPE AND METHODOLOGY

During our fieldwork, GAO was conducting a review which focused on what work products are selected for peer review and why. GAO's report entitled "Federal Research - Peer Review Practices at Federal Science Agencies Vary (March 1999)"

reported the results of their review of 12 federal agencies, including their peer review policies and quality assurance processes used in conducting peer reviews of their scientific products. Therefore, to avoid duplication of effort, our survey focused solely on EPA's procedures to identify conditions which would prevent or limit a reviewer from providing an objective review. We did not evaluate how effective the peer reviews were.

Our objectives were to address the following questions:

- Are management's controls sufficient to select independent peer reviewers?
- Does the selection of peer reviewers adhere to both EPA policy and Federal Acquisition Regulation (FAR) requirements relating to inherently governmental functions, personal services, and conflict of interest (COI)?
- Can EPA make improvements to the process?

To accomplish our survey objectives, we reviewed relevant documents and discussed current procedures for the selection of peer reviewers with officials from the SAB and SAP; the Office of Research and Development (ORD); the Office of Air and Radiation (OAR); the Office of Policy (OP); the Office of Prevention, Pesticides, and Toxic Substances (OPPTS); the Office of Solid Waste and Emergency Response (OSWER); the Office of Water (OW); and EPA Region 5 (Chicago). We also contacted certain peer reviewers to discuss their participation on peer review panels.

We selected a sample of 32 work products from ORD's 1997 list of 338 work products which received an external peer review in 1997 or were scheduled to receive an external peer review in 1998. Of the 32 work products peer reviewed: 14 were by reviewers selected by EPA program offices, 12 by reviewers selected by contractors, and 6 by panel members within the SAB and SAP.

To determine whether management controls were sufficient to select independent peer reviewers, we reviewed EPA, contractor and SAB and SAP procedures for: (1) determining if conditions existed which might prevent a potential peer reviewer from providing an objective review and (2) resolving concerns regarding a potential reviewer's independence. We reviewed Office of Government Ethics (OGE) Form 450 (Executive Branch Financial Disclosure Report) for panel members who performed peer reviews for the SAP on work products included in our sample. Our work relating to the Federal Managers' Financial Integrity Act (FMFIA) was limited to determining if any program offices' reports mentioned weaknesses in identifying independence concerns with potential peer reviewers. None of the FY 1998 FMFIA assurance letters for the program offices reviewed did so.

We assessed whether the Agency adhered to applicable EPA policy and FAR requirements relating to inherently governmental functions, personal services, and COI. To accomplish this, we reviewed contract documents and interviewed project officers (POs), work assignment managers (WAMs), and peer review panel members for the 12 work products in our sample in which the Agency used a contractor to select the peer reviewers. We inquired whether: (1) EPA staff asked peer reviewers to perform tasks other than those related to the peer review and (2) reviewers received instructions from contractor personnel, or directly from EPA staff. Receiving instructions directly from EPA staff would constitute a personal service relationship.

Finally, we checked EPA's automated grants and contract record systems to determine whether a peer reviewer for the cases sampled had a grant or contract with EPA during or close to the period he/she conducted the peer review. If so, we questioned contractor personnel, EPA project officers and peer review leaders on whether they made this information known to EPA. We did not formally assess the validity or reliability of the data and internal controls for the EPA automated systems accessed during our survey.

We performed this survey in accordance with the GAO's Government Auditing Standards, 1994 Revision. No other OIG reports have been issued on this subject.

We held an exit conference with ORD officials, who provided the Agency's consolidated response, on September 27, 1999. The Agency's comments, except for a section of editorial and other suggestions which are reflected in this report, are included as Appendix 4.

FINDINGS AND RECOMMENDATIONS

EFFORTS TO IDENTIFY INDEPENDENCE CONCERNS CAN BE IMPROVED

Part Three of the Handbook discusses management controls for selecting peer reviewers, whether conducted by EPA staff, the SAB and SAP or contractors. We found that while the SAB and SAP were implementing sufficient management controls, peer review leaders in program offices and EPA contractor staff did not always attempt to determine whether a potential conflict might exist. Contract documents did not always include specific provisions to ensure that contractors identified and addressed independence concerns. Finally, we believe that the process will be enhanced if peer review leaders and contractors specifically inquire whether candidates have had a financial relationship with EPA and by documenting the results of efforts to identify and resolve independence concerns.

While we believe improvements can be made, we found no evidence of personal service relationships between EPA and contractor staff, or of contractors performing inherently governmental work.

Controls Working for Reviewers Selected by the SAB and SAP

We found sufficient management controls in place with the six sampled peer reviews in which the SAB and SAP selected the sitting panel members. Both the SAB and SAP conduct formal, public external reviews of EPA work products, which represent a key scientific peer review mechanism available to the Agency in implementing the Peer Review Policy. Peer reviews carried out by formal Federal advisory committees (such as the SAB and SAP) are subject to the Federal Advisory Committee Act (FACA), which imposes open meeting, balanced membership, and chartering requirements before the Agency establishes or utilizes an advisory committee for advice or recommendations.

We noted that both Federal advisory committees strive to remain in compliance with FACA requirements, maintain an objective, arms-length relationship with the Agency and its work products, and place a major emphasis on avoiding any perceived or actual conflicts of interest. For instance, both advisory committees perform a detailed screening of potential panel members, in part to identify any potential independence questions. Also, panel members usually only serve a two-year term which allows rotation on the panel and helps to avoid biased reviews from members based on repetitiveness. Officials from both advisory committees also informed us that each sitting panel member is subject to federal conflict of interest laws, and required to complete OGE Form 450 (Executive Branch Confidential Financial Disclosure Report).

We met with SAP officials in OPPTS and found they maintained OGE Form 450s for each of the panel members selected for review of work products included in our sample. We did not identify any matters of concern from our review of these reports. Also, an SAB official stated that, as a matter of Board policy, panel members give verbal disclosure of any potential independence issues during FACA meetings. Types of information divulged include organizational affiliation, their field of specialization, their public pronouncement on any issue relevant to the matter before the Board, their funding from EPA, or any other issues an individual may wish to present to allow other panel members to judge their linkage to a particular issue.

Program Offices Did Not Always Address Independence Questions with Review Candidates

Part 3.4.6 of the Handbook provides that before finalizing the selection of reviewers, the peer review leader should ask potential reviewers if they have any real or perceived conflicts of interest. As presented in Appendix 1, six of the 14 peer review leaders in program offices did not attempt to determine whether circumstances existed which could prevent or limit the candidate from conducting an independent review. The six situations involved three reviews conducted by the Office of Policy, two by Region 5, and one by OW. Four other peer review leaders discounted the issue given the nature of the product, but did not document his/her rationale or include the information as part of the peer review files, as required under Part 3.4.6 of the Handbook. Such conditions may be attributed to the fact that most of the peer review leaders we interviewed were performing in that capacity for the first time, without the benefit of the 1998 Handbook guidance for selecting peer reviewers and subsequent training.

In our view, program offices can provide for objective peer reviews if management emphasizes the need to identify and resolve independence concerns and peer review leaders ask potential candidates whether conditions exist which may limit or prevent the candidates from providing an objective analysis. If such conditions exist, the Agency has the option of (1) selecting another candidate or (2) selecting other panel members so that the panel, taken as a whole, can provide an objective review.

Some offices have already held training sessions. However, according to an Agency official, the training materials do not particularly emphasize the importance of the independence issue or contain a relevant discussion of how to identify and resolve independence concerns. ORD should revise its training materials to provide a broader discussion of the independence issue. Peer review coordinators, with the support of the Assistant Administrators in program offices, need to require that management and peer review leaders attend training on the revised material, or, if they have already held the training, to discuss the revised ORD material to ensure a clear understanding.

Process to Select Candidates Via Contractors Can Be Strengthened

For the twelve cases reviewed involving contractors, we found no evidence of (1) personal service relationships between EPA and contractor staff or (2) contractors performing work considered inherently governmental. However, for two cases in OAR, neither the basic contract and work assignment issued by EPA, nor the contractor's work plan specifically addressed identifying independence concerns. The peer review leaders could not tell us what the contractor did to determine the independence of peer review candidates for these two cases. Moreover, in four other cases, EPA's selection decision did not take into account pre-existing financial relationships between EPA and peer reviewers.

Part 1.4.8 of the Handbook indicates that peer reviewers should be free of real or perceived independence concerns, and if there are concerns, they should fully identify them to ensure a credible review. While Parts 3.6.5 and 3.6.6 discuss procedures for contracting for peer review services, the Handbook does not specifically require contractors to document their efforts to identify and resolve independence concerns and submit this information to EPA. To provide for a more effective process, we are recommending that ORD issue supplemental guidance to the Handbook to help identify and resolve independence concerns.

No Concerns Identified Regarding Personal Services and Inherently Governmental Functions

Our review of contract documents and interviews with EPA project officers, Agency work assignment managers, and selected peer review panel members for the twelve contracts included in our sample did not identify concerns of personal service relationships between EPA staff and peer reviewers. In addition, the peer reviewers we spoke with did not indicate EPA personnel had requested that they provide any service other than performing their peer review duties.

Contract Documents Should Include Provisions to Ensure that Contractors Address Independence Concerns

As shown in Appendix 2, for two cases reviewed, neither the basic contract nor the work assignments contained specific provisions requiring contractors to ensure the independence of peer review candidates. For these two cases and for another case where the work assignment mentioned the contractor's responsibility for determining the independence of subcontractors, the contractor's work plans did not discuss how they would inquire about the independence of candidates prior to their participation as peer reviewer. When we questioned EPA personnel (the appropriate peer review leader, work assignment manager, and project officer) how they confirmed whether

contractors addressed the independence of peer review candidates in these instances, we were told that they either: (1) relied on the overall conflict of interest statement in the basic contract; or, (2) no confirmation was done since it was not required in the work assignment. Thus, for these three cases, EPA personnel could not demonstrate that the contractor effectively pursued the independence issue with potential peer review candidates.

We believe EPA program offices should ensure that contract documents (the basic contract, work assignments and work plans) consistently include specific provisions for contractors to address independence concerns with peer review candidates. Furthermore, contractors should be required to (1) describe how this will be done in the work plan, and (2) document the results for retention in the peer review record maintained by program offices.

Program Offices Should Document Actions to Identify and Resolve Financial Independence Concerns

When a potential peer reviewer holds a grant or contract with the EPA, he/she may not be able to render impartial assistance or advice. A key factor to be considered is the relationship between the grant/contract work and the product to be peer reviewed. However, the Handbook does not specifically require EPA personnel or contractors to determine whether candidates had, or have, a grant or contract with EPA. Agency officials responsible for peer reviews should be aware of such situations and determine the degree to which the nature of the grant or contract relates to the subject matter of the peer review. In accordance with Part 3.4.5 of the Handbook, where there is a close relationship, selection officials should consult with EPA's Office of General Counsel (OGC). OGC should determine if the relationship constitutes an independence concern that is so direct and substantial as to rule out a particular expert. If it is not deemed to be a significant independence concern, the peer review leader should ensure that the financial relationship is properly disclosed and documented, and the panel as a whole has appropriate balance.

Our analysis of data obtained from the Agency's Grants Information and Control System (GICS) for the sampled peer reviews revealed five cases (see Appendix 3) where reviewers held grants with the Agency at the time they were selected as peer reviewers. Four of the cases involved selections made by three EPA contractors working for OSWER and OW. We discussed this issue with personnel for two of the three contractors who could recall discussing independence issues with peer review candidates, but could not specifically recall asking candidates whether they had a grant or contract with the Agency nor did they document the results of their oral discussions for retention in the peer review files. In reviewing the grants awarded to the peer review candidates, we concluded that the nature of the grants were not closely related

to the applicable peer review. Although we did not identify any questionable selections, we believe EPA's process will be enhanced if EPA and contractors consistently inquire whether peer review candidates have had any financial relationship with EPA.

The fifth case we identified involved a selection made by a peer review leader within EPA's Office of Policy, who stated that he was aware of the candidate's grant with the Agency at the time of selection. Our review of grant files confirmed that the grant held by the peer reviewer was substantially similar in nature to the scope of the peer review performed. We were told the candidate was selected because she was one of only a few remaining candidates who had not assisted the Agency in preparing the work product. We did not find any concern with the other two peer reviewers selected to this particular review panel. Thus, the panel as a whole appeared to have sufficient balance.

We also checked EPA contract records to determine if the selected peer reviewers for our sampled cases held a contract with EPA. We noted only one instance where the peer reviewer's organization, a large university, held a contract with the Agency. We did not find this situation to be of concern.

RECOMMENDATIONS

We recommend that the Assistant Administrator of the Office of Research and Development:

- 1-1 Issue supplemental guidance to the Handbook which:
 - directs peer review leaders in program offices, or contractors working for them, to inquire whether peer review candidates have had a financial relationship with EPA; and
 - specifies that contract documents require contractors to provide EPA a summary of the work performed to identify and resolve independence concerns with peer review candidates.
- 1-2 In accordance with supplemental guidance, revise or supplement peer review training materials to provide a broader discussion of identifying and resolving independence concerns with peer review candidates. The revised materials should discuss the need to determine whether a candidate has had a grant or contract so closely related to the peer review that another candidate should be selected or other safeguards taken.

- 1-3 Provide the revised or supplemental training materials on the independence issue to peer review coordinators.

We recommend that the Assistant Administrators and Regional Administrators:

- 2-1 Direct their program's peer review coordinators to instruct managers and peer review leaders in the revised training materials.
- 2-2 Require that the peer review leaders document, in the peer review files, their efforts, or the efforts of contractors, to identify and resolve concerns with the independence of peer reviewers.

ORD Comments and OIG Evaluation

On September 2, 1999, the Assistant Administrator for Research and Development (AA/ORD) issued a Memorandum of Response to our draft report which included a proposed corrective action plan to our draft recommendations. The response represented consolidated comments received from Assistant and Regional Administrators. The AA/ORD stated that, in general, the Agency found the draft report to be reasonable and concurred with most of the recommendations. However the AA/ORD stressed three points: (1) conflict-of-interest encompasses a wide variety of factors which may prevent an independent review and is not limited to financial issues, such as whether a peer review candidate has had a grant or contract with EPA; (2) checking EPA's automated grant and contract information systems, as the OIG recommended in its draft report, would not be of significant benefit because the system contains limited information on grantee and contractor personnel; and (3) ORD believes that the draft report recommendations can be addressed by issuing a guidance document supplementing the Handbook, rather than revising the Handbook itself. ORD's proposed actions are described on page 19.

OIG Evaluation

We agree there are several ways an individual may have a conflict of interest (with financial being only one of them), and that peer reviewers should disclose all financial dealings that relate to the subject of the review. We also recognize that having a grant or contract with EPA would not necessarily disqualify a potential candidate. Our concern, as we found in our sample, is that a candidate may not always disclose a financial relationship with EPA unless specifically asked to do so.

Concerning EPA's grant and contract information systems, we were able to

identify four situations where a reviewer had a financial relationship with the Agency and that information was not known by the Agency during the selection process. Accordingly, we considered our draft report recommendation to be a low-cost, easy way to assist the selection process. In its response, ORD requested that the concern about financial relationships be handled by requiring peer review leaders and contractors to clearly document, on a peer review specific basis, how they determined whether any financial relationships exist, and if relationships are found, how they were evaluated to ensure that they do not impair the independence of the review. In accord with ORD's proposed corrective action, we revised our report to recommend 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.

We also agree that issuing supplemental guidance, rather than revising the Handbook, will be an effective way to address our concerns. We have revised the final report recommendations accordingly.

Finally, where necessary, we incorporated changes to specific ORD comments (not included in Appendix 4, but available in our working papers) to improve the overall quality of the report. Based on ORD's Corrective Actions Plan included with its response, we believe that the planned actions will improve the Agency's overall process for selecting peer reviewers.

OTHER ISSUES

The ORD listing we used to make our sample selections represented (as of June 1997) candidate work products to be peer reviewed in 1997 and scheduled for review in 1998. In working with this information, we found that data was not always accurate, especially actual (not estimated) dates indicating when EPA program offices had received peer reviewer comments and when a peer review was initiated. For example, the listing included dates which showed that program offices had received reviewer comments, even though a peer review panel had yet to be selected to perform a peer review. In addition, the listing included dates indicating that peer reviews had been initiated, when no peer review activity had begun for a particular work product.

We discussed this issue with the Director of ORD's Quality Assurance Division (QAD), who is responsible for maintaining ORD's database and inquired about controls for ensuring the accuracy of data. We were informed that ORD periodically requests information from program and regional offices concerning EPA work products that: (1) are future candidates for peer review, (2) have already been peer reviewed, and (3) are not scheduled for peer reviewed. In addition, the reports should, among other things, provide an accurate account of the date the peer review was initiated and the

date peer review comments were received from the reviewer. We were told that the data is only as accurate as the information provided to ORD by the program and regional offices, who are responsible for ensuring the accuracy of the data they report. The Director indicated that these reports are compiled by peer review coordinators and peer review leaders, and signed at the divisional and regional levels which should provide a degree of assurance about the quality of the data being presented. She added that ORD's Office of Science Policy reviews submitted reports for completeness with regards to the products listed, the selection of the appropriate peer review mechanism, and to evaluate if products are listed in the right categories.

A new peer review database became operational in July 1999. The new data base will report similar information tracked under the old data base system, and enable users to track the current status of a work product, make appropriate forms available for reporting information, and include the capability of downloading report files submitted by regions and program offices. Some peer review coordinators indicated that past data discrepancies could be attributable to unclear definitions for various reportable categories. We were told that the definitions would be clarified for the new system.

We did not conduct an evaluation of existing or planned controls over data quality for peer review information and are simply raising this issue for consideration by those involved. We believe sufficient management controls must be implemented at both the program and regional levels to ensure the accuracy and reliability of the data to be recorded in the new database. Given past problems, ORD may want to spot check information reported to it until ORD is assured that accurate and timely data is being submitted. An accurate reliable information system is essential for managing and reporting on the peer review process.

EPA's Selection of Peer Reviewers

Appendix 1
Page 1 of 1

Results of OIG Analysis of Selections Made by Program Office Personnel

<u>AA'ship/ Region</u>	<u>Work Product</u>	<u>Experience as Peer Review Leader/Training on Selecting Peer Reviews</u>	<u>Were Independence Questions Addressed with Peer Review Candidates?</u>
OP	Center for Environmental Information	First time/none	no
OP	Environmental Regulations and Small Plants	First time/none	no
OP	Wise Rule Tools	First time/none	COI was discounted given the nature of the document
OP	Pricing Residential Waste Management Services	Past experience/none	no
OPPTS	Evaporation of Pure Liquids from Open Surfaces	First time/none	COI was discounted given the nature of the document
OPPTS	Environmental Life Cycle	First time/none	yes
OSWER	Risk Management Model Plan: Warehouses	First Time/previous	yes
OSWER	Wastech Monograph Sets	Past experience/none	yes
OW	The Assessment of Solar Aquatics	First time/none	no
OW	Guidance on Preventing Impacts Due to Run-off	Past experience/previous	COI was discounted given the nature of the document
OW	Information Management Support for Watersheds	Past experience/none	COI was discounted given the nature of the document
OW	Environmental Impact from Separate Sewer Overflow	First time/none	yes
Region 5	Integrated Atmospheric Deposition Network	First time/none	no
Region 5	Lake Michigan Mass Balance	First time/previous	no

Summary

The six examples where peer review leaders in program offices did not attempt to address independence concerns with peer review candidates involved three by OP, two by Region 5, and one by OW. Four other peer review leaders discounted addressing peer reviewer independence given the nature of the work product. For each of the cases identified, we noted that the peer review leader did not document his or her rationale for not addressing independence in the peer review file.

OIG Analysis of Sample Cases Involving Contractors

<u>AA' ship</u>	<u>Contract/Work Assignment No.</u>	<u>Did the Basic Contract or Work Assignment Specifically Require Contractors to Ensure Peer Reviewer Independence?</u>	<u>Did the Contractor's Work Plan Discuss How They Would Inquire of Independence?</u>	<u>Manner by which the Agency confirmed that the contractor addressed conflict of interest with peer review candidates</u>
OAR	68D98092/1-01	no	no	Relied on standard COI statement in basic contract
OAR	68D20160/4-107	yes	yes	Certification statement
OAR	68D30033/II-55	no	no	No confirmation was done since it was not required in work assignment
OPPTS	68W60022/2-30	yes	yes	Certification statement
OPPTS	68D50012/2-25	yes	yes	Certification statement
OPPTS	68D50012/2-33	yes	yes	Certification statement
ORD	68C60041/ 0-8	yes	yes	Certification statement
OSWER	68W40040/2-23	yes	yes	Certification statement
OSWER	68W40042/3-40	yes	no	Relied on standard COI statement in basic contract
OSWER	68W50057/ 320	yes	yes	Certification statement
OW	68C70002/B-33	yes	yes	Certification statement
OW	68C70002/B-30	yes	yes	Certification statement

Summary

For two cases reviewed (see "no" in column three), neither the basic contract nor the work assignments specifically required contractors to ensure the independence of peer review candidates. For these two cases and for another case where the basic contract mentioned the contractors responsibility for determining the independence of subcontractors, the contractors' work plans did not discuss how they would inquire about the independence of candidates prior to their participation as peer reviewer (see "no" in column four).

Data Obtained from the Agency's Grants Information and Control System (GICS)
for the Five Sampled Cases Where Peer Reviewers Held A Grant With the Agency

<u>AA' ship</u>	<u>Grant No./Description</u>	<u>Period of Performance</u>	<u>Work Product</u>	<u>Date of Peer Review</u>
OP	CR822927010 (Unit Based Pricing of Residential Waste)	9/01/94 - 8/31/97	Pricing Residential Waste Services	July 1997
*1. OSWER *2. OW	CR821050010 (Remediation of Metal Contaminated Soil)	9/15/94 - 9/14/99	1. Silver Study 2. Criteria for Tributyltin	1.Aug. 1997 2. May 1997
OSWER	CX825522010 (Alternative Approach for Streamlining Local Pretreatment Limits)	7/01/97 - 12/31/99	Silver Study	August 1997
OSWER	R826297010 (Federal Demonstration Partnership)	12/15/97- 12/14/00	Silver Study	August 1997

* - The same peer reviewer was selected to review both work products.

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

OFFICE OF
RESEARCH AND DEVELOPMENT

September 2, 1999

MEMORANDUM

SUBJECT: Response to OIG Draft Survey Report - EPA's Selection of Peer Reviewers, E1JBB8-11-0019

FROM: Norine E. Noonan /s/
Assistant Administrator (8101R)

TO: Elissa R. Karpf
Deputy Assistant Inspector General for External Audits (2421)

PURPOSE

This memorandum responds to the Office of the Inspector General's (OIG) Draft Survey Report of EPA's Selection of Peer Reviewers, E1JBB8-11-0019, dated July 20, 1999.

BACKGROUND/DISCUSSION

In general, we find the draft report reasonable and we concur with most of the recommendations. The draft report was distributed to Assistant and Regional Administrators; this memorandum consolidates the comments received. As a result of the Agency-wide review, there are a few points which we feel still require additional discussion.

1. Independence of review versus financial conflict of interest. The draft report discusses these two issues, sometimes appearing to use the terms interchangeably. There are several ways in which an individual may have a conflict of interest – financial is only one of them. The report seems to imply that having a financial agreement with the Agency, in the same, or a different area, is a conflict and may not allow an individual to provide independent advice. Peer reviewers must disclose all financial dealings that relate to the subject of the review, regardless of whether the financial dealings are with the Agency or another entity. This information, along with publications, public statements, etc., is reviewed before a decision is made about selecting the reviewer. It is important that the role of financial relationships with the Agency not be over stressed in comparison to the need for thorough review of the potential peer reviewer's past and ongoing work history.

2. Use of automated grant and contract information systems to determine whether a potential peer reviewer has had a financial relationship with EPA. The Peer Review Handbook contains extensive discussion on the requirements for ensuring that peer reviewers are free of conflict of interest and can provide independent advice to the Agency. As noted above, financial relationships are but one of the concerns in planning and conducting peer reviews. For level-of-effort or other large, multi-task contracts, the requirements of the EPA Acquisition Regulations (EPAAR) are quite clear in defining a contractor's responsibilities for ensuring that employees (direct and subcontractors) have no conflict of interest for the particular tasks they are undertaking. In the case of

Appendix 4
Page 2 of 3

individual peer reviewers who are hired using simplified procurement procedures specifically to conduct peer reviews, a statement certifying that the individual has no conflict of interest is required as part of the procurement documentation. The Agency does not have information on all the employees of contractors/grantees who might be considered as potential peer reviewers; the existing systems may contain project managers, principle investigators, and limited numbers of key staff for current financial agreements, but there are no records of work conducted through expired or closed agreements. In addition to concerns about the completeness and currency of staff listings in the information systems, the description of the work to be performed under the contract or grant is very limited and is likely to be insufficient to determine whether the product to be peer reviewed is, in some way related. Financial dealings with the Agency should be determined and evaluated as part of the selection process for peer reviewers; the contents and structures of the Agency's existing data bases do not support this proposed use. We request that the concern about financial relationships be handled by requiring peer review leaders and contractors to clearly document, on a peer review specific basis, how they determined whether any financial relationships exist, and if relationships are found, how they were evaluated to ensure that they do not impair the independence of the review. We believe that Recommendation 3-1 should be removed; our proposed corrective action plan presents an approach that we believe will satisfactorily address the issue. **(See note below)**

3. Need to revise the Peer Review Handbook at this time to reflect report's recommendations. There are a number of issues regarding instruction on the evaluation and documentation of potential conflicts of interest raised in the draft report. The Peer Review Handbook was issued in 1998, and reporting on peer reviews conducted since issuance of the Handbook is underway. Once the reports on peer review activities are received in September 1999, an evaluation of the reports, on-site reviews of files supporting the reports, and interviews with peer review leaders, coordinators and managers will be conducted to determine whether the Handbook has been effective in providing consistent guidance on conducting peer reviews. After the evaluation is completed, clarifications or supplements to the Handbook may be needed. We prefer to address the issues raised by the draft report in a supplement to the Handbook; the supplement would be issued in a more timely fashion versus waiting for the results of the Agency-wide evaluation, as noted in our proposed corrective action plan.

We have a number of additional comments which, if addressed, will improve the quality of the report. These detailed comments are attached and speak to the primary report findings and recommendations.

We appreciate the opportunity to respond to this draft report. We believe that your attention to the issues identified in the report will help to improve the selection process of peer reviewers. Attached is the Agency's proposed corrective action plan. Should your staff have any questions, or require additional information, please contact Nancy Wentworth on 202-564-6830 or Cheryl Varkalis on 202-564-6688.

Attachments:

1. Consolidated Comments
2. Corrective Action Plan

cc: Assistant Administrators
Regional Administrators
Peer Review Coordinators

(OIG note: We deleted recommendations 3-1 and 3-2 in our draft report but expanded draft report recommendation 1-3 to address our concern. Draft report recommendation 1-3 appears as recommendation 1-1 in the final report.)

EPA's Selection of Peer Reviewers

Appendix 4
Page 3 of 3

Proposed Corrective Action Plan to OIG Draft Survey Report

Rec. #	Draft Report Recommendation	Corrective Action	Action Official	Due Date
*1-1	Revise or supplement peer review training materials to provide a broader discussion of identifying and resolving independence concerns with peer review candidates. The revised materials should discuss the need to determine whether a candidate has had or has a grant or contract so closely related to the peer review that another candidate should be selected or other safeguards taken.	EPA will develop supplemental training materials (in conjunction with the memorandum noted in Recommendation 1-3) to address OIG's concerns on review and documentation of independence and conflict-of-interest of peer reviewers.	AA/ORD	3/2000
*1-2	Provide the revised or supplemental training materials on the independence issue to peer review coordinators.	The supplemental training material will be provided in electronic form to peer review coordinators.	AA/ORD	3/2000
Rec. #	Draft Report Recommendation	Corrective Action	Action Official	Due Date
*1-3	Revise the <u>Handbook</u> to specify that Agency contract documents require contractors to provide EPA a summary of work performed to identify and resolve independence concerns with peer review candidates.	ORD will issue a clarifying memorandum to be used in conjunction with the <u>Peer Review Handbook</u> . The memorandum will remind peer review leaders to include a requirement for documentation of their actions regarding these concerns in the work assignments that support peer review.	AA/ORD	3/2000
2-1	Direct their program's peer review coordinators to instruct managers and peer review leaders in the revised training materials.	Senior managers will direct their peer review coordinators to provide the training material (Recommendation 1-2) to appropriate staff.	AAs/RAs	5/2000
2-2	Require that the peer review leaders document, in the peer review files, their efforts, or the efforts of contractors, to identify and resolve concerns with the independence of peer reviewers.	The memorandum noted in Recommendation 1-3 above will include discussion on the record-keeping requirements for this information.	AAs/RAs	3/2000
#3-1	Establish a mechanism for use by peer review leaders and/or program office personnel that would allow them to easily check EPA's information systems for grants and contracts prior to selection to determine if candidates have, or had, a financial relationship with EPA for similar work.	The Agency will continue to rely on existing contractual conflict of interest requirements. However, the memorandum noted in Recommendation 1-3 will include requirements for documenting procedures used to determine if potential conflicts exist and the results of any discovery/resolution of conflicts that are found.	AA/ORD	3/2000
#3-2	Maintain documentation of the work performed above in the peer review file.	The memorandum noted in Recommendation 1-3 above will include discussion on the record-keeping requirements for the information.	AA's/RA's	3/2000

Legend

* - Draft report recommendations 1-1,1-2 and 1-3 are revised as reflected on page 10. The Agency's proposed actions should effectively address the OIG's revised recommendations.

- Draft report recommendations 3-1 and 3-2 have been deleted from the final report.

Distribution List

General Counsel, Office of General Counsel (2310)
Director, Quality Assurance Division (ORD/National Center for Environmental Research
and Quality Assurance (8724R)
Audit Follow-up Coordinator (OARM) 3101
Audit Follow-up Coordinator (OAR) 6101
Audit Follow-up Coordinator (OECA) 2201
Audit Follow-up Coordinator (OP) 2111
Audit Follow-up Coordinator (OPPTS) 7101
Audit Follow-up Coordinator (ORD) 8101
Audit Follow-up Coordinator (OSWER) 5101
Audit Follow-up Coordinator (OW) 4101
Audit Follow-up Coordinator, Region 1
Audit Follow-up Coordinator, Region 2
Audit Follow-up Coordinator, Region 3
Audit Follow-up Coordinator, Region 4
Audit Follow-up Coordinator, Region 5
Audit Follow-up Coordinator, Region 6
Audit Follow-up Coordinator, Region 7
Audit Follow-up Coordinator, Region 8
Audit Follow-up Coordinator, Region 9
Audit Follow-up Coordinator, Region 10