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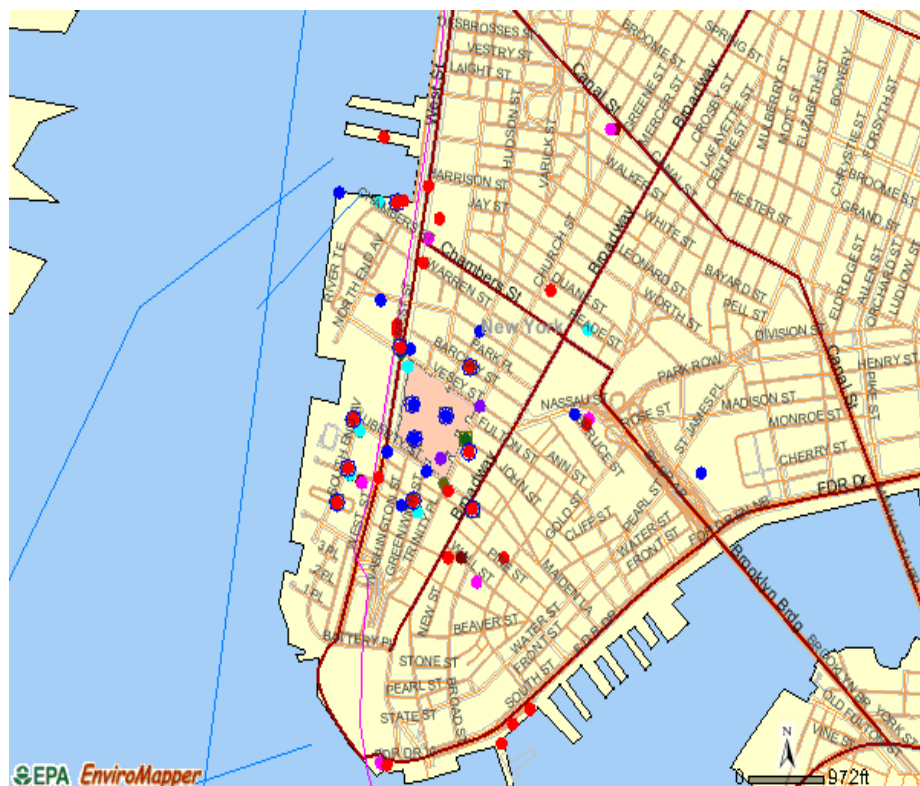
Catalyst for Improving the Environment

Special Report

Review of Conflict of Interest Allegations Pertaining to the Peer Review of EPA's Draft Report, "Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster"

Report No. 2005-S-00003

November 4, 2004



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Abbreviations:

COI	Conflict of Interest
EPA	Environmental Protection Agency
FAR	Federal Acquisition Regulation
GAO	Government Accountability Office (formerly General Accounting Office)
NCEA	National Center for Environmental Assessment
NCP	National Contingency Plan
OIG	Office of Inspector General
SAB	Science Advisory Board
WTC	World Trade Center

Cover photo: EPA map of ambient air monitoring locations in lower Manhattan; developed with EPA's EnviroMapper. Source: <http://www.epa.gov/wtc/em/>



At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We performed this special review to (a) determine the validity of multiple allegations that three peer review panelists had conflicts of interest or biases which might have impaired their judgments in their peer review of EPA's draft assessment of the health hazards caused by the collapse of the World Trade Center (WTC) towers, and (b) assess the adequacy of steps taken to balance the peer review panel.

Background

The impartiality of three peer review panelists was questioned because one panelist allegedly had a working relationship with an asbestos company and two other panelists had publically expressed their viewpoints, prior to commencement of the peer review, regarding health hazards at the WTC site. One way such concerns can sometimes be addressed is by using a balanced panel.

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link:

www.epa.gov/oig/reports/2005/20041104-2005-S-00003.pdf

Review of Conflict of Interest Allegations Pertaining to the Peer Review of EPA's Draft Report, "Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster"

What We Found

The seven-member peer review panel selected to review EPA's draft report included one panelist with an extensive history of providing expert testimony and similar services for defendants in asbestos lawsuits, and two panelists who had made prior public statements regarding the safety of the air around the WTC site. These circumstances provided a basis for the perception that one panelist had a potential conflict of interest and two panelists had potential biases that would prevent them from providing impartial input. We found that EPA's Contractor did not inquire whether the three panelists had received funding from industry or had publically expressed viewpoints on the issues to be reviewed. However, our examination of the peer review record did not find that the panel's input was biased, nor that perceived biases and conflicts were so "direct and substantial" that any of the panelists should have been excluded from the panel.

In our view additional measures should have been taken during the peer review selection process to disclose the information about panel members upon which the allegations of conflicts of interest or bias were later made. Specifically, had EPA's Contractor inquired about industry funding, learned whether panelists had expressed opinions publically about the peer review issues, and taken other actions to identify the bases for these perceived conflicts and biases prior to the selection of the panel, EPA would have been better able to consider the need for additional actions to balance the panel or otherwise resolve these perceived, potential conflicts and biases prior to conducting the peer review.

What We Recommend

We made a number of recommendations to better ensure that guidance in EPA's Peer Review Handbook will be fully followed, including that EPA provide:

- better oversight of peer review contracts to ensure that potential panelists are asked about industry financing and their relationship with clients; and
- supplemental guidance and training of peer review leaders regarding the types of information they may need to obtain about potential panelists' opinions and viewpoints when they assess whether panels are independent and balanced.

EPA agreed with our conclusions and recommendations and has either taken actions, or set milestones for completing actions, to address our concerns.



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

OFFICE OF
THE INSPECTOR GENERAL

November 4, 2004

MEMORANDUM

SUBJECT: Evaluation Report: Review of Conflict of Interest Allegations Pertaining to the Peer Review of EPA's Draft Report, "Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster"
Report No. 2005-S-00003

FROM: Kwai-Cheung Chan /s/
Assistant Inspector General for Program Evaluation

TO: Dr. J. Paul Gilman
Assistant Administrator for Research and Development

Dr. Peter R. Preuss
Director, National Center for Environmental Assessment

Attached is our final report regarding allegations that the above Environmental Protection Agency (EPA) draft report had not received an impartial peer review. Our report contains findings and recommendations that should help EPA better ensure impartial, balanced peer reviews of its scientific and technical work products. Our report represents the opinion of the OIG and the findings contained in this report do not necessarily represent the final EPA position.

Our final report acknowledges and includes your October 21, 2004, response to our draft report, the corrective action plan, and the new peer review policy. We commend the Office of Research and Development (ORD) and the National Center for Environmental Assessment (NCEA) for the actions already completed, as well as the actions planned.

Action Required

The October 7, 2004, NCEA Policy Announcement addresses many of our concerns, and the ORD Action Plan, if properly implemented, addresses our other concerns. Therefore, in accordance with EPA Manual 2750, we are closing out this final report upon issuance. As outlined in EPA Manual 2750, Agency management is responsible for tracking implementation of these recommendations in its Management Tracking System. We appreciate the efforts of ORD and NCEA officials and staff, and EPA's peer review contractor, in working with us to develop this report. For your convenience, this report will be available at <http://www.epa.gov/oig>.

If you or your staff have any questions regarding this report, please contact me at (202) 566-0827 or Rick Beusse, Director for Program Evaluation - Air Issues, at (919) 541-5747.

Attachment

cc: Cheryl Varkalis, Audit Liaison, Office of Research and Development
Matt Lorber, National Center for Environmental Assessment/ORD
Elizabeth Grossman, Office of Program Evaluation/OIG

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Chapter 1

Introduction

Purpose

The Office of Inspector General (OIG) conducted a review of six allegations concerning the peer review that was performed on a draft report, issued by the Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), entitled: "Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster" (Draft Assessment). Based on the allegations made by the Complainant, our objectives were to answer the following six questions:

- Does the National Contingency Plan require that the public be given an opportunity to comment on the choice of peer review panelists, or suggest other experts who could represent the views of the community?
- Was NCEA obligated to evaluate the sensitivity of the work being performed as allegedly required by its guidance for handling conflict of interest situations that are identified after contract award?
- Was NCEA obligated to ensure that its peer review Contractor required potential panelists to disclose all substantial public statements they had made about the World Trade Center (WTC) disaster and all business relationships with industries that could be effected by NCEA's findings on WTC exposure hazards?
- Did panelist Dr. Eric Chatfield have a conflict of interest and did his resumé lack information which would have underscored this conflict of interest?
- Did panelists Dr. Alison Geyh and Dr. Patrick Kinney have a bias because they had publically expressed prejudicial opinions before the peer review process began that ". . . there were no hazards from WTC exposures"?
- What steps were taken to ensure that the panel was balanced?

Appendix A provides more information on the allegations.

Background

In the aftermath of the collapse of the WTC towers on September 11, 2001, various government entities initiated numerous air monitoring activities to better understand the ongoing impact of emissions at the disaster site. At the request of EPA Region 2 in New York City, NCEA officials used the data collected from

these monitoring activities to conduct an inhalation exposure and human health risk assessment for airborne pollution from the WTC disaster. The issue of potential health impacts from exposure to airborne pollutants resulting from the collapse of the towers and the continuing fires at Ground Zero was a highly sensitive and controversial subject. Accordingly, most government pronouncements and data regarding this subject were and continue to be highly scrutinized.

In December 2002, NCEA issued its Draft Assessment for public comment. NCEA officials first obtained a proposal from the National Academy of Sciences for the peer review of this Assessment; however, they subsequently decided the National Academy of Sciences proposal would take too long and cost too much. As such, they decided to obtain the peer review by issuing a task order to Versar, Inc. under an existing 5-year contract for peer review and risk assessment support (Contract).¹ Versar, in turn, obtained the services of seven peer reviewers by issuing seven Work Assignment Authorizations. Versar held a public peer review meeting on July 14-15, 2003. A summary of the peer review panel's comments and meeting is available on EPA's public website.

EPA's Guidance For Conducting Peer Reviews

The Agency's guidance concerning peer reviews is contained in EPA's Peer Review Handbook, Second Edition, December 2000 (Handbook), which was issued by EPA's Science Policy Council. This guidance applies whether EPA obtains peer reviewers directly, or contracts for another entity to obtain appropriate peer reviewers. According to the Handbook, the principal reason for having a peer review is to ensure the scientific integrity and technical credibility of a work product which supports a policy or decision, through a complete, independent, objective, and competent review. The peer review process is intended to uncover any technical problems or unresolved issues in a preliminary work product through the use of independent experts. Peer review panelists do not formulate EPA policy; instead, they provide expert input on technical issues which underpin EPA conclusions or policies, such as whether a particular sampling procedure is an acceptable method for obtaining data used by EPA officials to reach conclusions or formulate policy.

The Handbook states that selecting an independent peer review panel is crucial to an effective peer review, and therefore, EPA should make every effort during panel formation to use peer reviewers who do not have any real or perceived bias or conflicts of interest and who are completely independent.

¹The Contract, entitled *NCEA Support for Peer Review and Risk Assessment Guidelines Activities*, is a task order contract which provides for services from August 1, 2002 through July 31, 2007.

Scope and Methodology

To ensure that we accurately and comprehensively addressed the Complainant's concerns, we interviewed the Complainant. We subsequently discussed in detail our understanding of the Complainant's allegations, and reached agreement that we had stated the allegations fully and accurately. We requested any additional documentation in the Complainant's possession which provided support for the allegations, and we reviewed the documentation subsequently provided that appeared relevant to the allegations.

To identify EPA's efforts to ensure that an adequate peer review was carried out, we interviewed NCEA's Work Assignment Manager for the subject peer review task order and Versar's Senior Project Manager for this order. We requested and reviewed all documentation concerning the peer review process and screened these documents for applicability to the allegations. We reviewed those documents relating to the establishment and selection of the peer review panel including, but not limited to, the work assignment authorizations for the peer review services, personal conflict of interest statements, resumes, records of discussions with panelists, and e-mail correspondence.

We reviewed EPA's Peer Review Handbook to determine Agency guidance for identifying and addressing potential conflicts of interest and bias issues. We also reviewed other government related peer review guidance (such as that used by the Science Advisory Board, National Academy of Sciences, or recommended by the Office of Management and Budget) to determine how these documents addressed the issue of balance in peer review panels. To enhance our understanding of the history and development of the Peer Review Handbook, we interviewed one of the two principal authors of EPA's Handbook. Similarly, to enhance our understanding of the peer review balance and panel formation processes and procedures used by the Science Advisory Board, we interviewed the Science Advisory Board's Director and an Ethics Official. We also reviewed prior General Accounting Office (GAO) and EPA OIG reports to identify any previously reported issues relevant to the questions we addressed in this review.

To assess whether the panel's input to the NCEA Assessment was biased, we obtained and reviewed (listened to) the entire audio tape of the two-day peer review meeting. Further, we had our OIG Certified Industrial Hygienist review the draft and final Summary Peer Review Report, which included all written comments from the peer review panelists. In addition, we obtained the responses of all 7 panelists to 13 questions about their perception of the peer review process, as well as detailed responses of 3 panelists to additional questions about the specific allegations directed at them. Also, at the request of panelist Dr. Eric Chatfield, we met with him and discussed his responses to the specific allegations made against him. In addition, our Certified Industrial Hygienist interviewed NCEA's Work Assignment Manager concerning the Manager's efforts to

incorporate the recommendations made by the peer review panel about asbestos in NCEA's Final Assessment. However, since this work had not been completed at the time our field work ended, our Certified Industrial Hygienist was not able to confirm the extent to which the panel's recommendations about asbestos may or may not be included in NCEA's Final Assessment. Subsequent to the completion of our field work, the NCEA Work Assignment Manager indicated that all changes recommended by the panel were incorporated into the working draft of the Risk Assessment.

To ensure that we accurately interpreted key criteria regarding these issues, our OIG Office of Counsel advised us on the applicability of the National Contingency Plan (NCP), Federal Acquisition Regulation, and Agency guidance on the peer review process. We performed our review and analysis from October 2003 through June 2004 in accordance with *Government Auditing Standards* issued by the Comptroller General of the United States.

Prior OIG Report

EPA's Selection of Peer Reviewers, EPA/OIG, Report No. 1999-P-217, September 1999. The applicable findings of this report are discussed in Chapter 3.

Results in Brief

The seven-member peer review panel selected to review NCEA's draft report included one panelist with an extensive history of providing expert testimony and similar services for defendants in asbestos lawsuits, and two panelists who had made prior public statements regarding the safety of the air around the World Trade Center (WTC) site. These circumstances provided a basis for the perception that one panelist had a potential conflict of interest and two panelists had potential biases that would prevent them from providing impartial input. However, we did not find that the panel's input was biased, nor that these perceived biases and conflicts were so "direct and substantial" that any of the panelists should have been excluded from the panel. None of the seven panelists had concerns about the way the peer review process was conducted.

Nonetheless, given the highly sensitive and controversial nature of the subject, in our view additional measures should have been taken during the peer review selection process to disclose the information about panel members upon which the allegations of bias and conflicts were later made. Specifically, had EPA's Contractor taken additional actions – such as inquiring about publicly expressed viewpoints on the subject matter – to disclose this information prior to the selection of the panel, EPA's Contractor could have considered the need to balance the panel or otherwise resolve these perceived, potential conflicts and

biases prior to conducting the July 2003 peer review. Regarding the six allegations, we found that:

- The National Contingency Plan does not require, as alleged, that the public be given an opportunity to comment on the choice of peer review panelists, or the opportunity to suggest other experts who could represent the views of the community.
- Neither EPA nor its Contractor was required by Procurement Policy Notice 95-04, as alleged, to evaluate the sensitivity of the work being performed when evaluating potential post-award conflicts of interest.
- EPA's Contractor did not obtain as much information on prospective panelists as would be needed to adequately assess potential conflicts of interest and biases. Specifically, the Contractor did not inquire as to whether the three prospective panelists had received funding from industry, or had expressed viewpoints on the issues to be reviewed.
- The asbestos expert did not have a "direct and substantial" conflict of interest, as alleged, but there was a basis for the perception of a potential conflict of interest.
- The two panelists who had publicly expressed opinions regarding certain WTC hazards did not appear to have significant biases, as alleged, because the opinions expressed were either sufficiently qualified or not directly related to the subject matter to be peer reviewed.
- EPA or its Contractor could have taken additional measures to obtain more information on prospective panelists' work experience and viewpoints, which would have necessitated additional actions on the part of EPA or the Contractor to assess the balance of the panel.

EPA's Peer Review Handbook provides significant flexibility to the peer review leader in forming a panel considering the range and variety of EPA scientific and technical work products that are peer reviewed. The Handbook also acknowledges that obtaining appropriate expertise may mean that some panelists with potential conflicts and biases are nonetheless needed. We noted that the Handbook did not always give sufficient instructions on how to define and treat issues such as bias and panel balance, and additional guidance and training of peer review leaders on handling sensitive or controversial peer reviews could be helpful.

Recommendations

We are making a number of recommendations to EPA to better ensure that guidance in EPA's Peer Review Handbook is fully followed, including (1) better oversight of peer review contracts to ensure that potential panelists are asked about the industry financing they have received, and their relationship with any clients whose interests might be affected by the subject being peer reviewed; and (2) supplemental guidance and training of peer review leaders regarding the types of information they may need to obtain about potential panelists' opinions and viewpoints when they assess whether panels are independent and balanced.

Agency Comments and OIG Evaluation

The Agency agreed with our draft report findings, conclusions, and recommendations. See Appendix C for the Office of Research and Development's (ORD) response to our draft report. Additionally, in response to our draft report, on October 7, 2004, ORD issued Policy Announcement #NCEA-EM-05-01 which requires that specific conflict of interest (COI) provisions be included in task order statements of work for EPA peer reviews, unless these provisions are waived by the NCEA Director (see Appendix E for this Policy Announcement). These provisions adequately address many of our concerns. ORD also identified milestone dates for (a) developing additional guidance to supplement the existing EPA Peer Review Handbook, (b) revising existing training materials, and (c) developing a Peer Review Website. Further, ORD stated it would ask the Science Policy Council to adopt an Agency-wide policy directing its contractors to use the information-collection forms that are currently being used by the EPA Science Advisory Board and the National Academy of Sciences to aid staff in assessing peer review panel balance.

We commend the Office of Research and Development and the National Center for Environmental Assessment for the actions already completed, ongoing, and planned to ensure that scientific and technical work products consistently receive adequate peer reviews. ORD's completed and planned actions are summarized in the Corrective Action Plan (see Appendix D). Agency officials also made a number of technical comments and clarifications to our draft report, which we have included as appropriate.

Chapter 2

Results of Review of the Six Allegations

A discussion of each allegation and the results of our review follows.

Question 1: Did the NCP Require Public Participation in Peer Review Panel Selection?

The Complainant alleged that the public was not given an opportunity to comment on the choice of the seven panelists, or an opportunity to suggest other members who could represent the views of the community, as the complainant claimed was required by the National Contingency Plan (NCP). We found that neither the NCP nor the Peer Review Handbook require public participation in the selection of a peer review panel. Although the public did not participate in the selection of the panel, the peer review meeting was held in public and the public was given the opportunity to comment on the panel composition and the Draft Assessment during this meeting. Although the extent of this participation may have been less than the Complainant or others may have desired, the extent of the participation was consistent with Agency peer review guidelines and prior practices.

The Handbook acknowledges the general principle that obtaining a peer review should be a transparent process: “Remember, the Agency is committed to working ‘as if in a fishbowl’ and most of its activities are transparent to the public (except where confidential business information is concerned).” The Director of EPA’s National Center for Environmental Research and Quality Assurance, Versar’s Senior Project Manager for the peer review of NCEA’s Draft Assessment, and NCEA’s Work Assignment Manager for the peer review told us there was no requirement for public participation in the peer review process. We confirmed that this was the case during our examination of the NCP. The officials further stated that EPA has conducted numerous peer reviews in the past without allowing the public to suggest panelists or otherwise participate in the selection of panelists. The Director estimated that for every thousand panels EPA has convened, “fewer than ten would have public involvement” in the process of selecting panelists.

Although the Handbook does not require the Agency to involve the public in the panel selection process, the public was involved in the peer review meeting. NCEA’s task order to Versar contained the following requirements with respect to public participation:

- the peer review meeting would be announced to the public through a Federal Register Notice;

- the deliberations of the panel would be open to the public;
- there would be a 2 to 3 hour period during which the public could address the panel with specific comments;
- each person who asked to address the panel would be granted 5 minutes to address the meeting; and
- the public could also submit comments in writing.

Based on our review of the audio tape and other documentation of the peer review meeting, these requirements were fulfilled. For example, several individuals from the general public accepted the opportunity to communicate directly with the panelists. In addition, NCEA's Draft Assessment was made available to the public prior to the meeting and comments were accepted from the public. Additionally, the public was allowed to submit comments after the peer review meeting to be included in the peer review summary report. The summary report has also been made available to the public via EPA's public website.

Question 2: Was NCEA Obligated by Procurement Policy Notice 95-04 to Evaluate the Sensitivity of the Work Being Performed?

The Complainant alleged that EPA did not follow the procedures outlined in "EPA Procurement Policy Notice No. 95-04, Procedures for Handling Post Award Organizational Conflicts of Interest" to address potential conflicts of interest as defined in Federal Acquisition Regulation (FAR) Section 9.501. The Complainant alleged that the Procurement Policy Notice provides specific questions that EPA should ask contractors to determine whether potential conflicts of interest exist, and requires EPA to evaluate the sensitivity of the work being performed by the Contractor.

EPA's Procurement Policy Notice No. 95-04 provides guidance for evaluating potential organizational conflicts of interest and does not apply to individual potential conflicts of interest pertaining to a peer review panelist. The requirements of the Procurement Policy Notice apply only to the government-contractor relationship and to potential organizational conflicts of interest that a contractor may have related to the work being performed for EPA.

We also reviewed the Peer Review Handbook for guidance on how potential conflicts of interest discovered after the selection of a panel should be addressed. The Handbook provides considerable guidance on how to address potential conflicts of interest in selecting the panel; however, it does not include guidance for handling potential conflicts of interest discovered after the panel had been selected.

Question 3: Was NCEA Obligated to Ensure that Its Peer Review Contractor Required Potential Panelists to Disclose All Substantial Public Statements and All Business Relationships?

The Complainant alleged that EPA did not require its Contractor to obtain all relevant information from potential panelists, including asking potential panelists whether they had made prior public statements about WTC hazards, or to require full disclosure of business relationships with industries that would be affected by EPA’s findings on WTC exposure hazards. We found that EPA’s Contractor did not obtain all the necessary information on prospective panelists that would be needed to adequately assess potential conflicts of interest and biases. For example, the Contractor did not inquire as to whether the three prospective panelists had received funding from industry, or had expressed viewpoints on the issues to be reviewed.

EPA Guidance for Using Contractors to Arrange for Peer Review Services

The Handbook includes specific requirements and procedures to be followed when EPA uses a contractor to arrange for peer review services. The Handbook states that:

The Statement of Work (SOW) must clearly specify that the contractor is responsible for preparing peer review evaluations and set forth guidelines for the peer review of scientific or technical documents. The contractor may perform the peer review with in-house staff, subcontractors, or consultants. Any guidelines for performing peer reviews to ensure soundness and defensibility must be developed by the program office and made part of the contract. The contractor would then ensure that peer reviews adhere to the guidelines.

According to the Handbook, the Statement of Work should direct the contractor “. . . to inquire whether prospective peer reviewers have any actual or potential organizational or personnel conflicts of interest or other matters that would create the appearance of a lack of impartiality, including whether they have had or presently have a financial relationship with EPA.” According to the Handbook,

When the peer review process is being conducted by a contractor, the requirement for addressing peer reviewer’s possible conflicts of interest should be highlighted in the Statement of Work of the work ordering instrument (e.g., Work Assignment, Delivery Order, Task Order, etc.) and is a matter that is bound by contractual clauses with the Contracting Officer as the final Decision Maker in contracting matters.

When contracting for peer review services, EPA officials cannot select the peer reviewers. Such action would interfere with the contractor's authority and responsibility to perform the work under contract. EPA officials can establish the criteria for the type of individual that might participate on a peer review panel, but they should avoid commenting on the contractor's selection of peer review panelists other than to determine whether the panel, once selected, meets the criteria established.

EPA's Peer Review Guidance does not specifically require EPA – or its contractor when conducting the peer review for EPA – to specifically ask panelists about their prior public statements, if any, related to the matters to be peer reviewed, and no attempt was made to obtain prospective panelists' viewpoints on the subject matter for this peer review. However, the Peer Review Handbook states that a panel should represent a balanced range of technically legitimate viewpoints, and in general, panelists who have publicly commented on the subject should be avoided. Accordingly, it would be difficult to adequately carry out the intent of EPA's Peer Review Handbook without obtaining information on prospective panelists' stated positions or viewpoints.

NCEA's Actions to Ensure that Potential Conflicts of Interest or Biases Were Identified

NCEA's contract with Versar identified the actions that Versar was to take to ensure that potential conflicts of interest or biases were identified prior to selecting the peer review panel. Among other things, this contract defined a conflict of interest and required Versar to include a substantially similar definition in any subcontract or consultant agreement which provided services for the contract. NCEA's contract with Versar required Versar to obtain:

recognized, independent peer-reviewers who will provide impartial evaluations of NCEA products . . . [and] peer reviewers . . . shall be free of real or perceived conflicts of interest, and shall represent a balanced range of technically legitimate points of view and disciplinary mix.

NCEA's task order to Versar for the peer review of NCEA's Draft Assessment contained a statement of work which identified areas of expertise that were desired for the peer review panelists. However, NCEA's task order did not specifically discuss conflicts of interest or biases but contained a requirement that NCEA may, after receiving the list of potential panelists, provide feedback to Versar concerning "any known conflict of interest, or concern about the appropriate expertise."

Contractor's Actions to Identify Potential Conflicts of Interest or Biases

Versar took actions to identify potential conflicts of interest but did not take all of the actions that were required by its Contract with NCEA or the actions that were prescribed in its own internal guidance documents. Versar took the following principal actions to identify conflicts of interest:

- screened potential panelists to obtain diversity;
- discussed conflicts of interest with seven candidates over the telephone before their selection (according to Versar's Senior Project Manager);
- obtained personal conflict of interest statements from each selected panelist before the peer review meeting was held on July 14, 2004;
- obtained resumes from each of the panelists, which should have disclosed important working relationships; and
- required each panelist to orally discuss or confirm the absence of a conflict of interest at the beginning of the peer review meeting.

Versar identified at least 45 potential panelists before selecting 7 to serve as peer reviewers. Six of the seven panelists had performed some work related to the collapse of the WTC towers. In accordance with the requirements in NCEA's task order, Versar sought experts with different backgrounds and different areas of expertise. Versar's intent to get different viewpoints on the panel is illustrated by the fact that one candidate panelist was "not called" because he was known to collaborate with someone who had already been selected, or was likely to be selected, for the panel. Further, Versar excluded at least three other prospective panelists from consideration because of potential conflicts of interest or their work relationships.

Contractor Did Not Fully Follow Guidance for Identifying Conflicts

The work assignment authorizations used by Versar to obtain the services of peer review panelists did not define conflicts of interest or require panelists to report conflicts of interest as required in its contract with NCEA. Further, Versar did not take all of the actions which were prescribed in its own guidance documents for identifying potential conflicts of interest. In particular, Versar did not inquire specifically about industry funding of each panelist's work or each panelist's working relationships with companies that might have a vested interest in the results of NCEA's Draft Assessment. Such questions are important in uncovering potential conflicts of interest.

Versar's generic Conflict of Interest Management Plan required that subcontractors and consultants (selected panelists) perform "screenings" for conflicts of interest and report the results of such screenings to Versar. The screenings were to include, at a minimum, the identification of former and present clients at the site where work is or has been performed, the type of work performed, and the period of the performance. However, Versar did not follow

this guidance. Versar did not ask panelists to identify their clients whose interests might be affected by conclusions that could be drawn about WTC issues. When they submitted their resumes and personal conflict of interest statements to Versar, several panelists identified work they had completed related to the conditions at the WTC site. However, panelists were selected without specific questions being asked concerning the possible interest of the panelists' present or prior clients.

We reviewed a written script that Versar reportedly used to interview potential panelists over the telephone. The script contained a definition of conflict of interest which, according to Versar's Senior Project Manager for the peer review, was read over the phone to each panelist and discussed with them. This definition embodied the principal concept of objectivity and impartiality that is contained in EPA's Handbook and NCEA's Contract with Versar. The script also contained the following questions:

Are you doing other work at the World Trade Center currently? For whom? Other work at the WTC is not necessarily a COI (conflict of interest), we just need to be aware and disclose this information. In fact we see it as a potential asset.

Are you receiving funding from EPA currently? For what types of projects? Anything else to disclose that might be related to this review?

Versar's Senior Project Manager's notes, which summarize his telephone discussions with the seven panelists who were ultimately selected, indicate that he specifically discussed conflicts of interest with potential panelists. For example, one panelist, who was not cited in any of the allegations, expressed concern that he might have a conflict of interest because he mistakenly thought a paper he had co-authored concerning the WTC may have been partially funded by EPA. Aside from the documentation that indicates conflicts of interest were discussed orally with potential panelists, each panelist signed a personal conflict of interest statement that affirmed they did not have a conflict of interest.

The script did not include the following question that is contained in Versar's standard operating procedures document entitled: *Summary of Versar's Conflict of Interest Screening and Certification for Peer Reviewers Under NCEA Peer Review Contracts*:

Are you receiving funding from industry for efforts that might be related to this document?

We contacted the Versar Project Manager to determine why this question was not asked but had not received a response at the time this report was prepared. The NCEA work assignment manager told us he was satisfied that the panel met the criteria established for this panel.

Question 4: Did the Asbestos Expert Have a Conflict of Interest?

The Complainant alleged that one panelist, Dr. Eric Chatfield “. . . is a paid expert witness for W.R. Grace & Co., the firm responsible for the asbestos contamination in homes in Libby, Montana . . . ” and “In an expert report dated 8/30/02, Chatfield strongly opposed EPA’s analytical evaluation of risks in homes in Libby.” The Complainant further alleged that the resume that Dr. Chatfield submitted to Versar did not disclose this working relationship. The Complainant alleged that this relationship represented a conflict of interest since W.R. Grace & Co. was involved in litigation with the U.S. Department of Justice over responsibility for removing asbestos contamination in Libby. We determined that the asbestos expert did not have a “direct and substantial” conflict of interest, as alleged, but there was a basis for the perception of a potential conflict of interest.

Handbook Definition of Conflict of Interest and Procedures for Handling

EPA’s Peer Review Handbook defines a conflict of interest as follows:

Conflict of interest is a situation in which, because of other activities or relationships with other persons, an individual is unable or potentially unable to render impartial assistance or advice to the Agency, or the person’s objectivity in performing the work is or might be otherwise impaired, or a person has an unfair competitive advantage.

Further, the Handbook states that a conflict of interest may exist when a panelist’s “*professional standing and status or the significance of their principal area of work might be effected by the outcome of the peer review.*” The Handbook does not specifically define “bias,” but notes that the desire to select individuals with experience on a panel often comes from those who are considered as having a potential bias.

The Handbook discusses techniques to help ensure disclosure and appropriate resolution of potential conflicts of interest. Section 3.4.6 states:

One way of identifying conflicts of interest is to ask potential reviewers about current and prior work, and prior clients that might create conflicts or the appearance of a lack of impartiality in carrying out peer review activities. . . .

The Handbook also states that each potential conflict of interest situation is unique and must be treated on a case-by-case basis. The Handbook lists certain factors that should be considered in evaluating potential conflicts of interest. These factors include:

- attention to employment, financial, and professional affiliations of the participants;

- exploring directly the issue with each of the participants before the review process takes place;
- disclosing publicly at the beginning of meetings any previous involvement with the issue; and
- providing non-Federal peer reviewers with a copy of the peer review inquiry conflict of interest form, and conducting a follow-up discussion to discuss any relevant issues.

The Handbook offers additional guidance on when a person with a potential conflict of interest can be used on a panel and when such a potential conflict of interest would result in a person's exclusion from the panel. According to the Handbook,

In fact, experts with a stake in the outcome - - and therefore a potential conflict - - may be some of the most knowledgeable and up-to-date experts because they have concrete reasons to maintain their expertise. Such experts could be used provided the potential conflicts of interest are disclosed and the peer review panel or group being used as a whole is balanced. In some cases, however, the conflict may be so direct and substantial as to rule out a particular expert. . .

The Handbook's general definition of conflict of interest that would likely result in a prospective panelist's exclusion from a panel is as follows:

Generally, a conflict of interest arises when the person is affected by his/her private interests, when he/she or his/her associates would derive benefit from incorporation of their point of view in an Agency product, or when their professional standing and status or the significance of their principal area of work might be affected by the outcome of the peer review.

Those in charge of panel formation are encouraged to consult with EPA's Office of General Counsel "whenever there are questions about conflicts of interest."

Disclosure of Dr. Chatfield's Work Experience

In regard to the alleged incompleteness of Dr. Chatfield's resume, the resume he provided to Versar did not specifically disclose his working relationship with W.R. Grace & Co. In our view, this relationship should have been disclosed to the contractor during the screening process. However, Dr. Chatfield's 30-page, single-lined resume identified approximately 75 instances where he had acted on behalf of one or more defendants in litigation by providing "depositions," "certifications," "affidavits," "declarations," or "expert testimony." While not all of these instances may have involved asbestos, his resume disclosed that he had been an "expert witness on behalf of several defendants in asbestos property

damage suits” and “asbestos personal injury suits.” Accordingly, it should have been clear to NCEA and Versar officials, as well as other panelists, that Dr. Chatfield had extensive working relationships with asbestos companies, such as W.R. Grace & Co., and other defendants in asbestos cases.

According to the Complainant, Dr. Chatfield’s relationship with W.R. Grace & Co. was significant because as part of its legal defense, W.R. Grace & Co. was using comparisons of the cleanup standards required in Libby, Montana, to the cleanup standards being used around the WTC. Specifically, W.R. Grace & Co. was asserting that it was being held to a higher standard in removing asbestos contamination from buildings in Libby, even though they contended that the contamination levels in Libby were not as bad as the contamination levels in buildings around the WTC.

In regard to the extent of Dr. Chatfield’s relationship with W.R. Grace & Co., he maintains that his work for W.R. Grace & Co. involved minimal time and effort, involving less than 2 weeks total effort, and was not significant in relation to his many other activities, especially since he was never called to testify. A brief chronology of his work for W.R. Grace & Co. follows:

- Hired by W.R. Grace & Co. on August 6, 2002, for the purpose of being an expert rebuttal witness concerning data that were obtained by EPA using an analytical method which Dr. Chatfield developed.
- Submitted a report dated August 30, 2002, rebutting the analytical work done by EPA’s Contractor concerning air samples at Libby by transmission electron microscopy. The report documented cases of misidentification of fibers and misuse of the analytical method.
- Deposed by a U. S. Department of Justice attorney on September 29, 2002.
- In anticipation of a January 2003 trial, he made one visit to the attorney representing W.R. Grace & Co. to discuss this matter.
- Contractual services for W.R. Grace & Co. terminated in January 2003, when the parties settled out of court.

Dr. Chatfield stated that as a rebuttal witness for W.R. Grace & Co., his work was limited in that he could only rebut the evidence proffered by others in this matter, and could not introduce any unsolicited views. Dr. Chatfield also explained that he had never been a consultant for W.R. Grace & Co., but only an expert witness hired to provide testimony on data gathered by an analytical method which he helped to develop in the late 1970s. We did not identify any documentation that challenged Dr. Chatfield’s statements that he did “. . . less than two weeks work” or that he has “. . . never been a consultant for W.R. Grace either before or after this limited assignment.” In addition, the allegations pertaining to Dr. Chatfield’s relationship with W.R. Grace & Co. were raised at the public peer

review meeting, and were fully disclosed to other panelists at the meeting. The Peer Review Handbook notes that full disclosure and discussion of potential conflicts of interest before the entire panel is one method for resolving such conflicts.

Our review of Dr. Chatfield's past work as detailed in his resume did not identify any other work relationships between Dr. Chatfield and W.R. Grace & Co. Additionally, the work relationship between Dr. Chatfield and W.R. Grace & Co. did not appear to involve significant time and effort. Thus, this potential conflict of interest was not sufficiently "direct and substantial," as discussed in EPA's Peer Review Handbook, to warrant Dr. Chatfield's exclusion from the panel.

Notwithstanding Dr. Chatfield's limited relationship with W.R. Grace & Co., the fact that he had many working relationships with many asbestos companies over the years is a basis for a perception that he may have a potential conflict of interest. Accordingly, we evaluated his input to the peer review (both oral and written comments) for any indication of bias. We did not identify any biased input. During the peer review meeting and through his written peer review comments, he called for treating information cautiously. For example, he recommended that:

- NCEA's Final Assessment state specifically that there are a number of potential contaminants which have not been measured and that uncertainty remains, and he encouraged governmental officials to identify the limitations of their work; and
- all dust samples be treated as if they contained one half percent to 3 percent asbestos, even when a dust sample was reported to be free of asbestos.

Further, Dr. Chatfield did not comment on the health implications of the data. He told us that his area of expertise is asbestos sampling and analytical methodology, and that he did not feel qualified to address health issues. He told us that he does not make statements about health effects, but instead evaluates considerations such as sampling methodology and data quality.

Also, in a report on asbestos concentrations measured in two apartments near the WTC site, Dr. Chatfield recommended that nearby residents obtain professional cleaning of their residences at a time when the government was advising the public to clean their own residences with wet rags, wet mops, and vacuums with HEPA (high efficiency particulate air) filters as long as there was less than 1 percent asbestos in dust samples. The positions taken by Dr. Chatfield in his peer review of NCEA's Draft Assessment did not reflect biases on behalf of any asbestos company or an asbestos industry that retained his services in the past. In summary, Dr. Chatfield's relationship with W.R. Grace & Co. did not present a "direct and substantial" conflict of interest as alleged, but there was a basis for the perception of a potential conflict of interest.

Question 5: Did Two Panelists Have Biases Based on Their Prior Stated Conclusions Regarding WTC Health Hazards?

The Complainant alleged that two panelists, Dr. Alison Geyh and Dr. Patrick Kinney, “. . . are known to have advised the public through the press that there were no hazards from WTC exposures. Their statements are prejudicial, making it difficult for them to change their opinions at this later date to agree with any EPA conclusions . . . that there are potential or real risks from WTC exposures.” The Complainant asserted that potential liability issues for these individuals or their parent institutions would make it “difficult if not impossible” to agree with any of the draft report’s conclusions that differed from their prior public statements about the health risks. We evaluated the public statements attributed to Dr. Geyh and Dr. Kinney to determine whether they demonstrated that these panelists had “clearly taken a side” and whether these statements represented a “direct and substantial” conflict as discussed in EPA’s Handbook. In our opinion, these two panelists did not appear to have significant biases because the opinions expressed were either sufficiently qualified or not directly related to the subject matter to be peer reviewed.

EPA Guidance on Bias

The Handbook does not specifically define bias but discusses how a potential bias could impact panel formation. In discussing considerations for selecting peer reviewers, the Handbook recognizes that a panel can be comprised of individuals who are considered to have a potential bias and that this concern can be addressed by ensuring that the panel is balanced. The Handbook states that:

. . . the very need to have experienced individuals on a peer review, along with the desire to have appropriate technical balance and representation, can mean that the selection of potential peer reviewers often comes from those who are considered as having a potential bias. To reduce the concern that a potential panel may have unnecessary bias, it may be useful to obtain an informal review of the expertise and balance of potential peer reviewers from others in your organization, from OGC or even from outside groups

The Handbook provides additional discussion on the proper mix of a panel, and notes that:

As a general rule, experts who have made public pronouncements on an issue (e.g., those who have clearly ‘taken sides’) may have difficulty in being objective and should be avoided.

Dr. Geyh's Public Statements

The Complainant provided two news articles that contained quotations attributed to Dr. Geyh, an assistant professor of environmental health sciences at Johns Hopkins University Bloomberg School of Public Health. The two news articles contained her comments about a research study that she directed. The Complainant has not alleged that Dr. Geyh misinterpreted or misrepresented the results of her research study. This study concerned WTC cleanup workers, not the general public; thus, the focus of her study is different than NCEA's Draft Assessment. The principal quotations attributed to Dr. Geyh by one news article were:

Many of the workers we assessed reported coughing, wheezing, and sore throats while working at Ground Zero. These symptoms seemed to increase the longer they worked at the site. The good news is that we did not find unhealthy levels of asbestos but we don't know what the long term health risks may be regarding exposure to other airborne contaminants at the site.

A second news article reported that Dr. Geyh said there was no sign of lung obstruction, and quoted her as saying, *"For the general community this is a very good story . . ."*

We provided Dr. Geyh with a copy of the Complainant's allegations about her prior public statements. Dr. Geyh specifically denied stating there were no hazards associated with exposures at the WTC site, as alleged. Further, she noted that her statement about asbestos levels was "based on results of my own airborne asbestos monitoring data collected directly on the disaster site," and that none of her research involved residents, office workers, or first responders. She told us that:

I have no data regarding these groups and have made no definitive statements or come to any definitive conclusions about the relationship between asbestos levels and these groups.

We found that Dr. Geyh's statements reflected the factual results of her research study. Additionally, during the peer review, she noted the limitations of existing test data and the need for more data about the potential long-term health risks associated with exposures at the WTC site. As such, her statements did not demonstrate that she had "taken sides" with respect to the issues being peer reviewed. We concluded that any potential biases arising from these statements were not so material as to warrant her exclusion from the panel. However, the fact that such opinions were expressed provided a basis for the perception that there may have been a bias, and supports the need for EPA or its Contractor to improve their efforts to ensure that peer review panels as a whole are balanced.

Dr. Kinney's Public Statements

The Complainant provided several news articles that contained quotations attributed to Dr. Kinney. The principal quotations attributed to him by the news articles were:

The data that has been collected so far do not show concentrations of pollutants that are of concern . . . Based on what we know so far, there is no cause for alarm. . . . For the general public, as long as we are careful, I think the risks are quite low. . . . I do not think it was unwise to have people start repopulating the area [near the World Trade Center]. However, not all of the pollutants that you might want to look at have been monitored or, at least, reported yet. So the database is incomplete.

We provided Dr. Kinney with a copy of the Complainant's allegations about his prior public statements. He agreed that he had made these statements, but denied that it biased his input during the peer review. His written response to us included the following statement:

I never feel at all 'prejudiced' by a previous view I have held if new information points in a different direction. . . . I'm perfectly willing to change my mind on any issue based on new evidence. This is generally the way scientists behave.

Our review of Dr. Kinney's written peer review comments indicated that he, in fact, had advocated alerting the public to potential asbestos risks. He noted:

It would be good to append a concluding sentence to the effect that these data support the conclusion that the WTC collapse resulted in increased indoor asbestos levels in lower manhattan.

Dr. Kinney also advocated that NCEA provide more information in its assessment and clearly communicate the potential risks to the public. For example, Dr. Kinney's written comments expressed concern that the public may obtain an unwarranted sense of comfort from the wording in NCEA's Draft Assessment regarding occupational benchmarks. He noted that:

. . . the use of a health benchmark in a screening exercise is only valid if the health benchmark is appropriate for the population at risk, which I think is somewhat problematic here where occupational benchmarks are being used to screen risks in the general population. . . . somewhere early in the executive summary there needs to be a short paragraph explaining why occupational standards may not be directly relevant to general population health risk assessment, including issues of voluntary and compensated risks vs. involuntary risks, healthy workers vs. widely varying susceptibilities in general population. This very important point will not be obvious to the general reader.

Further, Dr. Kinney's oral comments during the peer review meeting July 14-15, 2003, showed his concern about the need for a comprehensive review of indoor air data and the need for EPA to earn the public's trust by advocating the use of the National Academy of Science's panel model to obtain an unimpeachable review of indoor air issues:

I would like to encourage them [EPA] to consider the advantages of having an independent scientific group take the lead on organizing it [an indoor air study or compilation of indoor air studies] mainly from the point of view that - the credibility of the results would probably be enhanced substantially over a purely sort of EPA or government- agency sponsored or centered effort. So, given the controversies that have existed to date, I think one way to sort of resolve the issues -- these really important issues about indoor air and exposure of health -- in a way that everybody is satisfied with, would be to get a bunch of external people . . . I am sort of thinking of the National Academy of Science's panel model, where on controversial issues, often government agencies will commission the National Academy of Science to form an independent group of scientists to go over an issue . . .

We also noted that Dr. Kinney's detailed written peer review comments reiterated his concern about the incomplete database. He stated that:

I believe that the overall conclusions of the evaluation are reasonable given the available data . . . The report [NCEA's Draft Assessment] is careful to point out that these are preliminary conclusions based on available data and that conclusions could change when new information becomes available.

Considering the qualification that was contained in the news article, Dr. Kinney's advocacy of full disclosure, his concern that the public understand the potential health risks, and the overall professional and constructive nature of the comments that Dr. Kinney made during the peer review process, his statements did not demonstrate that he had "taken sides" with respect to the issues being peer reviewed. We concluded that any potential biases arising from the statements cited by the Complainant were not so material as to warrant Dr. Kinney's exclusion from the panel. However, the fact that such opinions were expressed provided a basis for the perception that there may have been a bias, and supports the need for EPA or its Contractor to improve their efforts to ensure that peer review panels as a whole are balanced.

ORD's Perspective

ORD agreed that Versar could have done more to ensure balance regarding the viewpoints held by prospective panelists, but ORD emphasized that Versar sought balance regarding "scientific expertise," and ORD further stated that:

For this highly visible World Trade Center Assessment, the contractor, at EPA's direction, sought panelists who were familiar with the complex issues presented by this unique environmental disaster, even to the point of seeking out scientists who had conducted related research of their own on World Trade Center exposure and health impacts. The two scientists who had made the public comments noted in the complaint have both conducted World Trade Center exposure and health impact studies that ORD considers to be of high quality, and their input to the review spoke of their familiarity and expertise with the issues. In cases such as this, a strict adherence to a policy of avoiding scientists who have spoken on the topic being reviewed may not be warranted.

Question 6: Did EPA's Contractor Adequately Consider Balance in Selecting the Panel?

In expressing concerns about potential conflicts and biases with the panel, the Complainant noted that a wide divergence of opinions could be accommodated in a large balanced panel of expert scientists, but had concerns about a panel that only consisted of seven members for this peer review. In light of the allegations that certain panel members may have been biased in their points of view, we reviewed Versar's efforts to ensure that the panel was balanced. We believe EPA or its Contractor could have taken additional measures to obtain more information on prospective panelists' work experience and viewpoints, which would have necessitated additional actions on the part of EPA or the Contractor to assess the balance of the panel. For example, as noted in Section 4, Versar did not ask panelists to identify their present or prior clients whose interests might be affected by conclusions that could be drawn about WTC issues.

EPA Guidance Concerning Panel Balance

According to EPA's Peer Review Handbook, "the peer reviewers of a work product should represent a balanced range of technically legitimate points of view." The Handbook also points out that "cultural diversity and 'address' (e.g., industrial, academic, or environmental community) are other factors that can play a role in selecting peer reviewers."

The Handbook does not provide specific examples of inquiries that should be made to ascertain whether a panel "as a whole" is balanced with respect to viewpoints, but notes that established peer review groups such as EPA's Science Advisory Board (SAB) provide useful models for addressing balance and conflict of interest issues. As noted in a recent GAO report,² when selecting SAB panelists EPA specifically asks prospective panelists for information about their points of view related to the issue being reviewed.

²*Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance*, U.S. General Accounting Office, Rpt. No. GAO-04-328, April 2004.

Contractor's Efforts To Balance The Panel

The statement of work in NCEA's task order to Versar identified areas of expertise that were "desired" for the peer review panel. As required by EPA, Versar selected the 7 panelists from these areas. Although Versar took several steps to balance the panel, we saw no evidence of any special actions or considerations by Versar to ensure that the peer review panel for the NCEA Draft Assessment was balanced with respect to the specific allegations of the Complainant. As noted earlier, Versar did not inquire as to whether prospective panelists had publicly expressed viewpoints on the peer review subject matter. Accordingly, no consideration was given to the need to balance the panel with respect to publicly expressed viewpoints on the subject matter. We contacted the Versar Project Manager to determine whether other actions were taken to balance the panel, but we had not received a response at the time this report was prepared.

Panelists' Perspective on the Need To Balance WTC Draft Assessment Panel

We contacted each of the panelists to obtain their opinions on the balance of the WTC Draft Assessment Panel as a whole. Each panelist expressed his or her opinion that the panel, as a whole:

- contained the right mix of expertise,
- had an appropriate balance of ideas and opinions,
- examined the issues with an appropriate degree of balance, and
- allowed the expression of minority views.

None of the seven panelists had concerns about the way the peer review process was conducted. As shown in Appendix B, the peer review panelists' backgrounds included a variety of employers and technical expertise.

Conclusions

Additional measures could have been taken to identify potential biases and conflicts with prospective panel members. For example, EPA could have had its Contractor ask prospective peer review panelists if they had publicly expressed viewpoints – a procedure used in selecting EPA Science Advisory Board committees – regarding the issues to be peer reviewed. Further, EPA's Contractor did not take all the actions required by its contract with EPA, nor did the Contractor take all the actions prescribed in its own internal guidance documents. Had such measures been taken, it is likely that EPA's Contractor would have disclosed potential conflicts and perceived biases prior to formulation of the panel. As such, the Contractor could have identified the need to assess the

balance of the panel and taken steps to mitigate these perceived conflicts or biases.

Neither the statements made by the two panelists nor the work relationships of one panelist were so “direct and substantial” as to warrant their exclusion from the panel. Further, our review of the panel’s deliberations, comments, and peer review record did not disclose any biased input in the peer review process, and none of the panelists had concerns about the way the peer review process was conducted. However, in selecting future panels for sensitive or controversial issues, EPA and its contractors should take steps to identify prospective panelists’ viewpoints on the subject being reviewed, including prior public statements, and evaluate the need to resolve any potential biases disclosed through these actions, including whether the viewpoints of the panel should be balanced as a whole.

Recommendation

- 2-1 We recommend that the Director, National Center for Environmental Assessment, implement procedures to ensure that guidance in EPA’s Peer Review Handbook is followed in carrying out NCEA peer reviews, specifically that:
- a. NCEA’s peer review contracts, as well as any EPA peer review Contractors’ consultant agreements and subcontracts, contain written guidance concerning information to consider when evaluating potential conflicts of interest and biases, and
 - b. NCEA’s potential panelists are asked about the industry financing they have received, and their relationship with any clients whose interests might be affected by the subject being peer reviewed.

Agency Comments and OIG Evaluation

The Agency agreed that the contractor should have gathered more information from the prospective panelists and that ORD “should provide written guidance and detailed instructions to its peer review contractors concerning potential COI and biases.” On October 7, 2004, ORD issued Policy Announcement #NCEA-EM-05-01, which requires that specific conflict of interest (COI) provisions be included in task order statements of work for peer reviews, unless these provisions are waived by the NCEA Director (see Appendix E for this Policy Announcement). These provisions adequately address our concerns. ORD did not request any changes in the draft report wording of Chapter 2 except for the addition of a few words to our first recommendation. We made the requested change to reflect our agreement with ORD.

Chapter 3

Observations on Panel Formation and Balance

In addressing the six questions discussed in Chapter 2, we relied heavily upon EPA's Peer Review Handbook for guidance and criteria in evaluating EPA's and its Contractor's actions in conducting the peer review. The Handbook was viewed as the key guidance on how to conduct an EPA peer review. We noted that the Handbook did not always give sufficient instructions on how to define and treat issues such as bias and panel balance. Accordingly, we contacted EPA officials who helped develop the Handbook to better understand the intent of the Agency's guidance. Based on our review of the Handbook, our discussion with these EPA officials, and the issues discussed in Chapter 2, we believe EPA's Handbook should be supplemented with additional instructions on how EPA and its contractors should select panels for highly controversial and sensitive issues, such as the risk assessment conducted for the WTC Draft Assessment.

Handbook Guidance on Panel Balance

EPA's Peer Review Handbook says that "As a general rule, experts who have made public pronouncements on an issue (e.g., those who have 'taken sides') may have difficulty in being objective and should be avoided," and that EPA is "strongly encouraged to obtain peer reviewers who do not have a legal or perceived conflict of interest." Further, EPA is to exercise an extra degree of care in selecting panelists on sensitive or controversial issues, which in our view includes EPA's Draft Assessment on exposure and health risks from air pollution after the collapse of the WTC towers. However, EPA's Peer Review Handbook also notes that obtaining appropriate expertise may mean that some panelists with potential conflicts and biases are nonetheless needed. For example, the Handbook notes that key methods for handling such concerns involve, among other things, full disclosure of potential conflicts of interest and ensuring that the panel is balanced as a whole.

Experts' Comments on EPA's Peer Review Handbook

EPA's Peer Review Handbook states that established peer review groups, such as EPA's SAB, provide useful models for addressing balance and potential conflict of interest issues. As such, we discussed these issues with four knowledgeable experts on peer review issues – one of the principal authors of EPA's Handbook, the Director of EPA's SAB, an SAB Ethics Official, and a former EPA Office of General Counsel Attorney who advised the authors of the Handbook.

The principal author of the Handbook we contacted told us that, in creating the Handbook, the authors had not intended to provide a "cook book" but had, instead, intended to provide a generic document that provided significant

flexibility to the peer review leader in forming a panel considering the range and variety of EPA scientific and technical work products that are peer reviewed. He and the SAB Director noted that the Handbook allows the peer review leader to consider the sensitivity or controversial nature of the work product, and the importance of the document for Agency decision-making, as well as the cost and time required. They noted both cost and time can increase dramatically with more elaborate peer reviews.

In summary, they believed that the existing Peer Review Handbook, if properly implemented, generally provides sufficient guidance and flexibility for carrying out an effective peer review. The Handbook's principal author also noted that revising the Handbook would require a great deal of effort. Nonetheless, the principal author acknowledged that additional guidance for dealing with particularly complex issues – such as potential bias and panel balance – could be helpful. The Handbook author noted that he would prefer to do this by providing peer review leaders with supplemental guidance regarding the types of information they may need to obtain about potential panelists' opinions and viewpoints when they assess whether panels are independent and balanced. They could also issue a supplemental package of training materials to peer review leaders, and ensure that EPA project managers and EPA contractors receive this training.

We also discussed ways to mitigate the potential for public perceptions that a panelist might have a conflict of interest or a bias. The SAB Ethics Official told us that, generally, “the best disinfectant is public involvement.” Noting that the SAB now publicizes potential candidates on its website, we discussed the advantages and disadvantages of this practice for EPA's other peer reviews. The SAB Director and the Ethics Official noted that publicizing relevant biographical information about potential panelists on EPA's website for a specific time, such as 2 weeks, and soliciting and considering public input concerning the proposed composition of a panel during the panel formation process, would be possible. However, it would cost more and take longer, and some prospective panelists may exclude themselves from the candidate pool under this approach, making it even more difficult to find qualified peer reviewers. Both the SAB Director and the Ethics Official noted that considering public input on panel formation could be worthwhile for the more sensitive and controversial peer reviews.

Prior OIG Report Discussed Concerns With EPA Efforts to Assess Peer Reviewers' Independence

The OIG last reported³ on EPA's efforts to ensure proper implementation of peer reviews in 1999. The OIG reviewed 32 work products that were peer reviewed – 14 peer reviews arranged by EPA program offices, 12 by EPA contractors, and 6 by the SAB or the Science Advisory Panel. The OIG found that the SAB and

³*EPA's Selection of Peer Reviewers*, EPA Office of Inspector General, Rpt. No. 1999-P-217, Sept. 1999.

Science Advisory Panel's peer review procedures were effective and being followed. However, the OIG identified instances where peer review leaders in EPA program offices and contractors did not effectively attempt to determine whether conditions existed that may have precluded an independent review. Regarding peer reviews contracted by EPA's program offices, the report concluded that:

. . . 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. . . . we are recommending that ORD (Office of Research and Development) issue supplemental guidance to the Handbook to help identify and resolve independence concerns.

Increased Federal Attention to Peer Review Panel Balance

The selection of peer review panels for review of government documents has received considerable attention and scrutiny recently. In September 2003, the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs published a draft Peer Review Bulletin and, in April 2004, OMB issued a revised version based on the numerous comments received. Both versions, if approved, would establish minimum standards for when a peer review is required for "scientific information" and the types of peer review that should be considered by Federal agencies in different circumstances. The need for OMB guidance on conducting peer reviews is based, in part, on a 1999 GAO report which found variability in both the definition and implementation of peer reviews across Federal agencies.⁴ The OMB Bulletin specifically emphasizes consideration of expertise and balance when selecting peer reviewers. The Bulletin states that:

Reviewers should also be selected to represent a diversity of scientific opinions relevant to the subject. On most controversial issues, there exists a range of respected scientific viewpoints regarding the interpretation of the literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review.

With respect to reviewers who are not Federal employees, the draft Bulletin states that agencies should "adopt or adapt" the prevailing practices of the National Academy of Sciences regarding committee composition, conflicts, and balance. Potential candidates for National Academy of Sciences' peer review committees are required to complete a "Background Information and Confidential Conflict of Interest Disclosure" form. Among other things, this form asks that prospective panelists list their relevant articles, testimony, speeches, etc., and the relevant

⁴*Federal Research: Peer Review Practices at Federal Agencies Vary*, U.S. General Accounting Office, Rpt. No. GAO/RCED-99-99, March 1999.

positions of any organization or group with which the candidate is closely identified or associated. The form defines “relevant” as information

... related to – and might be reasonably of interest to others concerning – your knowledge, experience, and personal perspectives regarding the subject matter and issues to be addressed by the committee activity for which this form is being prepared.

An April 2004 GAO report⁵ commented on the lack of guidance to assist agencies in ensuring better independence and balance in Federal advisory committees, and provides useful information with respect to assessing conflict of interest and balance questions in other peer review efforts. For example, GAO reported that General Services Administration guidance on advisory committee management does not address the types of information that could be helpful to agencies in assessing the points of view of potential committee members, nor do agency procedures identify the information that should be collected about potential members to make decisions about committee balance.

Conclusions

Given the importance of peer review in maintaining the integrity of EPA’s various scientific and technical work products, EPA should take steps to ensure that the Handbook is followed when conducting peer reviews of highly sensitive or controversial subject matters, and that issues of potential bias and overall panel balance are sufficiently addressed. Two such actions would involve (1) issuing supplemental guidance for peer review leaders on the types of information they may need to obtain about potential panelists’ opinions and viewpoints when they assess whether panels are independent and balanced, and (2) ensuring that peer review leaders receive training on this supplemental guidance.

Recommendations

We recommend that the Assistant Administrator for Research and Development, as the Agency Science Advisor:

- 3-1 Revise the Peer Review Handbook or issue supplemental guidance – applicable to peer review of sensitive or controversial issues – that EPA and its contractor should follow in identifying and addressing potential conflicts of interest and biases, and for ensuring that panels are balanced as a whole. Among other things, this guidance should include procedures for:

⁵*Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance*, U.S. General Accounting Office, Rpt. No. GAO-04-328, April 2004.

- a. explicitly determining whether prospective panelists have viewpoints on the issues to be peer reviewed and, if so, whether these viewpoints have been expressed publicly;
 - b. using general guidelines to assist peer review leaders in determining whether a panel is balanced as a whole;
 - c. handling potential conflicts of interests and biases that are identified after the panel has been selected;
 - d. ensuring that contracts for peer review services reference the Peer Review Handbook as criteria to be used by the contractor in selecting panelists;
 - e. documenting the basis or rationale for final panel formation prior to commencement of the peer review, particularly the actions taken to address any potential conflicts of interest, biases, and to ensure panel balance; and
 - f. identifying the extent to which the public should be involved in the peer review process and, in particular, under what circumstances the Peer Review Leader should consider soliciting input from the public on the potential makeup of the peer review panel.
- 3-2 Revise the training materials for peer review leaders and others involved in peer reviews for identifying and addressing potential conflicts of interest and biases, and ensuring panel balance; and ensure that peer review leaders, EPA project managers, and EPA contractors receive this training.
- 3-3 For highly sensitive or controversial peer reviews, consider the development of procedures for using the Agency’s website to electronically post proposed panel designs, and obtain public comments on proposed panel designs prior to panel formation, in a manner similar to that presently employed by the Science Advisory Board.
- 3-4 In regard to the overriding need to obtain as much information as necessary to provide reasonable assurance that potential panelist will be impartial, consider the information-collection forms that are used by the Science Advisory Board and the National Academy of Sciences (these forms can be found at http://www.nas.edu/coi/BI-COI_FORM-2.pdf and at <http://www.epa.gov/sab/pdf/epafom3110-48.pdf>).

Agency Comments and OIG Evaluation

The Agency agreed with our recommendations, noting that “. . . additional steps are needed to ensure that additional attention is given to the formulation of peer review panels” Agency officials also stated that they plan to develop

“supplemental guidance and instructions that articulate the procedure(s) for identifying and addressing potential COI and biases as well as for ensuring that panels are balanced as a whole” The Agency also agreed that Versar could have done more to ensure balance regarding the viewpoints held by potential panelists, but pointed out that NCEA emphasized that Versar sought balance regarding “scientific expertise.” NCEA suggested wording be added to our report to this effect, which we included in its entirety at the end of our discussion of the fifth allegation. We also clarified one recommendation in this chapter, as requested by ORD, to recognize that ORD already provided training and training materials for peer review leaders and others involved in peer reviews, but that the Agency would be developing additional training emphasizing identifying and addressing potential conflicts of interest and biases, and ensuring panel balance. The actions already completed, ongoing, and planned to ensure that scientific and technical work products consistently receive adequate peer review, if properly implemented, address our concerns.

Complainant's Allegation Memorandum



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

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

DATE: July 16, 2003

MEMORANDUM

SUBJECT: Conflict of interest and prejudicial statements, expert peer review panelists for EPA NCEA report titled: "Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster"

TO: WTC Team, EPA Inspector General's Office: Jim Hatfield, Chris Dunlap, Geoff Pierce, Dana Gilmore, Sarah Fabickiewicz, Steve Schanemann, Nikki Tinsley, EPA Inspector General, Paul McKechnie, EPA Ombudsman

FROM: Cate Jenkins, Ph.D., Environmental Scientist,
Hazardous Waste Identification Division, OSW
jenkins.cate@epa.gov

The EPA National Center for Environmental Assessment (NCEA) document titled "Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster" dated October, 2002, released to the public in late December, is undergoing peer review by an outside expert panel. There are real conflicts of interest and prejudicial statements by 3 of the 7 panelists. This will harm the integrity of EPA's risk assessment.

A wide divergence of opinions could be accommodated in a large balanced panel of expert scientists. However, the expert review panel includes only 7 participants. The public was not given any opportunity to comment on the choice of these individuals, or an opportunity to suggest other members who could represent the views of the community, as required by the National Contingency Plan.

* The conclusions and opinions in this memorandum are those of the author and do not necessarily reflect those of the U.S. Environmental Protection Agency.

EPA has failed to insure that the government acts with impartiality and provide the public with full opportunity for participation in the risk assessment process for the WTC disaster. In my 7/4/03 report and memorandum to the EPA Inspector General,** evidence was provided of EPA's similar failure to prevent conflicts of interest in expert panelists chosen for the EPA/IRIS asbestos reassessment.

EPA did not require their contractor, Versar, to obtain all relevant information from potential panelists, including asking specific questions whether potential panelists had ever stated conclusions that there were no hazards from WTC exposures, or to require the submission of full disclosures of all business relationships with industries that would be affected by EPA findings on WTC exposure hazards.

The Federal Acquisition Regulations Section 9.501 define conflicts of interest of governmental contractors as follows:

“... because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person's objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage.”

EPA has issued specific guidance on evaluating and handling post contact award conflict of interest situations in Procurement Policy Notice No. 95 - 04, Procedures for Handling Post Award Organizational Conflicts of Interest (COI), dated 9/20/95, posted on the EPA website at <http://www.epa.gov/oam/ptod/COI/ppn95-04.pdf>. Specific questions are posed for EPA to inquire of contractors to determine potential conflicts. COI criteria also include EPA evaluations of the sensitivity of the work being performed by the contractor. EPA implemented none of these procedures to control COI in the expert peer review panel for the NCEA risk assessment.

Eric Chatfield, expert witness for W. R. Grace asbestos company

One member of EPA's peer review panel for the NCEA risk assessment is Eric Chatfield. He is a paid expert witness for W.R. Grace & Co., the firm responsible for the asbestos contamination in homes in Libby, Montana, the Superfund site. Litigation has been brought against Grace by the U.S. Department of Justice.

In an expert report dated 8/30/02, Chatfield strongly opposed EPA's analytical evaluation of risks in homes in Libby. A copy of his expert report is attached to this memorandum, which reads in part as follows:

** Jenkins, C. (1/4/03) Comments on the EPA Office of Inspector General's 1/27/03 interim report titled: EPA's Response to the World Trade Center Towers Collapse — A DOCUMENTARY BASIS FOR LITIGATION. This report is available at the following 2 websites:
www.NYenviroLAW.org (see banner at top of page) and <http://www.nycosh.org/#anchor15430>

I have reviewed the action memoranda for the Libby site, the administrative record for the period May 23, 2000 to June 4, 2002, the expert reports I have also reviewed the ATSDR Health Consultation dated December 12, 2000, a Report to the Community dated August 23, 2001, and a report entitled "Health Risks from Exposure to Zonolite Home Insulation: Critical Evaluation of the Scientific Evidence Available from the ATSDR Studies in Libby, Montana.

• • •

I have determined that there are significant deficiencies in the underlying analytical data that form the basis for the risk assessments conducted by EPA. I have also determined that some analytical methods have not been used in accordance with the specifications of the methods, and that some of the analytical methods used are not capable of providing a reliable foundation for the decisions being made.

• • •

[Report No. 02C029, Expert Report of Eric J Chatfield, Ph.D., in the matter of: United States v. WR. Grace & Co., et al., Civil Action No. 01-72-M-DWM (D.Mont.), 8/30/02]

On 7/14/03, Chatfield is reported as telling the participants in the peer review meeting for the EPA NCEA report that he did not think it was important to mention his work for Grace in the biography he provided to meeting participants, and that his work for Grace was minimal. He is incorrect on both points.

First, his work for Grace is not minimal or in the past. Providing an "expert report" to a defendant in active litigation is just one step in the services provided by an expert witness.*** In order for the expert report to be of any use to Grace, the expert also must make himself available to the litigant, in this case the Dept. of Justice, for deposition. Otherwise, the expert report would not be admissible as evidence. The expert witness would also need to be available to testify in court in the event that the case went to trial.

Second, his business connection with Grace is extremely relevant to the WTC investigation. This is because Grace has been using for its legal defense comparisons between EPA's stringent cleanup standards for homes in Libby compared to the lenient standards EPA has imposed for the WTC cleanup. Grace is also using in its defense the fact that homes in Libby are less contaminated with asbestos than buildings in Manhattan after the WTC collapse.

Thus, Grace has a vested interest in having EPA conclude (by way of the NCEA human health assessment document) that citizens in NYC are not at risk from asbestos exposures. They can then directly use these EPA conclusions to escape responsibility for the contamination in Libby.

*** As a note for the record, on 7/14/03, Chatfield told the meeting participants that it was I who was seeking a copy of his expert report through a Freedom of Information Act request, and that he would have gladly supplied me with a copy if I had written. This also is untrue, as it was a concerned parent from the Brookfield school system, Kathy Hulce, who sought this report and obtained it from EPA through the FOIA. Neither the citizen nor I knew of the existence of the expert report until it was provided by EPA. The FOIA request was broad and included all writings by Chatfield submitted to EPA regarding WR Grace. Furthermore, on 5/30/02 I wrote to Chatfield for clarification of claims he made to the same Ms. Hulce regarding the Brookfield school system and received no reply, so it would not have appeared fruitful for me to have made any new inquiries directly to Chatfield.

The following are two letters (attached) from Grace to EPA, written in the same time frame as Chatfield's expert report, which illustrate this point.

The first letter, below, attempts to gain more lenient cleanup standards for Libby based on the fact that EPA is imposing less stringent asbestos air and dust standards in New York City after the WTC collapse:

The purpose of this letter is to continue Grace's dialogue with EPA regarding Zonolite Attic insulation ("ZAI"), a home insulation product consisting of expanded vermiculite. For your background, ZAI has been insulating homes for over 60 years and there is no credible reason to believe that ZAI has ever caused an asbestos-related disease in anyone who has used it in his/her home. Nevertheless, EPA Region 8 is requesting that EPA declare, for the first time ever, that a "public health emergency exists at a (proposed) Superfund site.

. . .

Contrasted to Region 8's disregard of established norms, EPA's pronouncements and activities regarding the World Trade Center collapse reaffirm those norms. Thus, EPA's website reiterates that:

- EPA is using the 1% definition of an asbestos-containing material in evaluating dust and bulk samples.
- Air samples are the accurate measure of actual exposure potential, whereas the presence of asbestos in dust is not necessarily a significant health hazard.
- EPA uses the "extremely stringent" standard under AHERA of 70 structures/sq. mm. to evaluate the risk from asbestos in the outdoor and indoor air. That standard was expressly chosen because it is the most stringent and protective, and is based on assumptions of long-term exposure.
- Asbestos exposure becomes a health concern when high concentrations of asbestos fibers are inhaled over a long period of time. The fact that a small percentage of samples exceeded the AHERA standard was not considered to be evidence of a significant health risk.

We believe that sound science dictates that the same peer reviewed methodologies for assessing risks at the WTC should be applied across the board, including in Libby, Montana.

. . .

[emphasis in original] (letter to Christine Todd Whitman, Administrator, EPA, from William M. Corcoran, Vice President, W. A. Grace & Co., dated 4/10/02)

In the next letter, WR Grace compares asbestos contamination levels in Libby to those in NYC after the WTC collapse. WR Grace states that residences in Manhattan are more contaminated than in Libby (which is true). This is also offered as a rationale for not cleaning up Libby to the more stringent standards imposed by Region 8, since the cleanup in Manhattan is rudimentary and slipshod in comparison to that being required for Libby.

We appreciate the opportunity you gave us on January 31 to present Grace's view of the data from Libby, Montana that EPA is using to guide its decision regarding removal of Zonolite Attic Insulation from homes in that community.

I would like to summarize several of the points that were made in the meeting.

...

Based on the data we have seen, there are very low levels of asbestos in surface dust in homes in Libby, Montana. There is only chrysotile found on windowsills, which is a key collection point. In all surfaces in Libby, chrysotile fibers exceed amphibole fibers by 3X to 30X. In fact, asbestos concentrations in dust in Libby homes is significantly lower than that found in New York City before 9/11, is far below that found after 9/11, and is significantly lower than the concentrations that EPA found in studies of carpets, ceilings, and lights.

...

[letter to Michael Shapiro, Principal Deputy Assistant Administrator, Office of Solid Waste and Emergency Response, EPA, from William M. Corcoran, Vice President, W R. Grace & Co., dated 2/6/02]

Prejudicial statements by other panelists

Two other panelists are known to have advised the public through the press that there were no hazards from WTC exposures. Their statements are prejudicial, making it difficult for them to change their opinions at this later date to agree with any EPA conclusions, no matter what the data, that there are potential or real risks from WTC exposures.

There would not be the same kind of legal liability problem for a panelist and their parent institutions if the panelist had earlier advised the public to take precautions over and beyond those recommended by public officials at the time. Such a person could easily state that new evidence demonstrated that such precautions were unnecessary. They would not now be in a liability situation of having failed to warn the public in the past, puffing them at risk.

Prejudicial statements by Patrick Kinney

One panel member, Patrick Kinney, has gone on record to state that tests had conclusively demonstrated that asbestos concentrations as well as the other measured toxic constituents were not of concern.

It would be difficult if not impossible for Kinney to now agree with any conclusions by EPA that there are potential risks, because that would constitute a reversal of earlier advice Kinney offered to the public through the press on the safety of returning home and being exposed to uncontrolled WTC dust. Any findings or recommendations on the NCEA draft by Kinney would always be influenced by his earlier "on record" comments below. There may be many other places where Kinney made such statements as well.

More than six weeks after the September 11 terrorist attack on New York, fires are still smoldering under the debris of the former World Trade Center complex. The continuing smoke is worrying some city residents about the quality of the air they are breathing.

City officials have tried to reassure New Yorkers, ordering a series of on-going tests to monitor air quality. Patrick Kinney specializes in the effects of air quality on respiratory systems at Columbia University's School of Public Health. He says the tests show there are no toxic pollutants, like asbestos, tainting the quality of air. "The data that has been collected so far do not show concentrations of pollutants that are of concern," adds Professor Kinney. "However, not all of the pollutants that you might want to look at have been monitored or, at least, reported yet. So the database is incomplete. Based on what we know so far, there is no cause for alarm."

...

But Professor Kinney says it is unlikely that new data will show any pollutants that put people at risk. "I do not think it was unwise to have people start repopulating the area," he says. "I think that our noses are very sensitive and we pick up a lot of things that are not necessarily toxic. I think it is good to be careful, to minimize exposure as much as possible. For the general public, as long as we are careful, I think the risks are quite low."

...

[emphasis added] [NY Residents Worry About Air Quality, Barbara Schoetzau, New York, 10/28/01, <http://www.help-for-you.com/news/Oct2001/Oct28/PRT28-38Article.html>]

Prejudicial statements by Allison Gevh

The peer review panelist Alison Geyh has also made definitive conclusions that asbestos testing showed no harmful levels, and that there were no lung obstructive airway problems for citizens. As with the panelist Kinney, it would be difficult for Geyh from a liability standpoint to now agree with any EPA conclusions indicating a hazard or compromised health risk.

Investigators from the Johns Hopkins Bloomberg School of Public Health now believe that World Trade Center workers' respiratory problems are the result of exposure to dust and airborne contaminants at Ground Zero. Workers assigned to clear debris have reported coughing, wheezing and sore throats while working at Ground Zero. The symptoms seemed to increase the longer they worked at the site, according to Dr. Alison Geyh, the chief investigator and assistant professor of environmental health sciences at Johns Hopkins. "The good news is that we did not find unhealthy levels of asbestos, but we don't know what the long term health risks may be regarding exposure to other airborne contaminants at the site."

...

[emphasis added] World Trade Center Health Update Summarized by Cheryl Runyon from the Environment News Service AmeriScan, Aug. 23, 2002, <http://www.ncsl.org/programs/esnr/wtchealth.htm>]

In a study of more than 180 cleanup workers, researchers at Johns Hopkins Bloomberg School of Public Health found that acute respiratory symptoms such as coughs, phlegm and wheezing were more prevalent than before they began working at the site. But in most workers, said Dr. Alison Gevh, the lead researcher, there was no sign of lung obstruction.

"For the general community this is a very good story," Geyh said.

...

*[Researchers tell of health studies tied to WTC disaster; By Carl Glassman, 11/2/01,
Online News From The Tribeca Trib <http://www.tribecatrib.com/newsnov02/enviro2r.html>]*

cc: Peter Preuss, Director, EPA ORD NCEA
Lester Grant, Director, EPA ORD NCEA-RTP subdivision
Affected parties and other responsible officials

Peer Review Panelists and Backgrounds

Panelist	Title	Expertise	WTC Experience
Eric J. Chatfield, Ph.D.	President, Chatfield Technical Consulting Limited	Asbestos measurement methods	Performed limited indoor dust/asbestos sampling for Ground Zero Elected Officials Task Force.
Michael Dourson, Ph.D.	Director, Toxicology Excellence for Risk Assessment	Human health risk assessment	Organized and chaired the peer review of EPA's Contaminants of Potential Concern report.
Alison Geyh, Ph.D.	Assistant Professor, John Hopkins University Bloomberg School of Public Health	Particulate matter monitoring and exposure/ risk assessment; personal monitoring and epidemiology	Principal investigator on project to assess the health of workers who were involved in cleanup and recovery efforts at the WTC site and Fresh Kills Landfill.
Gary Hunt, M.S.	Vice President of Air Toxics Programs and Director of Air Toxics Monitoring, TRC Environmental Corporation	Characterization, quantification and control of toxic air pollutant emissions from stationary and fugitive sources.	Consultant to New York City Law Department relative to monitoring performed in the aftermath of the WTC collapse.
Patrick Kinney, Sc.D.	Associate Professor, Mailman School of Public Health at Columbia University	Human health impacts of air pollution	Limited involvement in Columbia University/National Institute of Environmental Health Sciences project to evaluate exposure and epidemiological data.
Margaret MacDonell, Ph.D.	Argonne National Laboratory, Department of Energy	Risk assessment	None
Clifford P. Weisel, Ph.D.	Deputy Director, Exposure Measurement and Assessment Division; Environmental & Occupational Health Sciences Institute	Exposure assessor (particulates, volatile organic compounds, other urban air pollutants)	Co-author on papers about exposure associated with WTC disaster based on samples collected and analyzed with funding from National Institute of Environmental Health Sciences.

Agency Response to Draft Report

October 21, 2004

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: Response to OIG Draft Special Report – World Trade Center Peer Review

FROM: Paul Gilman /s/ *William Farland* for
Assistant Administrator (8101R)

TO: Kwai-Cheung Chan
Assistant Inspector General for Program Evaluation (2460T)

Purpose

This memorandum responds to the OIG Draft Special Report: *Review of Conflict of Interest Allegations Pertaining to the Peer Review of EPA's Draft Report, "Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster,"* #2003-001585, dated September 15, 2004.

Background/Discussion

ORD generally finds the draft report prepared by the Office of the Inspector General (OIG) to be reasonable. Although we concur with most of the recommendations, there are several points which still merit clarification both with respect to the evaluation and specific recommendations. Detailed comments are attached that we believe will sharpen the quality and accuracy of the draft report (Attachment 1).

ORD agrees with the primary findings of the draft report that it does not appear the panel's input was biased and any potential perception of bias or conflict was not so direct and substantial that any of the panelists should have been excluded from the panel. Specifically, the draft report found that the two scientists who had publicly expressed opinions regarding certain World Trade Center (WTC) hazards do not appear to have had significant biases, and the specific scientist who was alleged to have a conflict of interest (COI) was found not to have such a conflict. We agree, however, that a prior business relationship of this latter scientist may have resulted in a perception of a COI. Further, while it appears that ORD's contractor (Versar) took reasonable steps to assemble a balanced panel for the review, we agree that we want our contractors to collect more information relevant to potential COI or bias than was the case here. ORD's National Center for Environmental Assessment (NCEA) will provide more specific direction to that effect to its contractors.

ORD wants to have the best peer review practices possible for Agency products. With that end in mind, I will comment on the specific recommendations provided in the draft report.

Recommendation 2-1: Specific Recommendations to the Director, National Center for Environmental Assessment, concerning peer review procedures and guidance

NCEA agrees with the OIG that the contractor could have gathered more information about financial ties with parties whose interests might have been affected by the conclusions presented in the health evaluation document. We agree with the recommendations in Chapter 2 that NCEA should provide written guidance and detailed instructions to its peer review contractors concerning potential COI and biases.

NCEA has been working on language to articulate more specifically the kinds of information to be collected by the contractor from potential peer reviewers in regard to employment and professional affiliations, financial relationships, prior involvement on related issues, and publicly made statements or a position taken on the subject chemical or topic under review. The Deputy Director of NCEA recently signed a memorandum with instructions to NCEA staff on this issue (Attachment 2). This information will provide the contractor the basis to determine whether such parties might be affected by the outcome of the peer review. Additionally, this information will be requested for all future NCEA peer review panels unless waived by the Center Director. In the future, NCEA's contractors will be required to provide a signed certification to the EPA that can be made public stating there are no unresolved actual or potential COI issues among the panel members and that the panel is suitably balanced with respect to any actual or apparent bias. We believe this fulfills Recommendation 2-1.

While not a specific recommendation in the report, I note that public input into the composition of a peer review panel is not a current requirement. Some bodies such as the EPA Science Advisory Board (SAB) have adopted that step into their procedures. NCEA may, at times, provide the public an opportunity for public input to the panel selection. In that circumstance, the public comments collected by the contractor on the composition of the proposed panel with respect to expertise, COI and bias may be considered and appropriate adjustments to the panel may be made.

Recommendation 3-1: Specific Recommendations to the Assistant Administrator for Research and Development concerning revision of the Peer Review Handbook

We agree that additional steps are needed to ensure that additional attention is given to the formulation of peer review panels for products anticipated to be highly controversial and/or address sensitive issues. An overarching recommendation from the OIG draft report is that the EPA's *Peer Review Handbook* be supplemented with additional instructions to address this issue (see page 22 of draft report). Our plan is to develop additional guidance to address Recommendation 3-1, "Revise the *Peer Review Handbook* or issue supplemental guidance – applicable to peer review of sensitive or controversial issues – that EPA and its contractor should follow in identifying and addressing potential COI and biases, and for ensuring that panels are

balanced as a whole.” We do not plan to revise the *Peer Review Handbook* per se, because we believe it stands, as written, as a good resource and is not intended to be a “cook book” of specific types of procedures. Rather, ORD and the Science Advisor believe that, to clarify how to manage peer reviews involving sensitive or controversial issues, it is more appropriate to use supplemental guidance and instructions that articulate the procedure(s) for identifying and addressing potential COI and biases as well as for ensuring that panels are balanced as a whole (e.g., follow and adhere to the guidance and intent of the *Handbook* and Federal Acquisition Regulations).

ORD and the Science Advisor view the specific recommendations and detailed suggestions (particularly Recommendations 3-1 to 3-4) as useful to consider in providing such supplemental guidance as a means to help ensure “that the Handbook is followed when conducting peer reviews of highly sensitive or controversial subject matters, and that issues of potential bias and overall panel balance are sufficiently addressed” (see conclusions page 25 of draft report). A list of example questions that peer review leaders and contractors might use can be incorporated into the supplemental instructions. Example questions could be: “What funding from any present or prior clients (e.g., industry, EPA, others) have you received?” and, “Have you expressed viewpoints on the issues being reviewed; if so, when and in what forum?” Also, the instructions can detail specific actions peer review leaders and contractors can take to address potential COI, documentation of actions, and public involvement. We believe these example questions and actions will incorporate the OIG’s specific points (Recommendation 3-1, a.-f.) .

Therefore, we request Recommendation 3-1 be revised to read: “EPA should consider providing further guidance on procedures.”

Recommendation 3-2: Specific Recommendations to the Assistant Administrator for Research and Development for the development of training materials

ORD’s Office of Science Policy has conducted peer review training for the Agency based on the policies and procedures described in the Agency’s Peer Review Handbook and guidance from the Office of Management and Budget (OMB). In addition, there are regular meetings of the Agency’s peer review coordinators to discuss peer review issues. We are currently revising the training materials and plan to conduct additional training in the future. We request the report be changed to state that training materials will be “revised” v. “developed.”

Recommendation 3-3: Specific Recommendations to the Assistant Administrator for Research and Development concerning the development of a peer review website

The Agency will develop a peer review website. We agree that the recommended changes to the existing website information and other changes required to respond to the proposed OMB guidelines on peer review should be available online.

Recommendation 3-4: Consider adoption of forms used by the Science Advisory Board (SAB) and the National Academy of Sciences (NAS)

The suggestion to use information-collection forms to obtain as much information as necessary is also very helpful. The Science Policy Council will be asked to adopt an Agency-wide policy directing its contractors to use the forms developed by the SAB and NAS.

We have also included the ORD corrective action plan to address recommendations made in the draft report. Since ORD has already completed some of the required actions and identified milestones for others, we believe the final report should state this and be closed upon issuance.

We appreciate the OIG making a careful evaluation of the accusations that were made about the peer review of the EPA Draft World Trade Center Report. Peer reviews are an important component of the Agency's quality assurance program, and we take seriously their conduct. Should your staff have questions or require further information, please have them contact Cheryl Varkalis at 202-564-6688.

Attachments (2)

cc: W. Farland
L. Matthews
K. Dearfield
P. Preuss
M. Lorber
J. Morris
C. Varkalis

ORD Corrective Action Plan

OIG Special Report: Review of Conflict of Interest Allegations Pertaining to the Peer Review of EPA’s Draft Report, “Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster”

Assignment No. 2003-001585

September 15, 2004

Rec #	Recommendation	Action Official	Corrective Action	Due Date
2-1	We recommend that the Director, National Center for Environmental Assessment, implement procedures to ensure that guidance in EPA’s Peer Review Handbook is followed in carrying out NCEA peer reviews, specifically that: (a) NCEA’s peer review contracts, as well as any EPA peer review Contractors’ consultant agreements and subcontracts, contain written guidance concerning potential conflicts of interest and biases, and (b) NCEA’s potential panelists are asked about the industry financing they have received, and their relationship with any clients whose interests might be affected by the subject being peer reviewed.	Director, NCEA	Memorandum on peer review conflicts of interests distributed to NCEA staff	Completed 10/07/2004
		Director, NCEA	Memorandum on peer review conflicts of interests distributed to NCEA staff	Completed 10/07/2004
3-1	Revise the Peer Review Handbook or issue supplemental guidance – applicable to peer review of sensitive or controversial issues – that EPA and its contractor should follow in identifying and addressing potential conflicts of interest and biases, and for ensuring that panels are balanced as a whole.	Assistant Administrator for Research and Development	Develop additional guidance to supplement the existing Peer Review Handbook	6/30/2005
3-2	Develop training materials for peer review leaders and others involved in peer reviews for identifying and addressing potential conflicts of interest, biases, and ensuring panel balance, and ensure that peer review leaders, EPA project managers, and EPA contractors receive this training.	Assistant Administrator for Research and Development	Revise existing training materials and augment as necessary to provide additional information concerning conflicts of interests.	6/30/2005

3-3	For highly sensitive or controversial peer reviews, consider the development of procedures for using the Agency's website to electronically post proposed panel designs, and obtain public comments on proposed panel designs prior to panel formation, in a manner similar to that presently employed by the Science Advisory Board.	Assistant Administrator for Research and Development	Develop a Peer Review Website to post peer review guidance and information on specific panels	6/30/2005
3-4	In regard to the overriding need to obtain as much information as necessary to provide reasonable assurance that potential panelists will be impartial, consider the information-collection forms that are used by the Science Advisory Board and the National Academy of Sciences.	Assistant Administrator for Research and Development	Request Science Policy Council to adopt an Agency-wide policy directing its contractors to use the forms developed by the SAB and NAS.	6/30/2005

NCEA Policy Announcement

OCT -- 7 2004

OFFICE OF
RESEARCH AND DEVELOPMENT

Policy Announcement - NCEA-EM-O5-O1

Subject: Avoiding Peer Review Conflicts of Interest (COT)

From: George W. Alapas
Deputy Director for Management
National Center For Environmental Assessment

To: Staff Directors
Division Directors

Purpose

This memorandum implements a new approach related to identification and resolution of Conflict of Interest (COI) for external Peer Review Panelists. The affected extramural vehicles are NCEA's peer review contracts *Support for Peer Review and Risk Assessment Guidelines Activities* and NCEA's Interagency Agreement with the Department of Energy/ORISE *IRIS Technical Support for Human Health Risk Assessment, Peer Review and Related Activities*.

Effective Date: Immediately

Background

To assure that peer reviewers are providing impartial advice on the scientific merits of NCEA products, NCEA is incorporating specific COI provisions into Task Order (TO) Statements of Work (SOW) for peer reviews. These provisions will serve as a "tool" to aid the contractor in identifying an actual or potential COI that might impair the objectivity of peer reviewers.

Policy Statement

Panel peer reviews procured through NCEA's peer review contracts *Support for Peer Review and Risk Assessment Guidelines Activities* and NCEA's IAG with Department of Energy/ORISE *IRIS Technical Support for Human Health Risk Assessment, Peer Review and Related Activities* must include the attached COI requirements in the TO SOW, unless the requirement is waived by the NCEA Director.

Guidance

Each TO procuring peer reviewers shall include the *Conflict of Interest Analysis and Certification* (Attachment 1) and *Revised Conflict of Interest Section* (Attachment 1 a). For independent Government estimating purposes, 40 labor hours at a Pt 3 or comparable rate is allocated to accomplish this task. This estimate may be adjusted once information on the actual hours incurred is obtained from the contractor. In addition to the mandatory COI task, standard language has been developed for purposes of providing *Opportunity for Public Input to Panel Selection* (Attachment 2). This is an optional task to be included in the SOW at the discretion of the TO Project Officer.

Please address questions concerning implementation of this policy to Karen Summers, NCEA's Extramural Management Specialist, at (202) 564-4453.

cc: Associate Directors
Deputy Division Directors
Branch Chiefs

Attachments (3)

Task #. - Conflict of Interest Analysis and Certification (Mandatory)

- a. Prior to selecting expert panelists, the contractor shall perform an evaluation to determine the existence of an actual or potential COI for each proposed panel member. The contractor shall incorporate the attached yes/no questions (a.- i.) and requests for supporting information (j.-r.) into its established process to evaluate and determine the presence of an actual or potential COI. All information provided by the proposed panel member shall be verified by the contractor.
- b. The contractor shall resolve issues of actual or potential conflicts of interest and panel composition before assembling the panel. As each situation must be evaluated on a case-by-case basis after consideration of specific circumstances, the contractor may consult with the Contract Officer (CO) in carrying out these responsibilities. Consultation between the contractor and the CO must be documented and provided to the CO to assure transparency in the process and full disclosure, if questions arise concerning COI.
- c. The contractor shall provide written basis and signed certification that might be made public for concluding that there are no unresolved actual or potential conflicts of interest issues among the panel members, and to ensure that the panel is suitably balanced with respect to any actual or apparent bias.

Deliverable: Written basis

Signed Certification (See TO “Conflict of Interest” Section)

- d. The contractor shall require each panel member to provide a signed declaration that the panel member is not arranging any new professional relationship with, or obtaining new financial holdings in, an entity which is not yet reported to the contractor or could be viewed as related to the topic under discussion and its associated stakeholders.

Deliverable: Panel member signed declaration

- e. The contractor shall provide the Project Officer (PO) resumes for all panel members. These resumes might later be made public.

Deliverable: Resumes

Task #. - Conflict of Interest Analysis and Certification
Questions and Supporting Information

- a. To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any of your and/or your spouse's compensated or uncompensated employment, including government service, during the past 24 months? Yes ____ No ____
- b. To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any of your and/or your spouse's research support and project funding, including from any government, during the past 24 months? Yes ____ No ____
- c. To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any consulting by you and/or your spouse, during the past 24 months? Yes ____ No ____
- d. To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any expert witness activity by you and/or your spouse, during the past 24 months? Yes ____ No ____
- e. To the best of your knowledge and belief, have you, your spouse, or dependent child, held in the past 24 months, any financial holdings (excluding well-diversified mutual funds and holdings, with a value less than \$15,000) with any connection to the subject chemical or topic? Yes ____ No ____
- f. Have you made any public statements or taken positions on or closely related to the subject chemical or topic under review? Yes ____ No ____
- g. Have you had previous involvement with the development of the document (or review materials) you have been asked to review? Yes ____ No ____
- h. To the best of your knowledge and belief, is there any other information that might reasonably raise a question about an actual or potential personal conflict of interest or bias? Yes ____ No ____
- i. To the best of your knowledge and belief, is there any financial benefit that might be gained by you or your spouse as a result of the outcome of this review? Yes ____ No ____

- j. Compensated and non-compensated employment (for panel member and spouse): list sources of compensated and uncompensated employment, including government service, for the preceding two years, including a brief description of Work.
- k. Research Funding (for panel member): list sources of research support and project funding, including from any government, for the preceding two years for which the panel member served as the Principal Investigator, Significant Collaborator, Project Manager or Director. For panel member's spouse, provide a general description of research and project activities in the preceding two years.
- l. Consulting (for panel member): compensated consulting activities during the preceding two years, including names of clients if compensation provided 15% or more of annual compensation. For panel member's spouse, provide a general description of consulting activities for the preceding two years.
- m. Expert witness activities (for panel member): list sources of compensated expert witness activities and a brief description of each issue and testimony. For panel member's spouse, provide a general description of expert testimony provided in the preceding 2 years.
- n. Assets: Stocks. Bonds. Real Estate. Business. Patents. Trademarks, and Royalties (for panel member, spouse and dependent children): specific financial holdings that collectively had a fair market value greater than \$15,000 at any time during the preceding 24-month period (excluding well-diversified mutual funds, money market funds, treasury bonds and personal residence).
- o. Liabilities (for panel member, spouse and dependent children): liabilities over \$10,000 owed at any time in the preceding twelve months (excluding a mortgage on personal residence, home equity loans, automobile and consumer loans).
- p. Public Statements: A brief description of public statement and/or positions on or closely related to the matter under review by the panel member.
- q. Involvement with document under review: A brief description of any previous involvement of the panel member in the development of the document (or review materials) the individual has been asked to review.
- r. Other potentially relevant information: A brief description of any other information that might reasonably raise a question about actual or potential personal conflict of interest or bias.

Insert into SOW Under Conflict Of Interest Section
(Mandatory)

1. Certifying describing analysis and conclusion

The contractor shall provide the CO and P0 written certification, within the time specified in the Task # of the SOW after an award, that:

- a. The contractor has resolved all conflict of interest issues, either by eliminating a particular reviewer from the panel or by determining that the interest will not impair the individual's objectivity nor create an unfair competitive advantage for any person or organization.
- b. The contractor recognizes its continuing obligation to identify and report any conflicts of interest arising during performance of the task order
- c. All personnel who perform work under this task order or relating to this task order have been informed of their obligation to report any conflict of interest to the contractor who shall, in turn, report to the contracting officer

2. Ongoing Compliance Review during contract performance

- a. The contractor shall require advanced notification from panelist concerning changes to information disclosed under Task #.a.
- b. The contractor shall inform the CO and P0 of any change in financial or professional relationships that may create either an actual or potential conflict of interest or bias during the period of performance.
- c. The contractor shall consult the CO and P0 concerning available options in cases where actual or potential conflict of interest is determined.

3. Disclosure of Information Used in Conflict of Interest Evaluation

The financial and professional information obtained by the contractor as part of the evaluation to determine existence of actual or potential conflict of interest is considered private and non-disclosable to EPA or outside entities except as required by law or requested as part of a formal investigation by the EPA Office of Inspector General, General Accountability Office, Congressional Committee.

Task # - Opportunity for Public Input to Panel Selection
(Task required only when public comment on a panelist is required)

a. Public opportunity to recommend panel members

As the contractor assembles a proposed panel, the contractor shall review and consider public recommendations. Public recommendations for panel members will be provided as identified in the EPA generated Federal Register Notice. This notice will identify how members of the public can provide information needed to judge the expertise and appropriateness of the recommended reviewer.

b. Public comment on panel composition

Subsequent to EPA's acceptance of the comprised expertise of the proposed panel members, the contractor shall make publicly available a description of the proposed panel, the contractors' statement as to why they judge the panel to be without conflict of interest, or without significant bias that has been appropriately disclosed and balanced. The contractor shall invite public comment on the composition of the proposed panel with respect to expertise, conflict of interest and bias. The contractor shall assemble and consider the comments received and make any further adjustments appropriate to the panel. Copies of any comments received shall be provided to the EPA project officer.

Distribution

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