

Addendum to the *Peer Review Handbook*, 3rd Edition: Appearance of a Lack of Impartiality in External Peer Reviews

Overview:

The Office of the Inspector General (OIG) evaluated the U.S. Environmental Protection Agency's (EPA or Agency) process for conducting external peer review panels and made several recommendations in their report "EPA Can Improve Its Process for Establishing Peer Review Panels."¹ One of the recommendations of the OIG report was for EPA to provide more detailed guidance on the definition of an appearance of a lack of impartiality with regard to external peer review panels conducted either by Government employees or through the use of outside employees whose services are procured through a contract mechanism. This addendum to the 3rd edition of the [EPA Peer Review Handbook](#) ("Handbook") responds to this recommendation of OIG.

This guidance provides:

- a definition of an appearance of a lack of impartiality for individuals who serve on peer review panels either as Government employees or as experts hired under a contract mechanism;
- the criteria for applying the definition of an appearance of a lack of impartiality; and
- illustrative examples.

I. Background:

As noted in the Handbook, there are a variety of mechanisms through which peer reviews may be accomplished. These include internal peer reviews conducted by EPA staff as well as external peer reviews conducted by Regular Government Employees (RGEs) of another Agency, Special Government Employees (SGEs), and/or outside employees whose services are procured through a contract mechanism.

All government employees (RGEs and SGEs) are covered under ethics regulations that apply to Executive Branch personnel. Non-government employees (such as contractors and experts hired by them to conduct peer reviews) are covered only by the terms of their contract. In order to further clarify this critical distinction, this addendum is divided into two sections: (1) appearance of a lack of impartiality for Government employees and (2) appearance of a lack of impartiality for experts hired under a contract mechanism. Additional information on ethical standards may be found in sections [3.4.5 \(Ethical Standards\)](#) and [3.6.4 \(Management Controls for Contracts\)](#) of the Handbook.

¹ U.S. Environmental Protection Agency, Office of Inspector General, *Evaluation Report: EPA Can Improve Its Process for Establishing Peer Review Panels*, Report No. 09-P-0147, April, 29, 2009, available at: <http://www.epa.gov/oig/reports/2009/20090429-09-P-0147.pdf>.

II. An Appearance of a Lack of Impartiality for Government Employees (SGEs & RGEs)

A. Definition of an Appearance of a Lack of Impartiality

The Standards of Ethical Conduct for Employees of the Executive Branch (“Standards of Conduct”) contain provisions intended to ensure that federal employees take appropriate steps to avoid an appearance of a lack of impartiality. For additional information, [see 5 C.F.R. Part 2635 Subpart E – Impartiality in Performing Official Duties.](#)

An appearance of a lack of impartiality can occur when an employee participating in a “particular matter involving specific parties” may cause a reasonable person with knowledge of the relevant facts to question that person’s ability to carry out official duties without bias or influence. The term “particular matter involving a specific party” is defined in 5 C.F.R. 2641.201(h)(1), and further information may be found in the Office of Government Ethics [DAEOgram 06-029](#), “Particular Matter Involving Specific Parties, Particular Matter and Matter.”

Situations that may raise impartiality concerns include those that are likely to have a direct and predictable effect on the financial interests of a member of the employee’s household, or where the employee knows that a person with whom the employee has a “covered relationship” is or represents a party to such matter. The term “covered relationship” is defined in 5 C.F.R. 2635.502(b)(1). The term “direct and predictable effect” is defined in 5 C.F.R. 2635.402(b)(1).

Where there is concern that circumstances other than those specifically described in the preceding paragraph would raise a question regarding an employee’s impartiality, the circumstances should be treated as appearance of a lack of impartiality and addressed accordingly.

B. Applying the Definition of an Appearance of a Lack of Impartiality

Applying the definition of an appearance of a lack of impartiality to employees is perhaps clearest with respect to the financial interests. For example, if a member of an employee’s household has a contract with a company to do all the marketing for a pesticide that has a pending pesticide registration before the Agency, and the Agency is convening a peer review panel to evaluate a study that will be pivotal in determining whether to grant the registration, few would question that the employee has an appearance problem with respect to participation in the peer review. However, the definition of an appearance of a lack of impartiality includes other interests and circumstances that may include general matters with broad impact. These situations may be more difficult to identify and address.

Appearances of a lack of impartiality for employees can be created by the following interests and activities. This list is not exhaustive:

- financial interests
- organizational relationships

- contributions to the materials that will be peer reviewed
- public statements about the materials that will be peer reviewed or closely related matters
- employee testimony related to the materials that will be peer reviewed or closely related matters.

C. Examples: Applying the Definition of an Appearance of a Lack of Impartiality

Example 1: A biologist is under consideration by the Science Advisory Board for an appointment to serve as an SGE on a Federal Advisory Committee (FACA) panel to review the toxicity of a chemical used for the production of children's toys. The work to be reviewed was substantially done through an Agency grant (now completed) where the biologist was the principal investigator. The Deputy Ethics Official (DEO) for the Science Advisory Board concludes that the biologist has an appearance of a lack of impartiality, since a reasonable person may have reason to question the biologist's impartiality due to previous involvement with the particular matter under review.

Example 2: An SGE working for a university is currently a panel member on a Science Advisory Board FACA committee that is providing input to the Office of Research and Development on general areas of future research. No specific chemicals, grants or funding are discussed. The SGE's spouse conducts chemical exposure assessments, some of which may be covered in these general areas. The DEO for the Science Advisory Board concludes that the SGE does not have an appearance of a lack of impartiality, because the nature of the work being done by the FACA committee is not a particular matter involving specific parties and the work of the SGE's spouse will not raise a question concerning the SGE's impartiality.

Example 3: A health effects expert is being considered for an appointment as an SGE to the Science Advisory Panel (FACA) for a pesticide registration. The expert's employer neither manufactures nor markets the pesticide nor does the expert have any financial interest in the pesticide's manufacturer. However, the expert's employer produces one of many precursors used in the manufacture of the active ingredient in the pesticide. The precursor is used in a large number of other applications, and the amount sold by the specialist's employer for the manufacture of the pesticide being reviewed is insignificant relative to the amount used for the other purposes. The DEO of the Science Advisory Panel concludes that the expert does not have an appearance of a lack of impartiality, because there is little likelihood of any direct and predictable effect on the expert's employer or financial interests.

D. Authorization by Agency Designee

Where an employee's participation in a peer review would cause a reasonable person to question the employee's impartiality, the appropriate DEO in the organization conducting the peer review may, in consultation with the Office of General Counsel's Ethics Office (OGC/Ethics), authorize the employee to participate in the review based on a determination, made in light of all relevant circumstances, that the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the Agency's programs and operations. More information is found in 5 C.F.R. 2635.502(d).

According to ethics regulations, the Deputy Ethics Official may take the following criteria into consideration:

- (1) The nature of the relationship involved;
- (2) The effect that resolution of the matter would have upon the financial interests of the person involved in the relationship;
- (3) The nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter;
- (4) The sensitivity of the matter;
- (5) The difficulty of finding other employees with similar expertise and perspective to participate in the review; and
- (6) Adjustments that may be made in the employee's review duties that would reduce or eliminate the likelihood that a reasonable person would question the employee's impartiality.

After considering these criteria, the appropriate Deputy Ethics Official may decide to authorize the employee's participation or, conversely, to prohibit it. Regardless of the outcome, OGC/Ethics strongly recommends that the Deputy Ethics Official issue a written determination that documents the final decision.

E. Examples of Authorization by an Agency Designee

Example 4: An engineer who previously worked at a university is being considered for service as an SGE on a Board of Scientific Counselors' (FACA) review panel that awards research grants to various academic institutions. One of the applicants is the SGE's former employer with which the SGE has severed all financial ties. Because of the sensitivity of the matter, the Deputy Ethics Official of the Board of Scientific Counselors may be unable to conclude that the Government's interest in the employee's participation on the panel outweighs the concern that a reasonable person may question the integrity of the panel's work, even though the SGE has severed all financial ties with the university. However, the Deputy Ethics Official of the Board of Scientific Counselors might also conclude that, based on consideration of all relevant circumstances, it is in the interest of the Government for the employee to participate in other parts of the panel's work that do not involve this particular university. In this case, the Deputy Ethics Official would, in consultation with OGC/Ethics, issue a written determination allowing the participation of the SGE in the parts of the panel's work that are not related to his previous employer.

Example 5: A toxicologist is serving as an SGE on a Science Advisory Board (FACA) review panel for a chemical made solely by ABC Corporation. The toxicologist is advised by her daughter that she has just accepted an entry-level position as a chemist with ABC Corporation. Because the work of the Science Advisory Board review panel is essentially complete and because the toxicologist has a unique expertise in this particular chemical, the Deputy Ethics Official might determine, after considering all relevant circumstances, that it is in the Government's interest for the toxicologist to complete her work on the review panel.

III. Appearance of a Lack of Impartiality for Experts Hired Under a Contract Mechanism

A. Overview of Peer Review by Contract Mechanism

As set forth in [section 3.6.2 \(Can You Use a Contract to Obtain Peer Review Services\)](#) of the Handbook, the Agency may obtain peer review services through a contract or purchase order. Typically, peer review services would be available under a “mission contract,” i.e., a contract with a broad scope covering a variety of services. It also is possible to have a contract or purchase order solely for peer reviews.

Under a contract mechanism, a contractor selects individual experts for service on a peer review panel. The Agency does not select the experts or review any ethics-related information related to the experts hired by the contractor. Some of the concepts concerning an appearance of a lack of impartiality that are applicable to government employees may be useful for a contractor to consider when employing experts for peer review hired under a contract mechanism. However, it should be clearly understood that the Standards of Ethical conduct for Employees of the Executive Branch (including 5 C.F.R. Part 2635 Subpart E on impartiality) and any other related regulations relating to Government employees **do not apply** to experts hired through a contract mechanism. Experts are held to the standards that are in their contract (see, e.g., "Organizational Conflicts of Interest" (EPAAR 1552.209-71) and "Notification of Conflicts of Interest Regarding Personnel" (EPAAR 1552.209-73)). As such, this section on the appearance of a lack of impartiality is intended only to provide illustrative information concerning the concept and definition of an appearance of a lack of impartiality for experts hired under a contract mechanism.

It should be clearly understood that EPA may provide comments to the contractor on the contractor's peer review only to the extent that the Agency is verifying that the contractor has satisfactorily completed the report in accordance with the contract and work assignment. EPA should not attempt to make any changes in the contractor's conclusions as this would compromise the independence of the peer review conducted by the contractor. See [section 2.8.3](#) of the Handbook for more information.

B. Definition of an Appearance of a Lack of Impartiality for Experts

Analogous to the standard for government employees, an appearance of a lack of impartiality can occur when an expert participating in a particular matter involving specific parties may cause a reasonable person with knowledge of the relevant facts to question the expert's ability to carry out official duties without bias or influence. Situations that may raise impartiality concerns include those that are likely to have a direct and predictable effect on the financial interests of a member of the expert's household, or where the expert knows that a person with whom the expert has a covered relationship is or represents a party to such matter.

Where there is concern that circumstances other than those specifically described in the preceding paragraph would raise a question regarding an expert's impartiality, the circumstances

should be treated as an appearance of a lack of impartiality and addressed accordingly. The same concepts used in the determination of an appearance of a lack of impartiality for government employees may be applied when a contractor considers experts hired under a contract mechanism.²

C. Criteria to Consider in Applying the Definition of an Appearance of a Lack of Impartiality to Experts

Applying the definition of an appearance of a lack of impartiality to experts hired under a contract mechanism is perhaps clearest with respect to the financial interests. For example, if a member of an expert's household has a contract with a company to do all the marketing for a pesticide that has a pending pesticide registration before the Agency and the Agency is convening a peer review panel to evaluate a study that will be pivotal in determining whether to grant the registration, few would question that the expert has an appearance problem with respect to participation in the peer review. However, the definition of an appearance of a lack of impartiality includes other interests and circumstances that may include general matters with broad impact. These situations may be more difficult to identify and address.

Appearances of a lack of impartiality for an expert can be created by the following interests and activities. This list is not exhaustive:

- financial interests
- organizational relationships
- contributions to the materials that will be peer reviewed
- public statements about the materials that will be peer reviewed or closely related matters
- testimony related to the materials that will be peer reviewed or closely related matters

D. Examples of Applying the Definition of an Appearance of a Lack of Impartiality to Experts Hired Under a Contract Mechanism.

Example 6: A contractor is considering hiring a toxicologist under a contract mechanism for EPA as one of many peer reviewers of a certain pesticide's hazard assessment. Previously, this toxicologist served as an expert witness in a class action law suit against the sole manufacturer of this pesticide based on allegations of harm caused by the pesticide's toxicity. The contractor may conclude that the toxicologist has an appearance of a lack of impartiality from serving as an expert witness on the same particular matter concerning specific parties as is now under consideration.

Example 7: An exposure specialist is being considered as an expert for a peer review panel that is being organized under a contract mechanism. This panel will review an EPA document concerning exposure to a chemical that is used in the production of automobile tires. The expert

² See the definitions for "particular matter", "direct and predictable effect", and "covered relationship." The term "particular matter involving a specific party" is defined in 5 C.F.R. 2641.201(h)(1). The term "covered relationship" is defined in 5 C.F.R. 2635.502(b)(1). The term "direct and predictable effect" is defined in 5 C.F.R. 2635.402(b)(1).

has stated publicly that this chemical should be not used in the production of food containers due to exposure via food stored in these containers. However the expert has made no statements concerning other uses of the chemical. The contractor may conclude that the expert does not necessarily have an appearance of a lack of impartiality, because this peer review concerns a particular matter that is different from the particular matter about which the expert made public statements. Whether the expert will be selected is a decision for the contractor, along with considerations of expertise and the desire for a balance of viewpoints.

E. Useful Criteria to Consider for Experts Who Might Have an Appearance of a Lack of Impartiality

Analogous to the concepts for Government employees, a contractor may find it useful to consider other criteria when considering experts who might have an appearance of a lack of impartiality such as:

- (1) The nature of the relationship involved;
- (2) The effect that resolution of the matter would have upon the financial interests of the person involved in the relationship;
- (3) The nature and importance of the expert's role in the matter, including the extent to which the expert is called upon to exercise discretion in the matter;
- (4) The sensitivity of the matter;
- (5) The difficulty of finding other experts with similar expertise and perspective to participate in the review;
- (6) Adjustments that may be made in the expert's review duties that would reduce or eliminate the likelihood that a reasonable person would question the expert's impartiality.

F. Examples of Applying Criteria of an Appearance of a Lack of Impartiality for Experts

Example 8: An expert is being employed by a contractor to review Agency grant applicants in a highly complex area for which he is one of the few experts. The contractor is then informed by the expert that his son has recently accepted an entry-level position with one of the universities applying for a grant in an area unrelated to his son's work. Since the area of research to be covered by the panel is unrelated to his son's work and because it would be difficult to find other experts with the same knowledge, the contractor might determine, considering all relevant circumstances, that is acceptable for the expert to continue to participate in the panel's work.

Example 9: An expert is being employed by a contractor to review the use of certain chemicals as fuel additives. One of the additives is manufactured by a company where the expert was recently employed. Because of the sensitivity of the matter, the contractor may be unable to conclude that the need for the expert's participation in on the panel outweighs the concern that a reasonable person may question the integrity of the panel's work, even though the expert has severed all financial ties with the former employer. However, the contractor might also conclude that, based on consideration of all relevant circumstances, it would be possible to allow this expert to participate in other parts of the panel's work that does not involve the chemical manufactured by the expert's former employer.