

**Supporting Statement for
The Occupational Safety and Health Administration's
Conflict of Interest and Disclosure Form (COI Form)
(November 2006)**

Justification

- 1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

The Office of Management and Budget (OMB) published the Final Information Quality Bulletin for Peer Review on December 15, 2004. The Bulletin established that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the federal government. Peer review is one of the important procedures used to ensure that the quality of published information meets the standards of the scientific and technical community. It is a form of deliberation involving an exchange of judgments about the appropriateness of methods and the strength of the author's inferences. Peer review involves the review of a draft product for quality by specialists in the field who were not involved in producing the draft. Some federal agencies make use of peer review to obtain evaluations of draft information that contains important scientific determinations. The selection of participants in a peer review is based on expertise, with due consideration of independence and conflict of interest. The Bulletin states "...the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency. This Bulletin requires agencies to adopt or adapt the committee selection policies employed by the National Academy of Sciences (NAS) when selecting peer reviewers who are not government employees." The NAS employs a Conflict of Interest Disclosure form to determine whether or not a conflict of interest exists for a provisional committee member.

A copy of the OMB Final Information Quality Bulletin for Peer Review, Introduction is included in this package (Attachment 1).

- 2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.**

OSHA's Contractor will obtain background information and conflict of interest information using a standardized format, referred to as the Conflict of Interest (COI) form to determine if the potential peer reviewers will not be compromised by a significant conflict of interest. The term conflict of interest means any financial or other interest that conflicts with the service of the individual because 1) it could significantly impair the individual's objectivity or 2) it could create an unfair competitive advantage for any person or organization. Except for those situations in which OSHA determines that a conflict of interest is unavoidable and promptly and publicly discloses the COI, no

individual can be selected to serve as a peer reviewer for OSHA if the individual has a COI that is relevant to the functions/services performed.

The OMB Bulletin applies stricter minimum requirements for the peer review of “highly influential scientific assessments, which are a subset of influential scientific information.” The products produced by OSHA that will be peer-reviewed will fall into the two categories of “influential” or “highly influential scientific information.” All potential peer reviewers will complete the Tier 1 questions on the COI form. Potential peer reviewers who will review “influential” scientific information will be required to complete only Tier 1 questions on the COI form. These questions elicit a yes/no answer and only require further response if a potential conflict is identified. Peer reviewers who will review “highly influential” scientific information will also be required in the Tier 2 section of the COI form to provide detailed information on areas of potential conflict such as employment, research funding, and assets. Tier 2 queries are adapted from the NAS COI Disclosure form as per the requirements of the OMB Bulletin.

The completed COI form will be returned by the potential peer reviewer to the OSHA contractor. The contractor will review the responses and determine whether potential peer reviewers have any conflicts of interest. The contractor will then convene the peer review panel.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burdens.

The respondents will receive the COI form as an attachment to an email from the OSHA contractor. The respondents may return the completed form as an email attachment, by mailing a hard copy to the contractor, or by fax.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The information required to be collected and maintained is specific to each invited expert and is not available or duplicated by another source. The information requested for the background information and conflict of interest disclosure is available only from the invited expert.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

No small businesses are involved. Requested information is provided from persons as potential expert witnesses, not as a small business.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than

30 days after receipt of it;

- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
- in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

Respondents may need to complete the COI form in fewer than 30 days after receipt of the form, depending on the timeframes that are tailored to each peer review panel. When possible, respondents will be provided 30 days or more to complete the form.

Under terms of the contract, OSHA's contractor will keep the completed COI forms confidential. See Item 10 of this Supporting Statement for further discussion of confidentiality agreements.

8. If applicable, provide a copy and identify the data and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the Federal Register on August 7, 2006 (71 FR 44714, Docket No. ICR-1218-ONEW-(2006)-01) requesting public comment on its request to the Office of Management and Budget for approval of the COI form. The notice was part of a preclearance consultation program that provides interested parties with an opportunity to comment on this request.

OSHA has received two comments from members of the public. One comment was from Stephen E. Sandherr, Chief Executive Officer of the Associated General Contractors of America (AGC) (Exhibit 2-1). Mr. Sandherr expressed the support of AGC for the Conflict of Interest and Disclosure Form. Mr. Sandherr stated:

“AGC supports OSHA’s efforts in addressing reviewers’ potential conflicts of interest while conducting peer reviews on OSHA draft products. AGC believes in the quality control of standards and guidance documents produced by OSHA and feels that the development of a Conflict of Interest and Disclosure Form would alleviate much of the concern as to whether a peer reviewer has a conflict of interest. AGC believes that this form is necessary for OSHA to ensure the integrity of the peer review process. AGC also supports the estimate of burden to the Agency for the collection requirements.”

The other public comment was from Marc E. Kolanz, Vice President, Environmental Health & Safety, Brush Wellman Inc. (Exhibit 4-1). Mr. Kolanz expressed the support of Brush Wellman for “the efforts of OSHA to require broad disclosure by prospective peer reviewers as to their interests in the topic for review.” Commenting on the form itself, Mr. Kolanz stated that “the proposed Form is consistent with the growing recognition of the need to identify relationships which create potential conflicts of interest, particularly in medical research.” However, Mr. Kolanz also stated that Brush Wellman believes that the period of time that a connection between the topic and the prospective peer reviewer must be reported should be lengthened from 24 months on the current Form to “at least five years [and] up to ten years...”

OSHA has considered the comment of Mr. Kolanz but believes that asking prospective peer reviewers to disclose information on business relationships or relevant financial holdings covering the preceding 24 months exceeds the requirements of the OMB Final Information Quality Bulletin for Peer Review. The OMB bulletin requires that agencies adopt or adapt the Conflict of Interest Disclosure Form used by the National Academies of Sciences (NAS) for their potential committee members. The NAS form requires only information on current connections. OSHA is aware of other federal agencies that request information covering a 24-month period and OSHA has decided to also use this time period. OSHA believes that this time period is sufficient to collect all information that is relevant for determining whether an apparent or potential conflict of interest exists.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

The Agency will not provide payments or gifts to the respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

There are no assurances of confidentiality provided to respondents based in statute, regulation or agency policy; however, under terms of the contract, OSHA’s contractor must keep the completed COI forms confidential.

OSHA’s contractor routinely collects, handles, and stores conflict-of-interest (COI) information while conducting peer review and peer consultation tasks for federal agencies. When identifying experts to review any document designated by the agency as a “highly influential scientific assessment (HISA),” the contractor requires candidate

reviewers to provide COI information that they may consider to be confidential, such as financial holdings, investments, property holdings, etc., in order to determine the potential for a COI.

To maintain the confidentiality of all such COI information, the contractor requires all staff who receive or handle such information to sign confidentiality agreements that require them to adhere to the following procedures:

- (i) The COI form shall be used only for the purposes of carrying out the work required for the peer review or consultation;
- (ii) The staff shall not disclose, discuss, or disseminate the information to or with anyone, both during the project and after the review or consultation is completed, unless that person is a staff person for the same contractor who has signed a confidentiality agreement;
- (iii) The staff working on the peer review/consultation project shall exercise due diligence in safeguarding and handling the COI forms and information the entire time it is in their possession;
- (iv) The contractor shall not make any copies (including paper copies and electronic copies) of any part of the COI form, except for the original paper copy for the project files;
- (v) The contractor shall not share COI information with the contracting agency or any outside entities, except as required to do so by law or as requested as part of a formal investigation by the Office of Inspector General, General Accountability Office, Congressional Committee;
- (vi) The contractor's project manager shall store the electronic copy of the COI form only on her/his individual password-protected work computer and only until the project is completed, at which point the electronic copy shall be deleted; and
- (vii) While the project is underway, the contractor's project manager shall store the COI forms in the individual task files, to be kept in locked file cabinets. When the project is complete, the files shall be stored in archival boxes in a secure off-site location.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature on the COI form.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual**

business practices.

- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**

Based on the number of OSHA products reaching the peer review stage per year for the last several years, OSHA estimates that there will be two peer review panels convened per year. OSHA estimates that 1 peer review panel per year will review a product that is categorized as an “influential scientific assessment” and thus will complete Tier 1 portion of the COI form. The other panel will review a “highly influential scientific assessment” and will complete both Tier 1 and Tier 2 portions of the COI form. For each peer review panel (that will have 6-9 members) OSHA estimates that the COI form will be sent to 18 potential peer reviewers.

Tier 1, Influential Scientific assessment:

OSHA estimates that it will take 0.5 hours to complete just the Tier 1 portion of the COI form. Thus, in each year 18 respondents will each spend 0.5 hours for a total of 9 hours completing the Tier 1 portion.

Tier 2, Highly Influential Scientific assessment:

OSHA estimates that it will take 18 respondents 1.0 hour to complete both Tier 1 and Tier 2 portions of the COI form, totaling 18 hours per year.

In summary, OSHA estimates that the total hours spent per year completing the COI form will be 27 hours.

The potential peer reviewers will all be senior scientists with a wage rate of \$100 per hour. Thus, OSHA estimates that the annual total cost burden to the respondents will be \$2,700.

13. **Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).**
- **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

The cost determined under Item 12 accounts for the total annual cost burden to the potential peer reviewers resulting from these collection of information requirements.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

Based on discussion with the contractor, OSHA estimates that it will cost \$26 per respondent for the contractor to conduct the background information and conflict of interest disclosure process. Thus, with 36 respondents per year, the total cost will be \$936.

15. Explain the reasons for any program changes or adjustments reported in items 13 or 14 of the OMB Form 83-1.

The Agency is requesting a program change increase of 27 hours for obtaining the necessary background information and disclosure of conflict of interest information to ensure invited experts not be compromised. There are no costs as discussed under Item 13 of the Supporting Statement.

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time scheduled for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

OSHA will not publish the information collected as a result to the Conflict of Interest, Disclosure form.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reason that display would be inappropriate.

OSHA will display the OMB and expiration date in the Background information and Conflict of Interest Disclosure package.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.

OSHA is not seeking an exception to the certification statement in item 19.

