

Applying OMB Peer Review Guidelines
(ML051600303)

Organizational Responsibilities and
Delegations of Authority:

Executive Director for Operations (EDO)

- M** Provides oversight of NRC's Information Quality Program.
- M** Performs functions assigned to "head of agency" by OMB Final Information Quality Bulletin on Peer Review
- M** Approves designation of Information as "influential scientific Information" (ISI) or a "highly influential scientific assessment" (HISA), that must be peer reviewed under OMB Final Information Quality Bulletin on Peer Review.

Deputy Executive Director for Information Services and Administration and Chief Information Officer (DEDIA)

- M** Provides oversight of NRC information management programs.

General Counsel (GC)

- M** Provides legal opinions and advice related to NRC's Information Quality Program.

Director, Office of Information Services (DOIS)

- M** Directs the agency's program to comply with the OMB's Final Information Quality Bulletin on Peer Review.
- M** Appoints the NRC Information Quality Coordinator.

Director, Office of Nuclear Regulatory Research, or other Office responsible for scientific information products.

- M** Reviews scientific research activities to determine if any of those activities would result in information products that should be evaluated to determine whether they could potentially qualify as ISI or HISA.
- M** Advises the Director of the Office of Nuclear Reactor Regulation, Office of Nuclear Material Safety, or other office having program responsibilities, of scientific information products that could possibly qualify as ISI or HISA that would have to be peer reviewed in accordance with the OMB Final Information Quality Bulletin on Peer Review.

- M** Conducts peer review of scientific information products that the Executive Director for Operations states constitute ISI or HISA.
- M** Appoints a Peer Review Coordinator.

Director, Office of Nuclear Reactor Regulation, Office of Nuclear Material Safety, and other office having program responsibilities.

- M** Evaluates the potential impact of scientific information products to determine if the information products could qualify as ISI or HISA that should be peer reviewed in accordance with the OMB Final Information Quality Bulletin on Peer Review.
- M** Recommends to Director, OIS, information products that the office determines qualify for peer review under OMB Final Information Quality Bulletin on Peer Review, and provides information to document how the information product qualifies.
- M** Assists the office responsible for conducting the peer review in preparing the peer review plan and conducting the peer review.
- M** Appoints a Peer Review Coordinator.

Information Quality Coordinator (IQC)

- M** Coordinates the agency's efforts to comply with the OMB's Final Information Quality Bulletin on Peer Review.

Peer Review Coordinator (PRC)

- M** Serves as office contact for processing the annual survey to identify information products that may qualify for peer review under OMB's Final Information Quality Bulletin on Peer Review.
- M** Serves as principal contact for the semiannual update to the Peer Review Agenda.
- M** Serves as principal contact for updates to a Peer Review Plan.

Procedures:

A. Identification of Scientific Information Subject to OMB Peer Review Guidelines

1. Introduction

On January 14, 2005, the Office of Management and Budget (OMB) issued the Final Information Quality Bulletin on Peer Review (70 FR 2664), hereinafter referred to as the OMB bulletin. The OMB bulletin (Exhibit 1) contains guidelines for conducting peer review of information that qualifies as "influential scientific information (ISI)" or a "highly influential scientific assessment"(HISA). The guidelines require that an agency post to its public Web site an agenda of peer review plans, describing all planned and ongoing peer reviews of information products qualifying as ISI and "highly influential scientific assessments." The agenda is to be updated at least semiannually. For each peer review, the agency is required to prepare a peer review plan and post the plan to its public Web site. Also, each agency must provide an annual report to OMB by December 15 of each year.

2. Definitions

- a. "Scientific information" means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This definition includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a Web page but does not include the provision of hyperlinks on a Web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered.
- b. "Influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or the private sector. Influential information, as defined in the NRC Information Quality Guidelines is information that forms the technical basis for a substantive rulemaking that has substantial impact on an industry. On a case-by-case basis, information that supports other regulatory actions or decisions may be deemed "influential."

In determining what constitutes influential scientific information, the NRC Information Quality Guidelines state that NRC considers two principal factors:

The information must have a clear and substantial impact that has a high probability of occurring.

The information must impact regulatory decisions affecting a broad class of applicants or licensees.

Note: There is a presumption that a “Major Rule” defined in the Congressional Review Act (see 5 U.S.C. §804 (2)) that is based on scientific information would be influential (for example >\$100 million impact)

- c. "Scientific assessment" is one type of scientific information and means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments. Such assessments often draw upon knowledge from multiple disciplines. Typically, the data and models used in scientific assessments have already been subject to some form of peer review (e.g., refereed journal peer review or peer review under Section II of the OMB bulletin).
- d. "Highly influential scientific assessment" is a scientific assessment utilized as the basis of a rulemaking or regulatory action that NRC or the Administrator, Office of Information and Regulatory Affairs, OMB, determines could have a potential impact of more than \$500 million in any single year on either the public or private sector or that the action represents a novel, controversial, or precedent-setting approach, or has significant interagency interest.

3. Annual Survey

A flow chart, Peer Review Identification Process, summarizing the annual process for identifying scientific information that may qualify for peer review under the OMB Final Bulletin on Peer Review is shown in Exhibit 2.

a. Initiation of the Survey

The Director, Office of Information Services (OIS) prior to September 1 of each year will survey NRC offices to determine if those offices will likely disseminate information within the next three years that will qualify as ISI or a “highly influential scientific assessment.”

b. Identification of Potential Information Products

The Office of Research and any other office involved in scientific research will review their scientific research activities to determine if any of those activities would result in information products that should be evaluated to determine whether they could potentially qualify as ISI or a “highly influential scientific assessment.” The information products identified are to be referred to the

Office of Nuclear Reactor Regulation (NRR) or the Office of Nuclear Material Safety and Safeguards (NMSS), as appropriate.

c. Evaluation of Impact

NRR and NMSS will evaluate information products identified as potentially qualifying as ISI or a "highly influential scientific assessment," to determine if the information product may be utilized to support a rulemaking or other regulatory action resulting in a substantial impact on an industry or class of applicants or licensees, thus requiring a peer review under OMB peer review guidelines.

4. Office Response

If NRR or NMSS identifies an information product that the office believes may qualify as ISI or a HISA, the Office Director will inform RES or another office responsible for the information product and will provide to the Director, OIS, the following information:

- a. A description of the scientific information product (e.g., research reports, other Federal agency report, etc).
- b. The date when the scientific information is expected to be made public (e.g., published).
- c. The anticipated rulemaking or other regulatory action for which the information will form the technical basis.
- d. The projected time frame during which the proposed rule will be issued.
- e. The industry or class of licensees or applicants that will be affected.
- f. A description of the nature of the impact on the affected industry or class of applicants or licensees as follows:
 - (1) The anticipated increase in costs or reduction in costs (i.e. benefits) to the affected industry or applicants or licensees.
 - (2) The anticipated increase in costs or reduction in costs (i.e., benefits) to other private sector activities and the general public.
 - (3) The highest financial costs or benefits that may occur in a single year.
 - (4) Brief analysis describing why the impact meets the standard of "having a clear and substantial impact on regulatory decisions affecting a broad class of applicants or licensees."
- g. If the scientific information product constitutes a "highly influential scientific assessment," provide the following additional information:

- (1) The research products relied upon in the assessment and the type of peer review, if any, that was performed on those products.
 - (2) Whether the financial impact will exceed \$500 million in any single year on either the public or private sector.
 - (3) Whether the anticipated rulemaking or other regulatory action represents a novel, controversial, or precedent-setting approach, or has significant interagency interest.
- h. Whether the projected rulemaking or other regulatory action is likely to qualify as a "major rule" under the Congressional Review Act (see 5 U.S.C. §804 (2)). This act states that any rulemaking or other regulatory action that would result in, for example, at least a \$100 million impact on an industry in any year, must be reported as a "major rule."
 - i. The NRC office that will be responsible for the peer review, if approved by the EDO.
 - j. An estimate of the resources required to conduct the peer review, including NRC staff resources and contractor resources.
 - k. Special circumstances, if any, the agency should consider that may merit deferral of the peer review or waiver of the requirement for a peer review. (See Section F of this part and OMB bulletin Section VIII.)
 - l. Scientific information products that may qualify for peer review but are exempt under the OMB bulletin or the NRC Information Quality Guidelines. (See Section G of this part and OMB bulletin Section IX.)

5. Adequacy of an Office Response

The Director of OIS will review each office's response to ensure, for any information product recommended for designation as either ISI or a "highly influential scientific assessment," that the information required in Section 4 above provides an adequate basis for the EDO to determine if a peer review is required.

6. Formal Designation as "Influential Scientific Information" or a "Highly Influential Scientific Assessment"

The Director of OIS, on the basis of an office response, will submit a report to the EDO prior to November 1 of each year, recommending the regulatory actions and associated information products that qualify as ISI or as a "highly influential scientific assessment." This report will be coordinated with the offices responsible for the information products and regulatory actions.

The EDO will approve or disapprove the recommendation and provide the decision to the Director of OIS prior to December 1 of each year.

7. Posting Peer Review on the NRC Public Web Site

On the basis of the EDO action, the Information Quality Coordinator will prepare and post an agenda of planned and ongoing peer reviews, if any, to the NRC public Web site. Where no peer reviews have been identified, a notice will be made on the public Web site.

8. Semiannual Update of the Peer Review Agenda

The Director of OIS will semiannually contact offices to update the status of the peer review agenda. If any information products are added, dropped, or changed from influential to highly influential or vice versa, OIS will obtain EDO approval before making the changes to the Web site.

B. Peer Review Plan

1. Responsibility

Once the EDO provides a decision, the Director of OIS will request each office responsible for a qualifying information product to prepare a peer review plan. The office assigned responsibility for conducting the peer review will, within 120 days of the approval by the EDO of an information product as either ISI or a "highly influential scientific assessment," prepare a Peer Review Plan.

2. Contents of a Peer Review Plan

- a. Include a beginning paragraph containing the title, subject and purpose of the planned report, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan;
- b. Indicate the type of information product (influential scientific information or a highly influential scientific assessment);
- c. Describe the timing of the review (including deferrals);
- d. Describe whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be employed);
- e. Describe whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided;
- f. Describe whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review;
- g. Describe the anticipated number of reviewers (3 or fewer; 4–10; or more than 10);

- h. Give a succinct description of the primary disciplines or expertise needed in the review;
 - i. Describe whether reviewers will be selected by a designated outside organization;
 - j. Describe whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers; and
 - k. Provide other information that OMB may request be included in a particular year's annual report, as communicated by OIS in the annual survey.
3. Posting the Peer Review Plan on the NRC Public Web site

The Peer Review Plan must be submitted to the Information Quality Coordinator who will post the plan on the NRC Public Web site.

C. Conduct of Peer Reviews

1. Influential Scientific Information

For that scientific information that the EDO has determined qualifies as "influential scientific information," the office director responsible for that information and resulting rulemaking or other regulatory action will conduct a peer review in accordance with requirements set forth in Section II of the OMB bulletin (Exhibit 2). Agencies are given broad discretion in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers. Any peer review for ISI must adhere to the guidance found in Section II of the OMB bulletin, highlights of which are set forth below.

- a. Peer Review Mechanisms: OMB Bulletin Section II.4
 - (1) Can range from individual letter reviews to panels.
 - (2) Considerations in selecting a peer review mechanism
 - (a) Novelty and complexity of the information to be reviewed.
 - (b) Importance of the information to the decision making.
 - (c) The extent of prior peer reviews.
 - (d) Expected benefits and costs of review.
 - (e) Transparency.

- b. Scope of peer reviewer charge: The review will be solely of scientific and technical matters; policy determinations are left for the agency (OMB bulletin Section II.1).
- c. Requirement to inform peer reviewers of applicable Federal information quality standards: Access, objectivity, reproducibility, and other quality standards under Federal laws governing information access and quality: OMB Bulletin Section II.1.
- d. Adequacy of prior peer reviews: OMB bulletin Section II.2.
 - (1) No further peer review is required if prior peer reviews are adequate. Publication in a refereed scientific journal may mean that adequate peer review has been performed. The agency must determine if such a peer review is adequate.
 - (2) In determining whether further peer review is required, consider—
 - (a) Novelty and complexity of the information to be reviewed.
 - (b) Importance of the information to the decision making.
 - (c) The extent of prior peer reviews.
 - (d) Expected benefits and costs of the review.
 - (3) National Academy of Sciences (NAS) principal findings, conclusions, and recommendations are generally presumed to be adequately peer reviewed.
- e. Selection of reviewers: OMB bulletin Section II.3 and Supplementary Information
 - (1) Expertise (OMB bulletin Section II.3.a and Supplementary Information)
 - (a) Most important factor.
 - (b) Reviewers must represent a necessary spectrum of knowledge where information spans a variety of scientific disciplines.
 - (c) Consider requesting that the public, including scientific and professional societies, nominate potential reviewers.
 - (2) Balance (OMB bulletin Section II.3.a and Supplementary Information)
 - (a) Represent diversity of scientific perspectives relevant to the information.

- (b) NAS policy on committee composition is a useful guide, www.nationalacademies.org/coi/BI-COI_FORM-o.pdf.
 - (3) Independence (OMB bulletin Section II.3.c)
 - (a) Reviewer should not be involved in producing information.
 - (b) Careful evaluation required for use of NRC employees as peer reviewers.
 - (c) Careful evaluation required for Government-funded scientists — may differ for grantees vs. contractors. (Grantees considered more independent than contractors unless the contractor is used only to perform a peer review.)
 - (d) Rotate peer reviewers.
 - (4) Conflict of interest (OMB bulletin Section II.3.b)
 - (a) Ensure financial arrangements and organizational relationships do not impair the individual's objectivity or create an unfair competitive advantage for a person or organization.
 - (b) Federal employees who serve as peer reviewers must comply with Federal ethics requirements.
 - (c) Adapt NAS policy for committee selection with respect to evaluating conflicts for potential non-Federal government peer reviewers.
- f. Public Participation: See OMB bulletin discussion on public participation
 - (1) Public comment is encouraged but not required for the peer review of "influential scientific information."
 - (2) Public comment can be obtained through a variety of means.
 - (3) Clearly specify the time period allowed for public comment.
- g. Transparency: OMB bulletin Section II.5, Peer Review Report

Peer reviewers will prepare a report that describes the nature of their review, findings, and conclusions, and will—

 - (a) include a verbatim copy of each reviewer's comments (either with or without attribution) or represent the views of the group as a whole, including any disparate and dissenting views

- (b) include the names of reviewers and their organizational affiliations. Reviewers will be notified in advance about the extent of disclosure and attribution planned by the agency. Public attribution of specific reviewer comments is not mandated. Prior to public disclosure of this information, consult with the NRC Freedom of Information Act (FOIA)/Privacy Act Officer.
- (c) The peer review report should be posted to the agency Public Web site.
- (d) The peer review report should be discussed in the preamble of any related rulemaking and include the administrative record of the agency.

h. Release of proprietary and other sensitive information to peer reviewers.

Consult the Office of the General Counsel if there is a need to disclose "proprietary" confidential commercial or financial information or intellectual property, or other sensitive unclassified information to the peer reviewers. The specific arrangements will depend on whether the peer reviewers are NRC employees, NRC consultants, other Federal employees, or NRC contractors.

i. Outside Management of Peer Review

The agency may commission independent entities to manage the peer review process, including selection of peer reviewers, in accordance with the OMB Bulletin.

2. Highly Influential Scientific Assessment

For that scientific information that the EDO has determined qualifies as a "highly influential scientific assessment," the office director responsible for that information and resulting rulemaking or other regulatory action will conduct a peer review in accordance with requirements set forth in Section III of the OMB bulletin (Exhibit 2). Section III of the OMB bulletin states that all the requirements in Section II (described in the preceding Subsection C.1) will be met for a peer review of a "highly influential scientific assessment," in addition to the requirements set forth in Section III. Section III should be consulted regarding additional requirements, the highlights of which are set forth below.

a. Presumption of peer review adequacy of NAS official reports

There is a general presumption that principal findings, conclusions, and recommendations in official reports of the NAS require no further peer review.

b. Selection of peer reviewers

- (1) Expertise and balance in selection of reviewers

- (a) Require expertise, experience, and skills, including specialists from multiple disciplines, as necessary.
- (b) Group of reviewers will be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge.
- (c) Agencies will consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

(2) Conflicts of interests

- (a) Federal Government employees serving as reviewers must meet Federal ethics requirements; for non-Federal government employees, adopt NAS policy on committee selection for evaluating potential conflicts.
- (b) For scientific assessments relevant to specific regulations, a reviewer's financial ties to regulated entities and other stakeholders will be carefully examined.

(3) Independence

Participation of scientists employed by the sponsoring agency is barred unless employment is only for conducting the peer review or qualifies for an exception by applying the NAS criteria for evaluating use of "employees of sponsors."

Refer to Section III.c of the OMB bulletin if an exception is needed.

(4) Rotation of peer reviewers

Repeated use of the same reviewers on multiple assessments needs to be avoided unless it is essential and reviewers cannot be obtained elsewhere.

c. Peer review access to information

Agencies are to provide peer reviewers access to sufficient information, including background information about key studies and models, to enable them to understand the data, analytic procedures, and assumptions used to support the key findings or conclusions of the draft scientific assessment. Consult the Office of the General Counsel if there is a need to disclose "proprietary" confidential commercial or financial information or intellectual property, or other sensitive unclassified information to the peer reviewers.

d. Public participation

- (1) Where feasible and appropriate, the draft scientific assessment being peer reviewed will be made available to the public for comment at the same time it is submitted to the peer reviewers, or during the time the peer review is being conducted.
 - (2) Public comment can be made by oral presentation or in writing before the peer reviewers.
 - (3) Peers reviewers, whenever practicable, are to be provided access to public comments on the draft scientific assessment.
 - (4) Time limits on public participation will be clearly specified
- e. Transparency: peer review report
- A peer review report will be prepared and include—
- (1) Information required by OMB bulletin Section II.5.
 - (2) The charge (i.e., instructions) given the peer reviewers.
 - (3) Short paragraph on both the credentials and relevant experiences of each peer reviewer. Prior to public disclosure of this information, consult with the NRC FOIA/Privacy Act Officer.
 - (4) Agency written response to the peer review explaining—
 - (a) Agency agreement or disagreement with the views expressed in the report.
 - (b) The actions the agency has undertaken or will undertake in response to the report.
 - (c) The reasons the agency believes those actions satisfy the key concerns stated in the report.
 - (5) The peer review report will be disseminated on the agency's Web site with the related material specified in OMB bulletin Section II.5.
- f. Agencies have the option to commission independent entities to manage the peer review process, including the selection of peer reviewers.

D. Administrative Record Certification

The NRC Information Quality Coordinator will, when NRC relies on ISI or a HISA to support a regulatory action, maintain an administrative record for that action including a certification, that is, a statement that explains how the agency has complied with the requirements of the OMB bulletin and the applicable information quality guidelines, along with relevant materials. This certification will also be maintained in the administrative record for the action.

E. Alternatives Procedures To Comply With Peer Review Requirements in the OMB Final Information Quality Bulletin on Peer Review. (Consult OMB Bulletin Section IV)

The following alternatives are available:

1. Rely on the principal findings, conclusions, and recommendations of a report produced by NAS.
2. Commission NAS to peer review an agency's draft scientific information.
3. Employ an alternative scientific procedure or process, specifically approved by the Director of Office of Information and Regulatory Affairs, OMB.

F. Waivers and Deferrals of Certain Requirements

The OMB bulletin provides for waivers and deferrals of the requirements in Sections II and III of the bulletin as follows:

1. Deferral of peer review is allowed — usually because of the need to comply with legal deadlines.
2. Waiver of the requirements is allowed in some instances (See OMB bulletin Section VIII)
3. Deferrals and waivers must have a compelling rationale, and be made by the agency head.
4. OMB bulletin notes deferrals and waivers should seldom be warranted.

G. Exemptions

The agency does not need to have a peer review conducted on an information product that is exempt from the application of Sections II and III of the OMB bulletin. To be exempt, an information product must qualify under one of the exemptions set forth in OMB bulletin Section IX that are summarized below:

1. Related to certain national security, foreign affairs, negotiations involving international treaties and trade where compliance with the OMB bulletin would interfere with the need for secrecy or promptness.
2. Information disseminated in the course of an individual agency adjudication or permit proceeding unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings.
3. A health or safety dissemination where the agency determines that the dissemination is time-sensitive.

4. An agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866, except for underlying data and analytical models.
5. Routine statistical information released by Federal statistical agencies and analyses of these data to compute standard indicators and trends.
6. Accounting, budget, actuarial, and financial information, including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes.
7. Information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.
8. Information products exempted under the NRC Information Quality Guidelines.

H. Privacy and Confidentiality

Individuals serving as peer reviewers have privacy interest about themselves. To the extent information about a reviewer (e.g. name, credentials, affiliations) will be disclosed along with his/her comments or analysis, the requirements of the Privacy Act, 5 U.S.C. 552a, as amended, must be applied including establishing a routine use for the disclosure.

I. Annual Report

1. Responsibility for Preparing the Annual Report

The Director of OIS will prepare the NRC Annual Report required by Section VI of the guidelines.

2. Contents of the Annual Report

The report will consist of a summary of the peer reviews conducted by the agency during the fiscal year, including the following:

- a. The number of peer reviews conducted subject to the OMB bulletin (i.e., for influential scientific information and highly influential scientific assessments);
- b. The number of times alternative procedures were invoked;
- c. The number of times waivers or deferrals were invoked (and in the case of deferrals, the length of time elapsed between the deferral and the peer review);
- d. Any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the OMB bulletin, including determinations by the Secretary pursuant to Section III(3)c);

- e. The number of peer review panels that were conducted in public and the number that allowed public comment;
 - f. The number of public comments provided on the agency's peer review plans; and
 - g. The number of peer reviewers that the agency used that were recommended by professional societies.
3. Submission of the Annual Report

The Director of OIS will submit the NRC Annual Report to the Director of the Office of Information and Regulatory Affairs, OMB, by December 15 of each year.