Peer Review Process
MANUAL

BSEE
Bureau of Safety and
Environmental Enforcement

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List of Acronyms

The following terms are defined for the purposes of this Peer Review Manual

ACI	American Concrete Institute
AISC	American Institute of Steel Construction, Inc.
ANPRMs	Advanced Notice of Proposed Rulemakings
ANSI	American National Standards Institute
API	American Petroleum Institute
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
BOEM	Bureau of Ocean Energy Management
BPA	Blanket Purchase Agreement
BSEE	Bureau of Safety And Environmental Enforcement
CBI	Confidential Business Information
COI	Conflict of Interest
DAEO	Designated Agency Ethics Official
DOE	Department of Energy
DOI	U.S. Department of the Interior
EERE	Office of Energy Efficiency and Renewable Energy
EPA	Environmental Protection Agency
FACA	Federal Advisory Committee Act

FAR	Federal Acquisition Regulation
HISA	Highly Influential Scientific Assessments
IOSC	International Oil Spill Conference
ISI	Influential Scientific Information
ISO	International Organization for Standardization
NAS	National Academy of Sciences
NTTAA	National Technology Transfer and Advancement Act of 1995
OCS	Outer Continental Shelf
OGE	Office of Government Ethics
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OORP	Office of Offshore Regulatory Programs
OSRR	Oil Spill Response Research
OTC	Offshore Technology Conference
RGE	Regular Government Employees
SGE	Special Government Employees
SOW	Statement of Work
TAP	Technology Assessment Programs
USCG	US Coast Guard

Disclaimer

This Manual includes BSEE's recommended practices for peer review based on applicable federal requirements and BSEE policies and procedures related to information quality and peer review. The Manual does not replace, revise, or substitute for any legal requirements. The Office of Management and Budget's "Final Information Quality Bulletin for Peer Review" (December 2004) "establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents." The guidance in this Manual complies with this Bulletin, and the Manual uses the terms "shall" or "must" to denote practices that are required by the Bulletin (except where indicated). The Manual uses the terms "should," "could," or "may" to denote BSEE's suggested practices for peer review.

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Introduction

The Bureau of Safety and Environmental Enforcement (BSEE) conducts and supports research that promotes the safety of offshore workers, enhances emergency preparedness, protects offshore environmental resources, and reduces potential impacts to our Nation's energy infrastructure and economic prosperity.

To maintain its mission of vigorous regulatory oversight and enforcement, BSEE continuously develops and supports research in the areas of operational safety, pollution prevention, and oil spill response methods and technologies. To keep up with rapidly evolving science and technology on the Outer Continental Shelf (OCS) and ensure the protection of energy and natural resources, it is essential that BSEE's research is based on strong science. Through peer review of its research products, BSEE takes steps to ensure that its research is salient, credible, objective, and accepted by experts in relevant scientific fields and by stakeholders. Such research is used to inform regulatory changes, support BSEE's work on industry standards, employ the use of appropriate technology on the OCS, contribute to operational safety and spill prevention, and improve the methods and technologies used for oil spill detection, containment, treatment, recovery, and cleanup.

This BSEE Peer Review Process Manual (hereafter referred to as "this Manual" or "the Manual") provides guidance to BSEE staff conducting peer reviews of research products. The Manual has been designed to educate BSEE staff about peer review, comply with all federal requirements, and provide an easy-to-follow systematic process for pursuing peer review of a research product. The Manual includes the following structure:

- The Manual begins by discussing why peer review is important to BSEE, a federal agency that produces, supports, and disseminates research that informs regulatory actions and assesses technology. The Manual then defines terms related to peer review and identifies the sets of requirements that are relevant to BSEE peer reviews.
- Next, the Manual identifies the roles and responsibilities of BSEE staff who are involved with the peer review process.
- The majority of the Manual provides guidance to help BSEE staff move through the peer review process from beginning to end, including detailed information on determining if a research product needs peer review, and planning, implementing, completing, and documenting a peer review.
- The Manual contains helpful visual aids and summary graphics for reference during the peer review process.
- Lastly, the Manual includes several resources in the form of appendices and tools to assist BSEE staff in conducting a successful peer review.

This Manual is an evolving document. BSEE will refine and update it through a process of continual improvement based on feedback from users. Please contact oilspillresponsedivision@bsee.gov if you have suggestions for improving this Manual.

Background of Peer Review

Peer review, or the formal review of a research product by a balanced group of independent, qualified experts in relevant technical fields, is a widely accepted method for ensuring quality of scientific information. Peer review is used by governments, publishing and professional organizations, and academic institutions to validate publications, models, research studies and analyses, technologies, and programs. Methodologies and forms of peer review vary depending on the goals of the group seeking the review, applicable standards for information quality, and time and budget constraints. For peer review conducted by federal agencies, the purpose is frequently two-fold: (1) to ensure information that will be disseminated is of adequate quality to be accepted by the scientific community and stakeholders; and (2) for information used in agency decision making, to document the critical independent technical review of the information in a transparent manner acceptable to the public.

Guidelines for peer review by federal agencies have been established by the Office of Management and Budget's (OMB) "Final Information Quality Bulletin for Peer Review" (December 2004), hereafter referred to as the "OMB Bulletin," which states that "important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the federal government." In cases when BSEE plans to disseminate a research product, the research product may be subject to peer review requirements under the OMB Bulletin. Additionally, even if a research product is not subject to federal peer review requirements, BSEE may decide that the technical quality and credibility of a research product would benefit from peer review. This Manual describes the peer review process for research products that BSEE decides should be peer reviewed.

Importance of Peer Review

BSEE's two major research programs, the Oil Spill Response Research (OSRR) program and the Technology Assessment Programs (TAP), conduct and support extensive research on operational safety and spill prevention, pollution prevention, oil spill response methods, and equipment and systems technologies. OSRR manages the funding for numerous research projects chosen to meet selected major topics each year. TAP provides a research element encompassed by the BSEE Office of Offshore Regulatory Programs (OORP) and has supported hundreds of research projects. The following are examples of research products conducted or supported by BSEE that could be subject to peer review:

- High-pressure, high-temperature drilling, completion, and production
- Deep water drilling, completion, production, pipeline transport and gathering topics
- Arctic, Pacific, or California drilling, completion, and production (especially novel technology/procedures and environmental impacts)
- Well control issues or concerns
- Blowout preventer equipment and systems
- Alternative technology
- Emerging technology
- Best Available and Safest Technology

- Handling hydrogen sulfide, carbon dioxide, and other compounds in offshore drilling, completion, and production
- Oil spill response plans, in particular projects designed to provide a scientific basis for decision making in the review process
- Assessment of industry oil spill response preparedness

A primary purpose for peer review at BSEE is to ensure that BSEE research products are based on sound science. Successful, defensible, and transparent peer review enhances the technical quality of BSEE research products. The potential benefits of peer review include the following:

- **Improved program performance:** Input and lessons learned from prior peer reviews inform the BSEE research planning process and improve the consistency and relevance of BSEE's research programs.
- **Strengthened research analysis:** By engaging a diverse panel of experts, the peer review process elicits a variety of perspectives. Considering these perspectives helps authors of BSEE research products strengthen the credibility of their analyses and associated research conclusions in the broader scientific community.
- **Improved return on research investments:** Peer review provides a structured process that enhances the quality of and instills confidence in research investments, thereby reducing the need to expend unnecessary resources and conduct additional analyses.
- **Defensibility of decision making:** Federal agencies are afforded a high level of judicial deference in their decision making capacity, but they still must prove that their actions are not arbitrary or capricious. Peer review aids BSEE in meeting this standard of review by providing the Bureau with a transparent and credible mechanism for supporting its policy and regulatory decisions. Employing peer review demonstrates BSEE's commitment to ensuring the highest quality of its disseminated information and supports the defensibility of its decisions. If compiled correctly, the Peer Review Record, a formal file containing peer review documents and decisions made by BSEE during a peer review, will contain the documentation necessary to describe BSEE's peer review efforts.

Another important reason why BSEE conducts peer review is to comply with federal requirements for information quality. Many of BSEE's research products are considered "influential" and are subject to OMB peer review requirements. To ensure an adequate level of information quality and consistency, it is important that BSEE staff follow the guidance discussed in this Manual. The guidance will be adapted as needed as BSEE research continues to advance and develop.

Definitions Related to Peer Review

The following terms, as applied to BSEE peer reviews, are used throughout the Manual:

Comment Response Documents represent the Bureau's formal response to the comments of peer reviewers. For peer reviews of highly influential scientific assessments and peer reviews utilizing public panels, a Comment Response Document is required. Comment Response Documents will be posted to the BSEE Web site as part of the Peer Review Record.

Dissemination refers to any distribution of information to the public that is sponsored or initiated by BSEE and represents an official position of BSEE. Per the OMB Bulletin, for research products that are funded by BSEE but do not represent the official views of BSEE, the information must include a clear disclaimer that "the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency."

There are several *exceptions* to what constitutes "dissemination" in the OMB Bulletin, and this Manual conforms to the definition and exemptions for "dissemination" used in the Bulletin.

The following constitute *exemptions to dissemination* under the OMB Bulletin:

- Distribution limited to government employees or BSEE contractors or grantees
- Intra- or inter-agency use or sharing of government information
- Responses to requests for BSEE records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act (FACA), the Government Performance and Results Act, or similar laws
- Distribution limited to correspondence with individuals or persons
- Press releases
- Archival records
- Public filings
- Subpoenas
- Adjudicative processes
- Information distributed for peer review in compliance with the OMB Bulletin or shared confidentially with scientific colleagues, provided that BSEE includes an appropriate and clear disclaimer on the information (see Section 3.4)
- Information supplied to the government by third parties that BSEE does not disseminate
- Research produced by government-funded scientists (e.g., those supported extramurally or intramurally by federal agencies or those working in state or local governments with federal support) if that information is not represented as the views of a department or agency (i.e., they are not official government disseminations), provided that the distributing agency includes an appropriate and clear disclaimer on the information (see Appendix F)

Highly influential scientific assessment, as defined in the OMB Bulletin, refers to a scientific assessment that BSEE or the Administrator of the Office of Information and Regulatory Affairs in the OMB (OIRA) "determines to be a scientific assessment that:

> (i) could have a potential impact of more than $500 million in any year, or
>
> (ii) is novel, controversial, or precedent-setting or has significant interagency interest."

In cases where BSEE is unable to predict the potential economic impacts associated with dissemination of a scientific assessment, BSEE may assess whether a scientific assessment is highly influential by assessing the applicability of item (ii) in the paragraph above.

BSEE staff may wish to refer to any BSEE internal guidance or processes addressing the determination of highly influential scientific assessments as it relates to BSEE peer reviews.

The **OMB Bulletin** provides the following guidance for determining if a research product is a ***highly influential scientific assessment***:

- Either the assessment approach or the interpretation of the information itself could be considered novel or precedent-setting
- If a section of a research product (e.g., a final numerical figure) falls under the category of influential scientific information or a highly influential scientific assessment, then the whole research product should be considered under these categories.
- A research product "can have a significant economic impact even if it is not part of a rulemaking."

Independence refers to the objectivity of the peer review process relative to the development of the research product. The level of independence can affect (and be affected by) the choice of peer review mechanism and peer reviewers and the decision about whether to use contractors to support the peer review process.

Influential scientific information, as defined in the OMB Bulletin, refers to "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." The OMB Bulletin clarifies that the term "influential" should be "interpreted consistently with OMB's government-wide information quality guidelines and the information quality guidelines of the agency." BSEE staff may wish to refer to any BSEE internal guidance or processes addressing the determination of influential scientific information as it relates to BSEE peer reviews.

Peer input refers to a situation in which internal or external stakeholders are informally consulted during the development of a research product. Although peer input can be used as a tool to help ensure that research products are based on sound science, it should not be used as a substitute for peer review. One of the essential benefits of peer review is the feedback provided by a group of independent reviewers, and individuals involved in the development of a research product generally cannot provide an independent assessment of the product. A combination of both peer input and peer review can help to ensure adequate information quality in BSEE research products.

Peer review, as used in this Manual, refers to the formal review of a research product by a balanced group of independent,[1] qualified experts in relevant technical fields. The review examines all aspects of a research product, including inputs, scope, methods, assumptions, relevance, and conclusions.

Peer reviewers are independent, qualified experts in relevant technical fields whose services are retained by BSEE (or a contractor) to evaluate a draft research product.

[1] The definition of "independent" as it relates to peer reviewers varies by peer review mechanism. See Step 3.2.1 for details.

Peer Review Agenda, per the requirements of the OMB Bulletin, refers to an agenda of all "planned and ongoing" BSEE peer reviews that is posted on the BSEE Web site and regularly updated. Each item on the agenda includes the elements of the Peer Review Plan with links to relevant documents.

Peer Review Charges are BSEE's formal request for feedback from peer reviewers.

Peer review mechanism refers to the format through which comments are solicited from peer reviewers. The Manual discusses three peer review mechanisms in detail: internal review, external letter review, and external panel review.

Peer Review Plans are plans developed for each peer review and posted to the BSEE Web Site. For each peer review, the Peer Review Plan serves as a tool for BSEE staff in planning and scheduling a peer review and informs the public about the timing, format, and content of the review.

Peer Review Records are formal files containing peer review documents and decisions made by BSEE during a peer review. For each peer review, the Peer Review Record includes information about the overall process of the review, including the format and logistics of the review, how reviewers were selected, and how reviewer comments were addressed. The Peer Review Record also includes all material disseminated and collected during the review, the Peer Review Report, and the final research product. The Peer Review Record is made publicly available at the end of the peer review process.

Peer Review Reports are written documents that detail the goals, process, and outcomes of a BSEE peer review. For each peer review, the Peer Review Report helps the reader understand why the peer review was undertaken, who the peer reviewers were and how they were selected, as well as how the reviewers responded to the Peer Review Charge. The Peer Review Report is made publicly available as part of the Peer Review Record at the end of the peer review process.

Public comment refers to the solicitation by federal agencies of comments from stakeholders and members of the public on agency regulatory actions and disseminated information, including Peer Review Plans and research products themselves. However, soliciting comments from the public on a draft research product does not ensure that the product will be evaluated by an independent group of experts; thus, for many agency scientific research products, peer review is still necessary even if public comments are requested.

Research product refers to all scientific information resulting from BSEE research that BSEE plans to disseminate. This definition includes products prepared by an external organization.

Scientific assessment, as defined in the OMB Bulletin, refers to "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." Scientific assessments generally include knowledge and conclusions from multiple fields. Some elements of a scientific assessment often have already been peer reviewed.

Scientific information, as defined in the OMB Bulletin, refers to "factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences." The term 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." For the purposes of this Manual, the term also includes information disseminated on the BSEE Web site, with the exception of hyperlinks to information disseminated by external organizations. This term does not include opinions, where BSEE makes clear in the presentation of the information that the information is opinion rather than fact.

Transparency refers to the conduct and documentation of the peer review process and results in a manner that is both accessible and comprehensible to the public. The peer review's level of transparency can affect (and be affected by) the use of public participation, the choice of peer review mechanism (discussed in Step 2.3) and peer reviewers, and the final documentation of the peer review.

Requirements for Peer Review

This section briefly discusses the following sets of peer review requirements that are relevant to BSEE peer reviews:

- **OMB Bulletin:** As discussed above, the OMB's "Final Information Quality Bulletin for Peer Review" (December 2004) provides peer review guidance to federal agencies to help ensure adequate information quality in agency products disseminated to the public and used in agency decision making. Appendix F references the relevant requirements of the OMB Bulletin for each chapter of this Manual. The "Information Quality Act" (Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554)) provides the general authority for both the OMB Bulletin and the U.S. Department of the Interior (DOI) Information Quality Guidelines.
- **DOI Information Quality Guidelines:** DOI published the "Information Quality Guidelines Pursuant to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001" to "ensure high quality information is generated, used, and disseminated at the Department of the Interior" and to comply with OMB direction to "issue and implement guidelines to ensure and maximize the quality, objectivity, utility, and integrity of Government information disseminated to the public."

Roles and Responsibilities for Peer Review

There are three main roles held by BSEE staff during the peer review process: Decision Maker, Peer Review Leader, and Peer Review Coordinator. In essence, for each research product, the Decision Maker makes the final decision as to whether a research product should be peer reviewed and assigns a Peer Review Leader (among other responsibilities). If a research product is subject to peer review, the Peer Review Leader is responsible for implementing the review, with guidance from the Decision Maker. The Peer Review Coordinator works with individual Peer Review Leaders to coordinate and monitor all BSEE peer reviews per any BSEE internal guidance and processes for peer review.

This section provides additional detail on each of these roles. Additional discussion on the specific responsibilities of BSEE staff involved in peer reviews is included throughout the Manual.

Responsibilities of the Decision Maker

The Decision Maker is the final person accountable for the peer review of a research product, such as a Division Chief. The Decision Maker oversees the commitment of peer review resources and provides general guidance during the peer review process. The Decision Maker has several responsibilities during the peer review process, including:

- Assess if a research product is influential scientific information or a highly influential scientific assessment, and decide if the research product should be subject to peer review
- Assign a Peer Review Leader
- With the Peer Review Leader, develop a Peer Review Plan for the peer review
- With the Peer Review Leader, determine the peer review mechanism
- With the Peer Review Leader, approve the selection of peer reviewers
- With the Peer Review Leader, approve the Peer Review Charge, and finalize the peer review schedule
- Approve the Peer Review Leader's proposed plan for incorporating and responding to comments from peer reviewers

Responsibilities of the Peer Review Leader

The Peer Review Leader, with assistance of other BSEE staff and research product author(s) as needed, serves as the facilitator of a peer review for a research product. The Decision Maker and the Peer Review Leader should not be the same person. The Peer Review Leader works in conjunction with the Peer Review Coordinator to ensure all appropriate guidance from BSEE policies and procedures are followed. The Peer Review Leader has several responsibilities during the peer review process, including:

- Provide updates to the Decision Maker regarding the status of the review and any issues that have occurred
- Provide the Peer Review Coordinator with necessary information to keep the peer review information on the BSEE Web site current
- With the Decision Maker, develop a Peer Review Plan for the peer review
- With the Decision Maker, determine the peer review mechanism
- Assess the need for public comment on the research product, and review the comments as required
- Research, select, and gain Decision Maker approval on the selection of peer reviewers
- Address all real and potential conflicts of interest
- Draft and brief the Decision Maker on a Peer Review Charge, and finalize the peer review schedule
- Ensure that peer reviewers understand their roles and responsibilities
- Distribute materials to peer reviewers. If public comments are collected before or during the peer review, ensure peer reviewers are provided the comments for consideration.

- Organize and facilitate any meetings or peer reviewer discussions
- Analyze the peer review comments and brief the Decision Maker on a proposed plan for incorporating and responding to comments from peer reviewers
- Draft the Peer Review Report and, if needed, the Bureau's response to the review (i.e., the Comment Response Document)

Note that some or many of these tasks are undertaken by a contractor in a contractor-led peer review, as discussed in further detail in Step 2.2.

Responsibilities of the Peer Review Coordinator

The Peer Review Coordinator coordinates and monitors all peer reviews of BSEE research products. To successfully perform the roles and responsibilities associated with this position, the Peer Review Coordinator should have expertise in the OMB Bulletin and this Manual. The Peer Review Coordinator has several responsibilities during the peer review process, including:

- Provide general oversight of BSEE peer reviews
- Provide guidance to Peer Review Leaders as needed
- Serve as an independent mediator between BSEE and others (e.g., the public, Peer Review Leaders, OMB, media) on peer review issues as needed
- Ensure that the Peer Review Agenda on the BSEE Web site is up-to-date
- Facilitate the posting of Peer Review Plans to the BSEE Web site
- Facilitate the posting of all Peer Review Records to the BSEE Web site and the BSEE peer review database
- File Peer Review Reports and Peer Review Records according to OMB requirements and applicable BSEE policies and procedures
- Review and compile lessons learned from Decision Maker(s) and Peer Review Leaders to improve BSEE peer review guidance
- Update and distribute BSEE peer review guidance as needed
- Compile and submit the required annual report on BSEE peer reviews for the Office of Information and Regulatory Affairs in the OMB (OIRA)

BSEE staff should refer to their managers, the Decision Maker, and/or Peer Review Coordinator for specific information on required peer review training. BSEE staff involved in peer reviews of BSEE research products should become familiar with the guidance within this Manual. The OMB Bulletin can be referenced for additional guidance as needed.

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The Peer Review Process

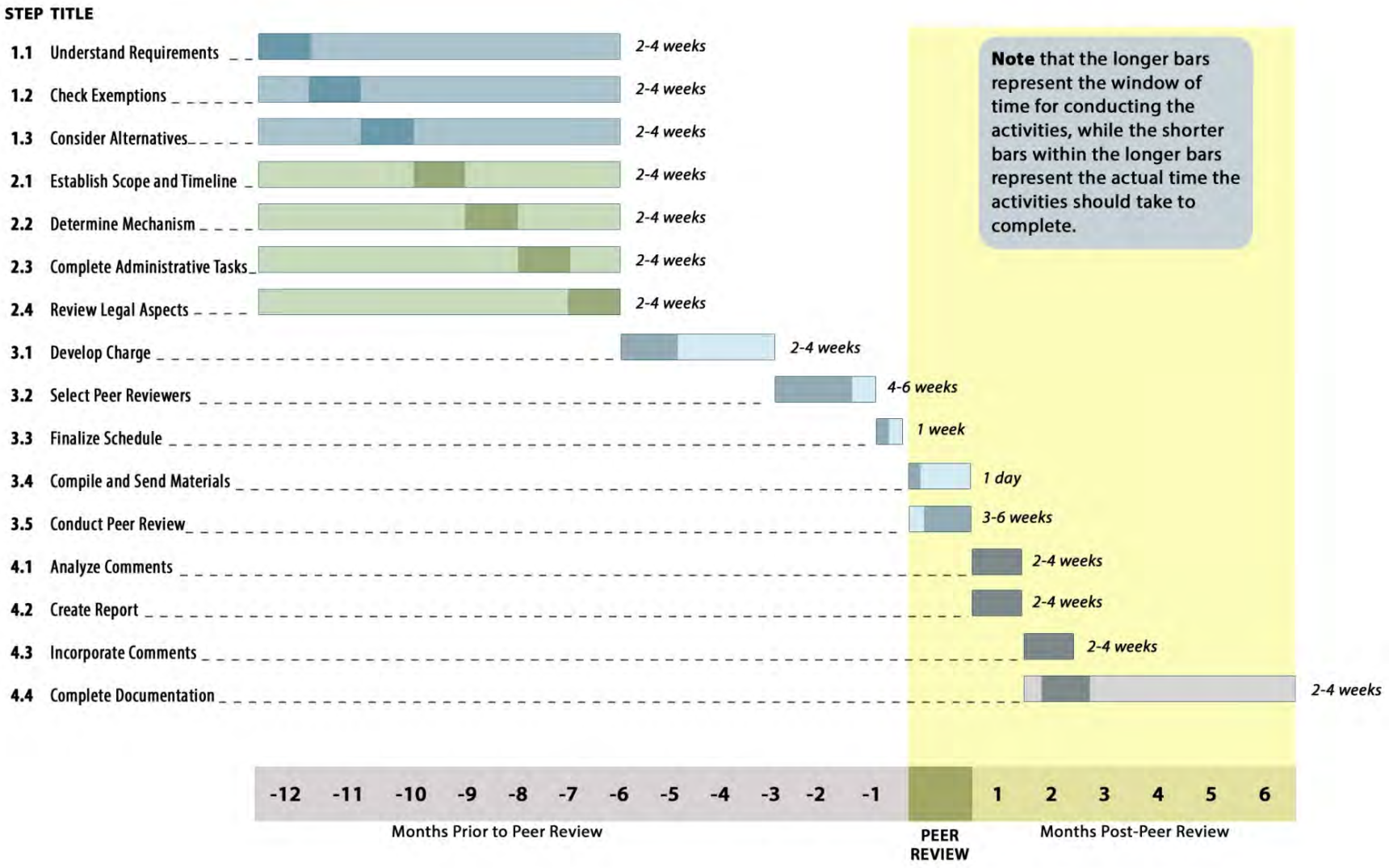
Graphic 1 provides an overview of the steps comprising the BSEE peer review process. Each step, as represented vertically, corresponds to a section in this Manual. This graphic includes sub-steps, the responsible party, and several highlighted activities that take place during each step.

GRAPHIC 1: PEER REVIEW PROCESS OVERVIEW

	Step/Responsible Party	Highlighted Activities
STEP 1 Determine When to Conduct a Peer Review	Step 1.1: Understand Peer Review Requirements *Decision Maker*	• Review requirements and guidance • Review OMB definitions for influential scientific information and highly influential scientific assessment • Consider prior peer review
	Step 1.2: Check Exemptions *Decision Maker*	• Review exemptions • Consider waivers or deferrals where applicable
	Step 1.3: Consider Alternatives *Decision Maker*	• Consider alternative processes
STEP 2 Plan the Peer Review	Step 2.1: Establish Scope and Timeline *Peer Review Leader with Decision Maker*	• Consider transparency and independence • Consider evaluation process and reviewer qualifications • Consider public involvement
	Step 2.2: Determine Peer Review Mechanism *Peer Review Leader with Decision Maker*	• Review pros/cons/costs of each mechanism • Consider method for selecting reviewers • Determine disposition and attribution of comments • Determine contractor involvement
	Step 2.3: Complete Administrative Tasks *Peer Review Leader, Peer Review Coordinator, and Decision Maker*	• Begin Peer Review Record • Create Peer Review Plan • Update Peer Review Agenda • Develop detailed budget • Draft Statement of Work (where applicable)
	Step 2.4: Review Legal Aspects *Peer Review Leader with Decision Maker*	• Review legal requirements associated with contractor-led peer reviews • Review legal requirements associated with consensus opinions
STEP 3 Implement the Peer Review	Step 3.1: Develop Peer Review Charge *Peer Review Leader with Decision Maker*	• Consider scope and evaluation criteria • Develop technical questions
	Step 3.2: Select Peer Reviewers *Peer Review Leader with Decision Maker*	• Develop list of potential candidates • Evaluate COI, balance, availability, and timeline • Select peer reviewers
	Step 3.3: Finalize Peer Review Schedule *Peer Review Leader with Decision Maker*	• Notify selected reviewers
	Step 3.4: Compile and Send Materials *Peer Review Leader*	• Confirm receipt of materials
	Step 3.5: Conduct Peer Review *Peer Review Leader*	• Facilitate meetings • Check in with peer reviewers • Collect comments
STEP 4 Complete and Document the Peer Review	Step 4.1: Analyze Comments *Peer Review Leader with Decision Maker*	• Determine if charge was adequately addressed • Brief senior management on significant comments
	Step 4.2: Create Peer Review Report *Peer Review Leader with Decision Maker*	• Consider peer reviewer disclosure • Disseminate completed Peer Review Report
	Step 4.3: Respond to and Incorporate Comments *Research Product Authors, Decision Maker, and Peer Review Leader*	• Create Comment Response Document
	Step 4.4: Complete Documentation *Peer Review Leader with Peer Review Coordinator*	• Document peer review in the research product • Complete Peer Review Record • Complete documentation of peer review for associated regulatory actions • Consider lessons learned

Graphic 2 provides a depiction of the expected timeline for a typical peer review, from start to finish. Each sub-step is accompanied by a bar that represents the window of time during which the activity should be conducted. For example, the activities in Step 1 should be conducted 6 to 12 months prior to the start of the peer review. Inside each bar is smaller darker bar, which represents the actual time (i.e., calendar time) that the activity should take to complete. For example, while Step 2.1 should be conducted somewhere between 6 and 12 months prior to the start of the peer review, the actual time it should take to complete Step 2.1 is 2 to 4 weeks. This graphic also illustrates that steps in the peer review process may be undertaken concurrently. For example, determining when to conduct a peer review (Step 1) and planning a peer review (Step 2) can occur in the same 6 to 12 month window prior to the start of the peer review.

GRAPHIC 2: PEER REVIEW TIMELINE



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Step 1: Determine When to Conduct a Peer Review

All BSEE research products and associated documents shall be *considered* for peer review. The need for peer review must be evaluated subject to the considerations described in this section. Consideration should include the full scope of any given research project, including hypothesis development, modeling, data collection and analysis, and conclusions. This step provides the Decision Maker with guidance for determining whether a research product will be subject to peer review, and Graphic 3 provides a visual overview of this decision making process.

The OMB Bulletin includes requirements regarding which federal agency products must be subject to peer review, as discussed in the Definitions Related to Peer Review section of this Manual and in further detail below. Research products subject to OMB Bulletin requirements constitute a minimum set, rather than an exhaustive list, of research products that should be peer reviewed.

When funding is allocated for the development of a research product, the Decision Maker should review the guidance in this section to determine if a research product will be subject to peer review. If the research product will be peer reviewed, funds should be allocated for the peer review. The specific amount of funds allocated for the peer review will depend on the type of research product and the peer review mechanism selected, as discussed in more detail in Step 2. In addition, if an external organization will be developing the research product, the Decision Maker should ensure that any activities stemming from peer review, such as the revision of the research product based on peer review comments, is included in the work specifications for that organization.

Step 1.1: Understand the Types of Research Products that Need Peer Review

This section provides an overview of OMB Bulletin requirements and BSEE recommended practices for determining whether a research product should be subject to peer review.

All research products considered influential scientific information shall be peer reviewed, with some exceptions discussed in Step 1.2 below. In addition, all research products that constitute a highly influential scientific assessment shall also be peer reviewed, with one exception.

Per the OMB Bulletin, "Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed." Highly influential scientific assessments must be subject to more stringent peer review requirements, as described in the sections below.

The Decision Maker should review the guidance in this section and definitions provided in this Manual when determining if a research product constitutes influential scientific information or a highly influential scientific assessment. Based on these considerations and the guidance provided in this subsection, the Decision Maker should make the final decision regarding whether a research product will be peer reviewed.

The remainder of Step 1.1 includes guidance for determining when to peer review research products that constitute influential scientific information. Even if a research product does not contain influential scientific information, peer review may be necessary. If it is determined that peer review will add substantial value to the product, it should be peer reviewed.

In cases where a research product is developed by BSEE and has not been subject to prior peer review, the decision regarding whether a product should be peer reviewed may be more straightforward. For products that have been previously peer reviewed or products developed by or with external organizations, apply the guidance listed below.

Adequacy of Prior Peer Reviews

For research products that constitute influential scientific information, the OMB Bulletin states that, "agencies need not have further peer review conducted on information that has already been subjected to adequate peer review." If a research product constitutes influential scientific information and has previously been peer reviewed, the Decision Maker should evaluate whether the prior peer review was adequate, using the guidance specified in this Manual. When determining if a previous peer review is adequate, per guidance in the OMB Bulletin, the Decision Maker shall consider, "the novelty and complexity of the science to be reviewed, the importance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review."

The **EPA "Peer Review Handbook"** provides the following general guidance on determining when a research product should be subject to peer review: "If there is any doubt about whether a work product needs peer review, go ahead and subject it to peer review."

Research products published in a refereed scientific journal will likely have undergone prior peer review that generally would be considered adequate for the purposes of this Manual. However, in these cases, the Decision Maker may still decide that the product should be subject to further, more stringent peer review.

Standards developed by voluntary consensus bodies (as defined by the National Technology Transfer and Advancement Act of 1995 (NTTAA)), hereafter referred to as "voluntary consensus standards," generally would not need to be peer reviewed because the processes used by the voluntary consensus bodies in developing the standards would ensure adequate information quality.

BSEE regulations incorporate by reference voluntary consensus standards from bodies such as: American Concrete Institute (ACI), American Petroleum Institute (API), American Institute of Steel Construction, Inc. (AISC), American Society of Mechanical Engineers (ASME), American National Standards Institute (ANSI), American Society for Testing and Materials (ASTM), and International Organization for Standardization (ISO). Such standards are generally of acceptable quality and do not need to be peer reviewed. If BSEE decides to use a standard that is not a voluntary consensus standard as defined by the NTTAA, peer review must be considered.

Products Developed by or in Agreement with External Organizations

BSEE's research products often are developed by or in agreement with external organizations. BSEE's Oil Spill Response Research (OSRR) program and Technology Assessment Programs (TAP) are cooperative efforts that bring together funding and expertise from research partners in government agencies, industry, universities, and the international community. The research programs operate through contracts and interagency agreements with universities, private firms, and government laboratories to assess safety-related technologies and to perform necessary applied research.

The OMB Bulletin does not specifically apply to information supplied to the federal government by external organizations, such as that provided under a research contract, unless the information is disseminated by a federal agency. As stated in the definitions above, dissemination is restricted to research products that represent an official opinion of BSEE. For research products supplied by external organizations, BSEE has historically applied this exemption to the OMB Bulletin by requiring that the external organization displays a disclaimer on the disseminated document that states, "the findings and conclusions in the report are those of the author(s) and do not necessarily represent the views of the funding agency."

However, there are instances in which BSEE will disseminate a research product developed by or in agreement with external organizations. In these cases, the research product must be evaluated for peer review and is subject to the same considerations as a research product produced by BSEE as described in Step 1. There are several processes through which BSEE research products are developed by or in agreement with external organizations, and each process has distinct considerations when determining which products will be subject to peer review.

If BSEE plans to disseminate a ***research product resulting from a grant, cooperative agreement, or contract***, the product must be considered for peer review. The organization that developed the research product should not conduct the peer review; however, guidance from the research product's author(s)

may be necessary to clarify any questions of the peer reviewers. The Decision Maker must be sure to consider any legal requirements related to the use of research products developed under grants, contracts, and cooperative agreements.

If BSEE plans to disseminate a ***research product developed under an interagency agreement***, the product must be considered for peer review. Although all federal agencies are subject to the peer review requirements of the OMB Bulletin, the other agency(ies) and BSEE may have differing standards for peer review.

Step 1.2: Determine if the Research Product Qualifies for an Exemption

If a research product is covered by the exemptions specified in the OMB Bulletin, the product does not need to be peer reviewed. This section assists the Decision Maker in determining if a research product falls under an exemption to the OMB Bulletin. Per the Bulletin, the following types of research products are exempt from peer review requirements:

- Information related to national security, foreign affairs, or negotiations involving international trade or treaties where peer review would interfere with the need for secrecy or promptness
- Information involving a health (including public health, or plant or animal infectious diseases) or safety dissemination that is time-sensitive
- A regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866, except for underlying data and analytical models used
- Routine statistical information (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends
- Accounting, budget, actuarial, and financial information
- Information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, loan programs, or the rights and obligations of recipients thereof

The OMB Bulletin also includes an ***exemption for information "disseminated in the course of an individual agency adjudication or permit proceeding*** (including a registration, approval, licensing, site-specific determination), 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." Per the OMB Bulletin, this exclusion covers, "among other things, licensing, approval and registration processes for specific product development activities as well as site-specific activities." ***BSEE has determined that the peer review of BSEE adjudications or permit proceedings is not "practical and appropriate;"*** thus, this exemption is employed by BSEE for such information.

Per the OMB Bulletin, if the first dissemination of a research product constitutes an exemption and the product is later disseminated in another context, the later dissemination must be considered for peer review.

In addition to these OMB exemptions, it is possible in exceptional circumstances for BSEE to waive or defer peer review requirements "where warranted by a compelling rationale." When deferrals are used, the peer review must be conducted as soon as possible. See Appendix F for details on waivers and deferrals.

Step 1.3: Determine if an Alternative Process is Appropriate

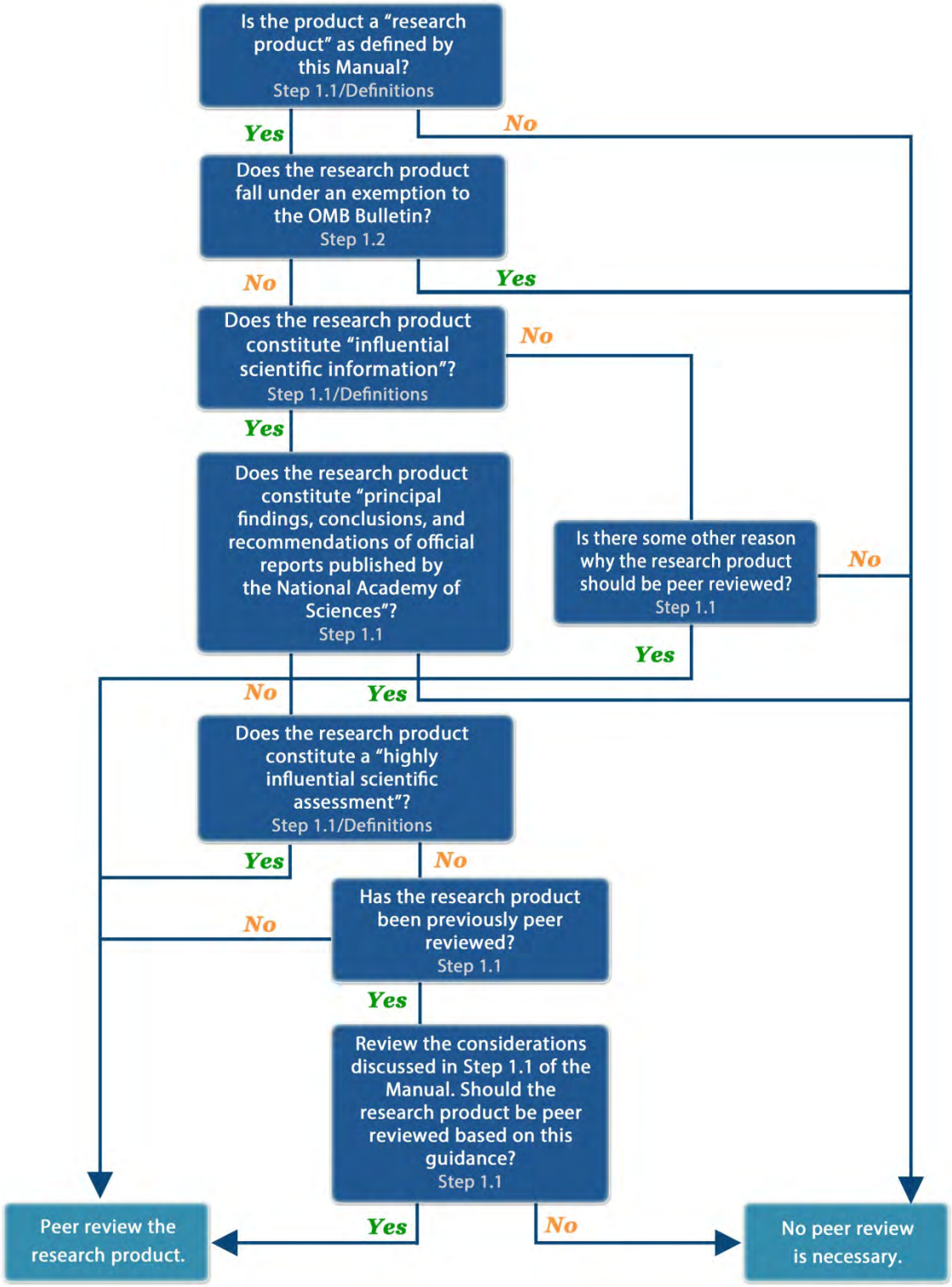
For research products that the Decision Maker determines should be peer reviewed, several alternative processes are available in addition to the peer review processes described in this Manual. The following are two acceptable alternative processes as specified by the OMB Bulletin:

- Commission the National Academy of Sciences (NAS) to peer review a draft research product
- Employ an alternative scientific procedure or process, specifically approved by the Administrator of the Office of Information and Regulatory Affairs in the OMB (OIRA) in consultation with the Office of Science and Technology Policy, which ensures the research product satisfies applicable information quality standards. The alternative procedure(s) may be applied to a designated product or group of products.[2]

Graphic 3 depicts a decision process to help BSEE staff determine whether a particular research product requires peer review.

[2] For additional discussion on examples of alternative procedures, see Appendix F.

Graphic 3: Determining if a Research Product Needs Peer Review



Step 2: Plan the Peer Review

Developing a plan for the peer review is an immensely important step in the peer review process. The efficiency, transparency, and outcomes of the peer review process are dependent on establishing effective goals and plans for the peer review from the start of the process.

After determining that a research product should be subject to peer review, the Decision Maker should assign a Peer Review Leader. The Peer Review Leader should be someone who is familiar with the research product, including its goals, results, and potential impacts. The Decision Maker has the responsibility and discretion to select the Peer Review Leader, based on any necessary qualifications, experience, and knowledge of the project.

The Decision Maker and Peer Review Leader should follow the steps in this section to establish a solid framework for the implementation, completion, and documentation of the peer review. The final result of peer review planning will be a Peer Review Plan that is posted to the BSEE Web site. Steps 2.1 through 2.3 provide guidance that will assist the Peer Review Leader and Decision Maker in making the decisions necessary to develop a Peer Review Plan.

Appendix A provides an overview of the peer review process, including the planning steps described in this section, in the form of a checklist for use by Peer Review Leaders.

For peer reviews of highly influential scientific assessments, "agencies typically will have to devote greater resources and attention" to considerations for planning the review, among other aspects of the review process.

-OMB Bulletin

Step 2.1: Establish the Scope and Timeline for the Peer Review

This section provides guidance to the Peer Review Leader and the Decision Maker on establishing the scope and timeline for the peer review. These two factors should be discussed both together and separately because decisions about scope of the peer review will likely impact decisions about the timeline, and vice versa. The Peer Review Leader and Decision Maker also will need to consider the costs of the peer review when determining the scope and timeline. Section 2.2 addresses resource considerations for peer review.

Make decisions by "beginning with the end in mind."

--Department of Energy Office of Energy Efficiency and Renewable Energy (EERE) Peer Review Guide

Determining the Scope of the Peer Review

The scope of the review will be a significant determinant in the kinds of feedback obtained from peer reviewers. When planning a peer review, the Peer Review Leader and Decision Maker should initially discuss the context and goals of the peer review, which will inform decision making about the peer review process. In determining the scope of the review, the Peer Review Leader and Decision Maker may consider the following questions:

- To what extent is the subject matter novel or complex in comparison to other research in its field(s)?
- What questions or issues does BSEE hope will be addressed by the peer review?
- How does the peer review align with other Bureau priorities?
- Does the research product address a controversial issue? If so, what is the issue? How might peer review help address concerns of the public or BSEE staff related to these issues?
- What are the key assumptions made in the research product? How might peer review address these assumptions?
- In what ways does the research product represent a departure from previous work in the subject area(s)?
- What uncertainties or limitations in the research product would benefit from peer review?
- Are there budget considerations that could limit the scope of the review?
- Are there internal or external timeline considerations that could limit the scope of the review?

The Peer Review Leader and Decision Maker also should discuss the desired level of ***transparency*** and ***independence*** of the peer review process. Transparency, as used in this Manual, refers to the documentation of the peer review process and results in a manner that is both accessible and comprehensible to the public. The peer review's level of transparency can affect (and be affected by) the use of public participation, the choice of peer review mechanism (discussed in Step 2.3) and peer reviewers, and the documentation of the peer review. Independence, as used in this Manual, refers to the objectivity of the peer review process relative to the development of the research product.

The level of independence can affect (and be affected by) the choice of peer review mechanism and peer reviewers, and the decision about whether to use contractors to support the peer review process. (Refer to Step 2.2 for further discussion on the use of contractors to lead the peer review.)

Keeping the scope and objective of the peer review in mind, there are several other planning elements that the Peer Review Leader and Decision Maker should begin to consider at this point in the peer review process:

- **Evaluation process for the research product:** The specific questions for peer reviewers will be finalized during development of the Peer Review Charge (see Step 3.1), but early consideration of charge questions, at least at a high level, will ensure adequate time and resources are available for the development of the evaluation methodology and materials. In particular, if peer reviewers will be asked to use a numeric rating system when evaluating the research product, it can be beneficial to begin the process of developing the rating system earlier in the peer review process. Appendix B contains a template to assist BSEE staff in creating an effective Peer Review Charge.

> BSEE staff involved in peer review should keep the following **OMB Bulletin** guidance in mind during the peer review process:
>
> "Agencies should strive to ensure that their peer review practices are characterized by both **scientific integrity** and **process integrity**.
>
> - Scientific integrity … refers to … expertise and balance of the panel members; the identification of the scientific issues and clarity of the charge to the panel; the quality, focus and depth of the discussion of the issues by the panel; the rationale and supportability of the panel's findings; and the accuracy and clarity of the panel report.
> - Process integrity includes … transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement, and adherence to defined procedures."

- **Necessary qualifications of the peer reviewers:** The scope of the review can both influence and be impacted by the necessary qualifications of the peer reviewers. When establishing the scope of the peer review, the Decision Maker and Peer Review Leader should begin to consider the number and expertise of reviewers that will be necessary to elicit the desired level of feedback. For detailed guidance on the selection and qualifications of reviewers, see Step 3.2.
- **Compensation:** The funds for peer reviewer compensation should have already been set aside as part of the funds for the peer review, and during the planning stage of the peer review process, the Peer Review Leader and Decision Maker should begin to think in more detail about the compensation amount that will be offered to peer reviewers. See Step 3.2.1 for information about reviewer compensation.
- **Confidential Business Information:** Per the OMB Bulletin, BSEE peer reviews must be conducted "in a manner that respects (i) confidential business information and (ii) intellectual property." If confidential business information (CBI) or other sensitive

information is included in the research product or any relevant background materials, the Peer Review Leader and Decision Maker will need to determine the best want to handle this information during the peer review. It may be possible for the sensitive information to be removed from the materials before sending them to peer reviewers. If the information is essential to the content of the research product, the Peer Review Leader and Decision Maker may consider requesting permission for peer reviewers to access the information for the purposes of the peer review (where possible). If peer reviewers are granted access to the information, they will need to sign non-disclosure forms.

Developing a Timeline for Peer Review

The Decision Maker and Peer Review Leader should establish a timeline for the peer review early in the peer review process, which includes determining both the optimal timing (i.e., when the process will start and ideally end) and a rough schedule (i.e., the amount of time each step will take) for the peer review process. Both aspects should be considered simultaneously because the schedule may impact the optimal timing of review, and, conversely, factors influencing the timing of the review (e.g., timeline for a proposed rule associated with the research product) may impact the schedule for the peer review.

The Peer Review Leader and Decision Maker should discuss the following considerations when developing the timeline for peer review:

- **Schedule for associated rulemakings:** When a research product is used in support of a rulemaking, the timeline for peer review can be largely driven by the schedule for the associated rulemaking. (See further discussion below.)
- **Schedule for development of the research product:** The timeline for peer review will be dictated by the timeline for the development of the research product.
- **Other internal or external deadlines:** Internal or external deadlines that could influence the peer review timeline could include deadlines for other peer reviews or projects, legal deadlines, and contractor deadlines. The Decision Maker, Peer Review Leader, and Peer Review Coordinator should provide insight on this whenever possible.
- **Budget for the peer review:** The length of the peer review could be influenced by the amount of available resources for the peer review and by funding allocation deadlines. For example, if resources are limited, the length of a peer review panel discussion might be shortened to limit meeting space costs (see further discussion in Step 2.3).
- **Schedule for and impacts of public participation:** Public involvement, especially the use of public comment, can lengthen the timeline for peer review. (See further discussion below.)
- **Peer reviewer availability:** In cases where there are a limited number of potentially qualified reviewers for a research product, the peer review timeline may be influenced by reviewer availability. In addition, the peer review timeline will be impacted by peer reviewers' external scheduling conflicts, such as holidays, vacations, and academic and stakeholder conferences.

Additional considerations with regard to developing a peer review timeline apply to ***research products that are used in support of rulemakings*** and ***highly influential scientific assessments,*** as discussed below.

Associated Rulemakings

Extra attention should be given to developing the timeline for peer review for ***research products that are used in support of rulemakings***. For research products that are critical to rulemaking, the OMB Bulletin guidance states that "it is important to obtain peer review before the agency announces its regulatory options." The rationale provided for this guidance is to ensure that, "any technical corrections can be made before the agency becomes invested in a specific approach or the positions of interest groups have hardened." Another benefit of conducting peer review early in the decision making process is the potential for peer review to decrease the likelihood of challenges to a rulemaking that could result in litigation. The Peer Review Leader and Decision Maker are encouraged, whenever possible, to schedule the peer review such that the peer review process is complete before BSEE proposes any associated rulemakings, or at least before the close of the comment period. The schedule for public comment periods on associated rulemakings can significantly affect the peer review process, and the Peer Review Leader and the Decision Maker should take this into account when developing a timeline for the peer review. To address the OMB requirements on public involvement for highly influential scientific assessments, the timeline will need to take into account that public comments will need to be collected and provided to peer reviewers before the commencement of the peer review (See discussion below on considering public involvement).

Highly Influential Scientific Assessments

For ***highly influential scientific assessments***, the impact of public participation on the timeline for peer review may be greater. The OMB Bulletin includes guidance on public comment and public meetings for these cases (see discussion on public involvement below). When there is public participation in the peer review process, the Bulletin specifies that, BSEE shall "specify time limits for public participation throughout the peer review process." Similarly, if public comments are solicited on a research product, BSEE must avoid open-ended comment periods.

During the planning stage of the peer review process, the Decision Maker and Peer Review Leader should establish a general timeline for each stage of review, and a more detailed schedule for implementing the peer review itself will be finalized later in the peer review process (see Step 3.3).

Considering Public Involvement

Both the timeline and the scope for the peer review may be impacted by the desired level of public involvement; similarly, the opportunities for public participation may be limited by scheduling constraints. The Peer Review Leader and Decision Maker should decide on the level of public participation based on the scope, timeline, and budget established for the peer review, as well as the anticipated level of stakeholder interest. For example, when peer review will be addressing potentially controversial topics, there may be a stronger case for public involvement.

For peer reviews of highly influential scientific assessments, the OMB Bulletin states that "wherever possible, provide for public participation." Conversely, there may be instances in which the timeline or budget limit the opportunities for public involvement. There are opportunities for public participation during many phases of the peer review process:

- **Public comment on the research product:** Public comments may be solicited on research products as deemed necessary by the Decision Maker and Peer Review Leader. One potential avenue for soliciting public comments is through the BSEE Web Site. Per the OMB Bulletin, whenever "feasible and appropriate" for highly influential scientific assessments, BSEE shall:
    - Make the draft research product available to the public for comment at the same time it is submitted for peer review[3] (or during the peer review process); and
    - Provide peer reviewers with access to public comments, if solicited, that address scientific or technical issues.
- **Public comment on the Peer Review Plan and Peer Review Agenda:** BSEE is required to solicit and consider public comments on the adequacy of its Peer Review Plans. For each research product that is influential scientific information, the OMB Bulletin specifies that the public shall be given sufficient time to provide comments on the Peer Review Plan.
- **Public nomination of peer reviewers:** Per the OMB Bulletin, BSEE must consider requesting nominations for peer reviewers from the public (including scientific or professional societies). BSEE staff also may consider requesting nominations from stakeholders. (See Step 3.2.1 for additional details on reviewer nominations.)
- **Open panels:** External peer review panel discussions may be open to the public. During open panel discussions, public comments may be solicited during or after the peer review. Opening panels to the public can improve the accountability and transparency of the panel discussion and the peer review in general. On the other hand, public participation may decrease the efficiency of the discussion and impact reviewer reactions to the research product. The Peer Review Leader and Decision Maker should weigh these factors when determining whether to open panel discussions to the public.
- **Public presentations:** Per the OMB Bulletin, for highly influential scientific assessments, whenever "feasible and appropriate," BSEE shall sponsor a public meeting where interested members of the public can make oral presentations on the relevant scientific issues.

[3] The research product should not be made available to the public at the same time it is provided to peer reviewers. Instead the research product should be made available to the public earlier in the peer review process (i.e., during the planning phase.)

Step 2.2: Determine the Peer Review Mechanism

In this Manual, a "peer review mechanism" refers to the format through which comments are solicited from peer reviewers. The OMB Bulletin provides federal agencies with the discretion to weigh the benefits and costs of using a particular peer review mechanism. The choice of peer review mechanism should take into account the various levels of risk, technical complexity, relevance to future regulations, and ultimate use of the peer reviewed research products. The Decision Maker and Peer Review Leader should use the guidance in this section to select the appropriate peer review mechanism for a research product.

Government agencies, research organizations, and academic institutions use many different kinds of peer review mechanisms. Peer review mechanisms at federal agencies can be divided into two broad categories: internal and external. This section (and the sections that follow) will focus on three common peer review mechanisms used in peer reviews of BSEE research products: ***internal reviews, external letter reviews,*** and ***external panel reviews***. Some other examples of peer review mechanisms used by federal agencies include: peer review conducted by a Federal Advisory Committee, peer review conducted by a board or commission appointed by an agency, and peer review workshops sponsored by an agency.

Table 2-1 presents an overview of the associated format, benefits, costs, challenges, and common uses for internal review, external letter review, and external panel review. The next section will delve into additional factors to consider when selecting a peer review mechanism.

TABLE 2-1A: DESCRIPTION OF PEER REVIEW MECHANISMS: INTERNAL REVIEW

Internal Review	
Format:	For internal peer reviews, peer reviewers are BSEE (or BOEM or DOI) staff members that are independent of the development of a research product. (For additional information on selecting internal peer reviewers, see Step 3.2). The format of an internal peer review can be tailored to the goals and scope of the peer review; a less time-intensive internal review might solicit individual comments from a small group of reviewers, while a more thorough internal review might convene a larger panel of reviewers and hold meetings for reviewer discussion in addition to soliciting written comments. Regardless of the specific method used for internal peer review (i.e., written comments, meetings of reviewers, or both), the costs in terms of resources and BSEE staff time generally are comparable. An internal peer review typically involves 3-5 reviewers.
Benefits:	• Relatively low costs associated with travel and reviewer compensation because the peer reviewers are Federal government staff • Relatively low resource management associated with scheduling and communicating with reviewers because reviewers' workload can be managed against overall BSEE goals and priorities • Relatively quick review process because no external reviewers need be involved • Ability to tailor the review based on the desired level of review and the amount of available staff time • Relatively high technical qualifications of reviewers due to their familiarity with BSEE's capabilities, goals, and mission
Challenges:	BSEE staff members, though available and technically proficient in the subject matter, do not always constitute a group of peer reviewers that is truly independent of the development of the research product. Even in cases where the Peer Review Leader is able to identify an independent group of internal reviewers, the level of independence of an internal review may appear to be less credible to stakeholders and members of the public.
Costs:	Internal peer reviews are the least expensive of peer review mechanisms, requiring only BSEE staff time and materials for reviewers.
Use When...	• Internal peer reviews may be desirable when there are significant time or budget constraints for the peer review process. • Due to the pioneering nature of BSEE's research, there may be instances in which BSEE is unable to identify a sufficient number of external independent reviewers who have the necessary expertise to peer review a research product. Thus, if the research product addresses a limited number of subjects or uniquely technical areas, and BSEE is able to identify independent internal reviewers, the Peer Review Leaders and Decision Makers might consider using internal peer review. • In instances when BSEE is developing a research product that relies heavily on confidential business information (CBI) or other highly sensitive information, and the research product does not fall under one of the exemptions discussed in Step 1.2 above, there might be a case for internal peer review. (Note that for some research products, it may be possible to conceal this information from peer reviewers for the purposes of peer review.)

TABLE 2-1B: DESCRIPTION OF PEER REVIEW MECHANISMS: EXTERNAL LETTER REVIEW

External Letter Review	
Format:	External peer reviews involve a group of independent peer reviewers who are external to BSEE. In an external letter review, comments are collected from the reviewers in written form, usually in response to a set of questions identified in a Peer Review Charge. An external letter review typically involves 3-5 reviewers.
Benefits:	• Opportunity to solicit opinions from external subject matter experts in a formal setting before dissemination of research products • Diverse perspectives from reviewers of varying backgrounds • Relatively high level of reviewer independence, resulting in enhanced credibility of peer review results as viewed by stakeholders, members of the public, and the scientific community
Challenges:	Although external peer review is associated with significant benefits over internal peer review, external peer review is associated with increased costs and risks. Depending on the location of the review, the number of peer reviewers, the stipend provided to reviewers, and whether a contractor is hired to coordinate the review, external peer reviews can require significantly more time and funding than internal peer reviews. In addition, it can be a challenge to manage external peer reviewers who have full-time jobs and other commitments beyond the peer review. However, in many cases, the benefits of an external review may outweigh the risks and costs, especially for high-visibility or high-impact projects.
Costs:	External letter reviews, when conducted by BSEE staff, require more BSEE staff time and resources than internal peer reviews. BSEE staff will need to spend time selecting the reviewers and overseeing the review. Also, the time it takes to conduct the peer review process will increase due to the wait time associated with reviewer responses. There will be a slight increase in material costs due to the necessity of mailing reviewer packets (although this cost can often be minimized through the use of technology). However, the most significant incremental cost, relative to an internal review, would be compensation to the reviewers for their evaluation (this cost will apply to any external peer review mechanism). Should BSEE staff members decide to use a contractor to conduct an external letter review, costs would increase further due to contractor fees; however, the amount of BSEE staff time needed to conduct the review would be less than under a BSEE-led letter review.
Use When...	• Peer Review Leaders may consider using an external letter review when the budget for an external peer review is somewhat limited. • External letter reviews also can be used in conjunction with external panel reviews in instances when a research product needs a particularly thorough peer review. In these instances, the research product would benefit from review by a large group of diverse individuals because different peer reviewers would be used for the external letter review and external panel review.

TABLE 2-1C: DESCRIPTION OF PEER REVIEW MECHANISMS: EXTERNAL PANEL REVIEW

External Panel Review	
Format:	In an external panel review, comments are solicited from reviewers both during and after a series of panel discussions among reviewers either on-site or via telecommunication. An external panel review typically consists of 3-10 reviewers.
Benefits:	• All benefits mentioned for external letter review • A high level of transparency if panels are open to the public • Benefits resulting from discussion among subject matter experts. Opportunities for reviewer discussion in an external panel review can also provide the potential for consensus among qualified experts, especially for more controversial or complex peer reviews. (Note that when BSEE staff members conduct external panel reviews, as opposed to peer reviews conducted by contractors, consensus should not be sought due to FACA considerations. See Step 2.3 for details.)
Challenges:	The challenges for an external panel review are the same as those mentioned for an external letter review. A further challenge of panel reviews is the coordination of several external individuals' schedules, plus BSEE staff, for the panel discussion and any associated travel.
Costs:	External panel reviews require the most resources of all of the peer review mechanisms. In general, each step of the peer review process will require more time to coordinate for an external panel review. In addition to the costs for external letter reviews, external panel reviews will include costs associated with hosting a panel discussion, either in person or virtually. For peer reviews hosted in person on-site at BSEE, costs will include peer reviewer travel costs (if compensation is provided) and costs associated with office supplies and audio/visual technology for recording the discussion. If the panel discussion is held at another location, space rental fees will be included in the costs of the peer review. All of these costs can be significantly decreased with the use of video-conferencing technology; however, there are benefits to in-person dialogue between experts, especially when the panels are open to the public. All of these costs still exist under a contractor-led review, but the peer reviewer and coordination labor (and, if applicable, travel) costs would be paid to a contractor responsible for organizing and facilitating the panel discussion.
Use When...	• External panels should be used in cases where BSEE staff goals for the peer review prioritize transparency in the peer review process. • Due to the benefits associated with transparency and discussion among reviewers, external panel reviews might be most appropriate for research products that have never been subject to peer review or research products that are novel, complex, or precedent-setting (see further discussion on these factors below). • External panels can be useful in technically complex projects when the interaction of reviewers can lead to more in-depth conclusions or review.

Factors to Consider when Choosing a Peer Review Mechanism

The decision of which peer review mechanism to employ generally is an exercise in weighing the costs against the benefits for each particular project while taking into consideration the available resources. The Peer Review Leader and Decision Maker must consider tradeoffs between timeliness and the depth of the peer review process.

BSEE staff should avoid using internal peer review for the peer review of ***highly influential scientific assessments*** (see Step 3.2 for further guidance on selecting peer reviewers).

"Peer review can be valuable in establishing the bounds of the scientific debate when methods or interpretations are a source of controversy among interested parties."

-OMB Bulletin

For ***influential scientific information***, the choice of peer review mechanism is left to the discretion of the Peer Review Leader and Decision Maker. In general, external panel reviews are considered the most credible and rigorous of the peer review mechanisms, and the OMB Bulletin states that they should be used whenever time and resources permit this type of review. Of course, these reviews also can require a significant investment of time and money, and the Peer Review Leader and Decision Maker should weigh the pros and cons of this kind of review for individual projects.

The OMB Bulletin states that for all influential scientific information, the choice of peer review mechanism shall be based on the following factors: the novelty and complexity of the information to be reviewed, the importance of the information to decision making, the extent of prior peer review, and the expected benefits and costs of review. The Peer Review Leader and Decision Maker must consider these factors, as well as the guidance provided below, when selecting a peer review mechanism.

"More rigorous peer review is necessary for information that is based on novel methods or presents complex challenges for interpretation. Furthermore, the need for rigorous peer review is greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact."

-OMB Bulletin

Novelty, Complexity, and Influence of the Research Product

The Peer Review Leader and Decision Maker should consider peer review mechanisms that are more independent, transparent, and thorough for research products that are novel, complex, precedent-setting, or likely to influence high-impact decisions. In order of rigor and credibility, the most common BSEE peer review mechanisms are ranked as follows: (1) external panel review led by a contractor (with opportunities provided for public participation), (2) external panel review led by BSEE staff (with opportunities provided for public participation), (3) external letter review led by a contractor, (4) external letter review led by BSEE

staff, and (5) internal peer review.

Whenever possible, the Decision Maker should provide insight into the likelihood of the peer review to influence high-impact decisions when determining a peer review mechanism. The rigor of the peer review should be correlated with the research product's level of significance and potential impact on policy decisions.

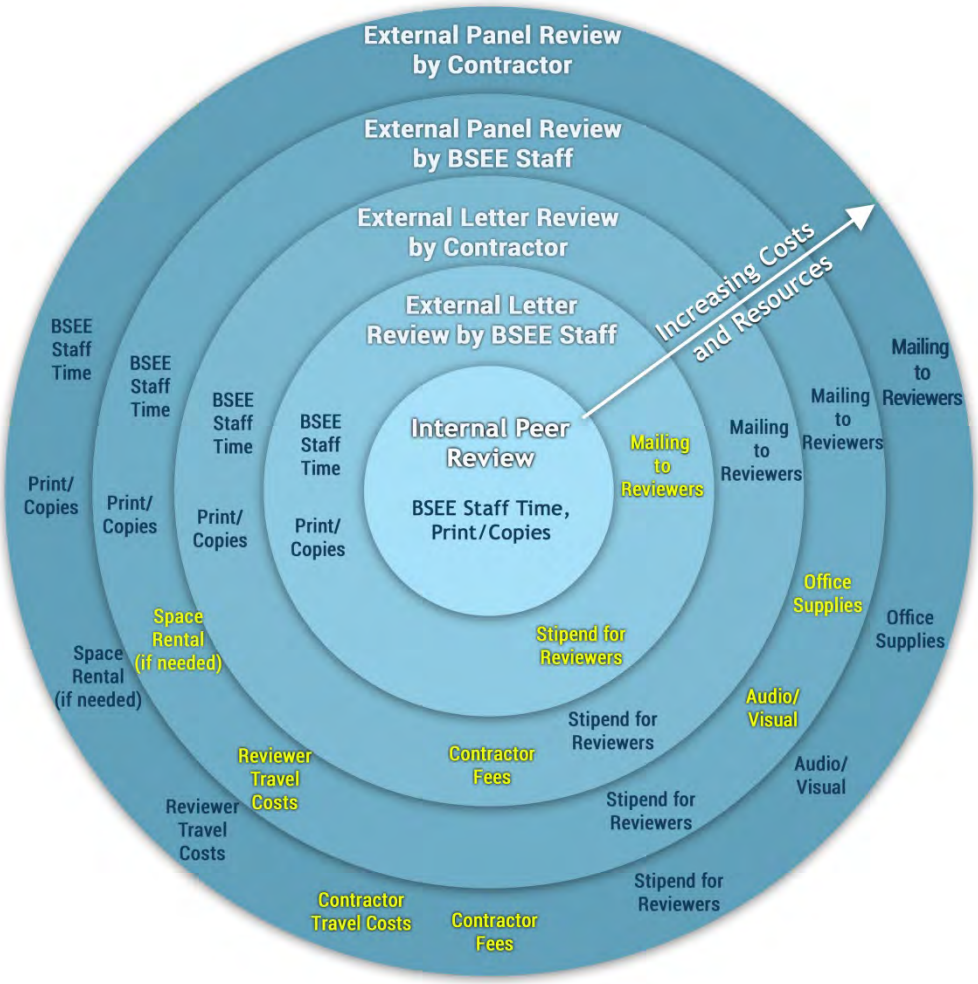
Resources and Costs

The required resources for a peer review will vary depending on peer review mechanism, funding, schedule, public participation, and the scope of the review. BSEE staff has significant discretion in tailoring peer review resources to the desired level of review. The Decision Maker should provide insight into the priority of the peer review in the context of other BSEE priorities whenever possible.

In selecting a peer review mechanism, the Decision Maker and Peer Review Leader will need to consider the required resources for each peer review mechanism, the available budget for peer review, and the use of contractors. Details on budgeting are discussed in Step 2.3. Details on costs for each peer review mechanism are included in Table 2-1.

Graphic 4 provides an overview of the relative cost elements for internal peer review, external letter review, and external panel review. Each ring, moving outward from the center, represents a more resource-intensive peer review mechanism. The incremental costs associated with each mechanism (relative to the ring inside of it), are highlighted in yellow.

GRAPHIC 4: RESOURCES AND COSTS BY PEER REVIEW MECHANISM



Prior Peer Review

The level of prior peer review may influence the choice of peer review mechanism (e.g., if a research product was previously subject to a thorough peer review, BSEE staff may determine that a less rigorous peer review mechanism is acceptable). The Peer Review Leader and Decision Maker should refer to the guidance in Step 1.1 on consideration of prior peer reviews.

Disclosure and Attribution

While selecting a peer review mechanism, the Peer Review Leader and Decision Maker must also consider: the method for selecting reviewers, the method for disposition of reviewer comments, and the level of attribution and disclosure of reviewer names and comments. Refer to Steps 4.2 and 4.3 for additional information on options for disposition of reviewer comments and disclosure and attribution of reviewer names and comments. Step 3.2 provides information on methods for selecting peer reviewers.

Graphic 5 compares "at a glance" several characteristics of an internal review, external letter review, and external panel review.

GRAPHIC 5: COMPARING PEER REVIEW MECHANISMS

Characteristic	Internal Review	External Letter Review	External Panel Review
Independence of Reviewers	Low	High	High
Number of Reviewers	Limited by Internal Resources Only	3-5	3-10
Costs/Resources	Low	Medium	High
Novelty/Complexity/Precedence of Research Product	Low	Medium	High
Diversity of Reviewer Experience	Low	High	High
Transparency	Low	Medium	High
Resource Management Time	Low	Medium	High
Availability of Independent External Experts	Reviewers are Challenging to Identify	Reviewers are Easily Identified	Reviewers are Easily Identified
Length of Peer Review Process	Short	Lengthy	Lengthy
Opportunity for Discussion Amongst Reviewers	High	Low	High

Contractors and Peer Reviews

One of the most important decisions about peer review resources is whether a contractor will be used to run the peer review. The Peer Review Leader and Decision Maker should carefully consider the role, if any, of contractors when selecting a peer review mechanism. This section provides guidance on determining if a contractor should be used and implementing a contractor-led review.

The OMB Bulletin specifies that federal agencies may use independent contractors (e.g., scientific or professional societies, firms specializing in peer review, or non-profit organizations with experience in peer review) to manage peer reviews. The primary benefit of using a contractor is an increased level of independence in the peer review process. Other potential benefits include process efficiency and increased credibility of the process resulting from using a contractor with extensive peer review experience. Potential risks associated with using a contractor include the contractor's lack of familiarity with Bureau priorities and goals for the research product and decreased control over the peer review process (however, a well-written Statement of Work [SOW], as discussed below, would overcome this risk). Costs include the contractor fees for labor and travel. The Peer Review Leader and Decision Maker should weigh the benefits of using a contractor with the costs and risks.

The ***role for BSEE staff in conducting and documenting peer reviews is lessened in contractor-led peer reviews***. The Peer Review Coordinator will play a comparable role during a contractor-led peer review (i.e., ensuring that all BSEE peer reviews are adequately documented and conducted in accordance with applicable peer review requirements). However, the roles of the Peer Review Leader and the Decision Maker will be lessened when contractors lead peer reviews. The contractor will manage all aspects of conducting and documenting the review, and the Decision Maker and Peer Review Leader will be involved only in the planning process and confirming that the contractor implemented the peer review as specified in the contract. In other words, BSEE staff will complete Steps 1 and 2 of this Manual in a contractor-led peer review. The contractor's role in conducting and documenting the review is outlined in Steps 3 and 4.

The Federal Advisory Committee Act (FACA) does not apply to BSEE peer reviews that are established, managed, or controlled by a contractor. The role for BSEE staff in contractor-led peer reviews is limited to ensure that contractor-led peer reviews do not become subject to ***FACA requirements*** and to increase the independence of the review process. FACA requirements are discussed in Step 2.4.

The limited role for BSEE staff in implementing, completing, and documenting the peer review when a peer review is led by contractors is discussed below.

- **Input into the peer review process:** In a contractor-led peer review, BSEE staff establish the peer review mechanism, draft or provide approval on a Peer Review Charge, provide guidance on reviewer qualifications, and approve the contractor's selection of peer reviewers. After BSEE staff determine a mechanism, the contractor proceeds with conducting the peer review and documenting the results. Outside of the requirements stipulated in the SOW, BSEE staff should not provide input on the specific schedule set for the peer review or the documentation of the review.

- **Relationship with peer reviewers:** BSEE staff should not interact with peer reviewers, with one exception. The contractor may ask BSEE staff to provide background information on the research product to the peer reviewers. These interactions must take place only during meetings run by the contractor, and at the contractor's request. Peer reviewers are considered subcontractors to the primary contractor in a contractor-led peer review.
- **Implementing the results of the review:** In a contractor-led peer review, the contractor will create the Peer Review Report. As in peer reviews conducted by BSEE staff, the results of a contractor-led peer review will be considered by BSEE staff, and BSEE will make decisions about dissemination of the research product. The BSEE decision-making process for research products that are peer reviewed by contractors needs to be well documented to establish that the contractor is not performing any inherently governmental activities.

Note that if a contractor developed the research product, that same contractor should not conduct the peer review of the research product. However, the contractor who developed the research product may provide technical guidance to the peer reviewers or answer their technical questions, as long as these activities are facilitated by the contractor leading the review and overseen by the Peer Review Leader.

Step 2.3: Complete Administrative Tasks

This step includes guidance on several administrative tasks that should be undertaken by BSEE staff after selecting a peer review mechanism and before selecting reviewers. BSEE staff should begin to document the peer review process, develop a detailed budget for the peer review, and draft an SOW if a contractor is being used to lead the peer review.

Initial Documentation of the Peer Review Process

To ensure transparency, BSEE staff should begin to document the peer review process while planning the peer review. The Peer Review Leader, Decision Maker, and Peer Review Coordinator all have responsibilities for documenting the peer review.

Peer Review Plan

The Peer Review Leader and the Decision Maker must create a Peer Review Plan based on the decisions made about the peer review mechanism, scope, and timeline. Per the OMB Bulletin, the Peer Review Plan shall contain the following information:

- Paragraph including the title, subject, and purpose of the research product, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan
- Names of authors, contributors, and key stakeholders, where applicable[4]
- Whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment
- Timing of the review (including deferrals)

[4] Although not required by OMB, BSEE follows the best practice of including names of authors, contributors, and stakeholders in the Peer Review Plan where applicable.

- Whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be employed)
- Whether there will be opportunities for the public to comment on the research product to be peer reviewed, and if so, how and when these opportunities will be provided
- Whether BSEE will provide significant and relevant public comments to the peer reviewers before they conduct their review
- Anticipated number of reviewers (3 or fewer; 4-10; or more than 10)
- Succinct description of the primary disciplines or expertise needed in the review
- Whether reviewers will be selected by the agency or by a designated outside organization
- Whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers

The Peer Review Coordinator must facilitate the posting of all Peer Review Plans to the BSEE Web site. BSEE accepts public comments on the adequacy of Peer Review Plans via the BSEE Web site. The Peer Review Coordinator should review and brief the Decision Maker on these comments.

Peer Review Agenda

The BSEE Web site contains a Peer Review Agenda that contains all BSEE Peer Review Plans. OMB requirements specify that the Peer Review Agenda must "describe all planned and ongoing influential scientific information" and include links to all documents that have been made public pursuant to the OMB Bulletin. The Peer Review Agenda must be updated by the Peer Review Coordinator at least every six months (or more often for highly influential scientific assessments and other particularly important information). Note that the Peer Review Agenda shall include information on those research products subject to OMB Bulletin waivers or deferrals (See Step 1.2 for additional information on waivers and deferrals). Additionally, if an alternative process will be used for the peer review (as discussed in Step 1.3), the Peer Review Plan must describe the alternative process.

Strategies for managing peer review costs include:

- Use teleconferencing and videoconferencing when possible
- Host meetings either on-site at BSEE or in a location that will require the lowest travel costs for reviewers, contractors, and BSEE staff
- Develop targeted questions for the reviewer charge (see Step 3 for further discussion)
- Develop the schedule and agenda for the review with efficiency in mind

Peer Review Record

The Peer Review Leader should begin to compile the Peer Review Record as soon as practicable. All documents and decisions made during the peer review process should be compiled for inclusion in the Peer Review Record. Thorough documentation of the peer review process is essential to the goals of the BSEE peer review process.

Detailed Budget for the Peer Review Process

As mentioned in Step 1, funding for the peer review should have been allocated during the development of the research product; at that time, resources should have been considered at a high level. The discussion on costs and resources in Step 2.2 above is meant to assist BSEE staff in developing a more detailed budget for the peer review. At this point in the peer review process, the Decision Maker and Peer Review Leader should consider the necessary resources and develop a budget for the peer review, consistent with BSEE protocols for project budgeting.

Statement of Work

If using a contractor to lead a peer review, BSEE staff should develop a Statement of Work (SOW) during the planning process for the peer review. ***A well-written SOW will ensure that a contractor-led peer review is conducted to BSEE's specifications***. All contracts with private entities to assist BSEE with the implementation of peer reviews should include a clear SOW. The SOW should not simply define the contractor's role as generally facilitating the services of peer reviewers and meeting logistics. Instead, the SOW should, in explicit terms, describe the contractor's responsibilities and the activities that the contractor is expected to perform. The SOW should be written with the intent of helping the contractor plan and cost out the review to BSEE's specifications in as specific terms as necessary to convey BSEE's expectations.

Table 2-2 presents the information that should be included in an SOW for a contractor-led peer review.

TABLE 2-2: WRITING AN EFFECTIVE SOW

Element to be included in SOW	Specific Information to Include
Overview of the research product	The following information should be included in the background section of the SOW: • Background of the research product • Working title • Contributors and collaborators • Format • Approximate length and complexity
Guidance for ensuring the credibility, transparency, and defensibility of the peer review, as determined by BSEE	• Instructions to comply with the BSEE Peer Review Process Manual • Discussion of sensitivities surrounding the research product • Guidance on peer reviewer disclosure and whether and how comments should be attributed to each peer reviewer • Requirements that the contractor include language in external panel peer review materials clarifying that the review is not subject to FACA
Requirements for evaluating COI	• Stipulation on whether or not the contractor will use the BSEE COI form • Requirement to submit a summary of the contractor's COI inquiries • Notation of contractor's obligation to identify and report COI throughout performance of the peer review
BSEE's desired format for the review and the expected number of reviewers	BSEE may stipulate, for example, that the review is to be a letter review conducted by a minimum of 3 individual reviewers.
A description of each task for which the contractor is responsible, including specific requirements under each task	BSEE could delegate the following tasks: • Selection of peer reviewers (including a discussion of expected qualifications) • Development of the Peer Review Charge (see below) • Facilitation of an introductory kick-off meeting • Delivery of peer review materials to reviewers • Facilitation of peer review panel, if applicable • Development of Peer Review Report (including format specifications and whether an outline and/or draft version will be submitted for BSEE review) • Assistance with compiling the Peer Review Record • Overall management of the peer review (kick-off meeting, check-in calls, monthly progress reports, etc.)
Information on the Peer Review Charge	• Stipulations on whether or not the contractor will assist in the development of the Peer Review Charge • The list of questions (draft or final) that BSEE wants the contractor to include in the Peer Review Charge • Requirement that the questions are to be submitted to and approved by BSEE before finalization
BSEE's expectations for the services peer reviewers should provide	BSEE could include the following expectations from peer reviewers: • Attendance at an introductory kick-off meeting • Written responses to the charge questions • Attendance at a panel discussion lasting approximately 4 hours, for example
The expected timing and due date of all deliverables required under the contract. A table works well to convey this type of information.	BSEE may stipulate the following, for example: • The contractor has 4 weeks from the start of the contract to develop and deliver the Peer Review Charge and select reviewers • The peer reviewers should have no less than 4 weeks to review the research product • The contractor has 3 weeks from receipt of comments to develop and deliver the Peer Review Report
Information regarding compensation for external peer reviewers	• A statement that BSEE will provide funds to the contractor to compensate eligible peer reviewers for their time and travel • An estimate of how many hours would be required for a peer reviewer to complete the review, including required meetings or calls

Refer to Appendix C for a template that can be used as a resource for BSEE staff when creating an SOW for a contractor-led peer review.

Step 2.4: Review the Legal Aspects of Peer Review

Although BSEE will consider the results of a peer review during the development and finalization of a research product, the decision about whether to disseminate a research product is within BSEE's discretion and is not in any way ceded to peer reviewers, as are policy recommendations and decisions. Similarly, decisions on whether to peer review research products are within BSEE's discretion. This Manual provides guidance for BSEE staff during the peer review process and does not create or impact any legal rights or obligations.

One legal aspect of peer review that should be kept in mind when planning and conducting a peer review is the ***Federal Advisory Committee Act*** (FACA). Any peer review conducted by a Federal Advisory Committee is subject to FACA. In general, external letter reviews that solicit individual reviewer feedback and peer reviews that are entirely run by a contractor will not fall under the requirements of this Act. (Peer Review Leaders and Decision Makers must follow guidance on contractor-led peer reviews provided in Step 2.2 to ensure that these peer reviews are not subject to FACA requirements.)

When BSEE staff members are conducting an external panel review, the Peer Review Leader and Decision Maker should consider that the peer review could be subject to FACA, depending on the format of the peer review. Committees subject to FACA must meet certain requirements regarding public participation, meeting records, and meeting procedures, among other requirements. To avoid having to conform to FACA requirements, Peer Review Leaders and Decision Makers must ensure that the panel is not asked to form consensus or collective recommendations, ratings, or opinions, and that panel reviewers understand that they should provide individual feedback on the research product. For additional information on FACA, BSEE staff may refer to DOI-specific guidance: http://www.doi.gov/pmb/cadr/toolkit/faca.cfm.

BSEE staff should also refer to their Contracting Officer for information on compliance with the Federal Acquisition Regulation (FAR) for contractor-led peer reviews.

Step 3: Implement the Peer Review

Once a solid framework for the peer review has been established in the planning phase, the Peer Review Leader and Decision Maker should implement the peer review process according to plan with transparency, integrity, and independence. This section outlines the process for implementing a successful peer review. Accompanying this guidance are several supporting Appendices that serve as additional resources for developing a Peer Review Charge, drafting a Statement of Work (SOW), and addressing peer reviewer conflict of interest (COI).

As discussed in Step 2, in a contractor-led peer review, the contractor facilitates the implementation of the peer review with guidance from BSEE staff, as outlined in the SOW (see Steps 2.2 and 2.3 for guidance on use of contractors and the development of an SOW). Specific implementation details for contractor-led peer reviews are discussed at the end of each subsection in Step 3.

Step 3.1: Develop the Peer Review Charge

The Peer Review Leader is responsible for developing the Peer Review Charge. As defined earlier in this Manual, a Peer Review Charge is BSEE's formal request for feedback from peer reviewers, containing instructions for the peer review and all questions for which BSEE would like to obtain input from the peer reviewers. This step provides guidance for the Peer Review Leader when developing a Peer Review Charge. Developing an effective Peer Review Charge can improve the efficiency of the peer review process and the utility of the final Peer Review Report. Refer to Appendix B for a template BSEE staff may use when creating a Peer Review Charge.

"Peer review is most powerful when the charge is specific and steers the reviewers to specific technical questions while also directing reviewers to offer a broad evaluation of the overall product."

-OMB Bulletin

As discussed in Step 2, the Peer Review Leader and Decision Maker should have considered, at least at a high level, the content of the Peer Review Charge. The Peer Review Charge must be finalized before peer reviewers are selected and should be aligned with the scope of the peer review, as discussed in Step 2.1.

The OMB Bulletin provides the following general guidance about developing the Peer Review Charge:

- Peer reviewers must be asked to ensure that "scientific uncertainties are clearly identified and characterized" and that "the potential implications of the uncertainties for the technical conclusions drawn are clear."
- The Peer Review Charge must clearly state that the reviewers are not being asked to provide and should not provide advice on the government's policies and decisions.
- Where appropriate, per OMB guidance, the Peer Review Charge must ask reviewers to "provide advice on the reasonableness of judgments made from the scientific evidence."

The following elements must be included in the Peer Review Charge:[5]

- Objectives of the peer review, including the clarification that reviewers are not being asked to provide advice on BSEE policies and decisions
- Summary description of the research product, including information on the goals for the research product, its development process, individuals and organizations involved, and any associated BSEE decision makings
- List of all materials being provided to the reviewer
- Peer review schedule and reviewer deadlines
- Details on comment attribution and peer reviewer disclosure
- Specific technical questions to be addressed by the peer reviewers
- A request for reviewers to provide an overall assessment of the research product
- Any other relevant information about how the reviewers should complete the review, including logistics for submitting comments and confidentiality requirements

Peer Review Charge Questions

The Peer Review Leader should keep in mind that all questions asked of the peer reviewers should have a purpose, and the questions should be tailored to the individual research product. Detailed and focused charge questions assist both the peer reviewer in assessing the research product and the Peer Review Leader in developing the Peer Review Report. The Peer Review Charge questions should be formatted so as to elicit detailed responses from the peer reviewers. For example, reviewers should be asked to explain their "yes/no" or numeric answers.

"If the response to a review question could not provide the basis for future action, asking the question would be a wasted effort."

-EERE Peer Review Guide

[5] Although not all of these elements are required by OMB, BSEE follows the best practice of including all of this information in the Peer Review Charge. The Peer Review Charge template contained in Appendix B, including the requested input from BSEE staff, includes all of these elements.

The Peer Review Leader should consider whether it would benefit the peer review process to develop a set of criteria on which to ask the peer reviewers to rate the research product. Quantitative data can be valuable when presenting peer reviewer responses to senior management and to the public, and can provide a metric on which to compare different peer reviews within BSEE's research programs. Example Peer Review Charge questions that solicit a numeric rating from peer reviewers are contained in Appendix B.

Finalizing the Peer Review Charge

After developing the Peer Review Charge, the Peer Review Leader should brief the Decision Maker on its contents before sending it to the peer reviewers. The Decision Maker should ensure that the Peer Review Charge accurately characterizes the goals for the peer review and clearly outlines all of BSEE's questions for the peer reviewers. The Peer Review Charge will eventually be posted to the BSEE Web site with other peer review materials in the Peer Review Report (see Step 4.2).

Specific Guidance for Drafting a Peer Review Charge under Contractor-Led Peer Reviews

Contractors may assist in the development of the Peer Review Charge, at BSEE's discretion. If the contractor is expected to help develop the Peer Review Charge, this expectation should be stipulated in the SOW. Further, if possible, the list of charge questions should be included in the SOW. After BSEE provides a list of draft questions, the contractor should then finalize the charge based on these questions and submit it for BSEE approval. When the Peer Review Charge is finalized and approved, the contractor should send the Peer Review Charge to the peer reviewers, along with the other peer review materials (see Step 3.4). In a contractor-led peer review, BSEE staff should communicate with the peer reviewers only as arranged by and through the prime contractor, and the role of BSEE staff should be limited to providing background and answering peer reviewer questions about the research product.

Step 3.2: Select the Peer Reviewers

After the Peer Review Charge has been drafted, the Peer Review Leader should select the peer reviewers. This peer review selection process is comprised of two tasks: (1) identify qualified peer reviewer candidates, and (2) determine the final group of peer reviewers based on evaluation of any potential COI, balance of the group of reviewers, and reviewer availability. This step addresses these tasks separately and also provides an overview of strategies for soliciting nominations and selecting reviewers, ensuring a balanced panel, and addressing COI.

A ***peer reviewer*** is an independent, qualified expert in a relevant technical field whose services are retained by BSEE (or a contractor) to evaluate a draft research product. The goal of the peer review selection process is to choose a group of independent experts who are free from COI and whose collective expertise is sufficient to provide a thorough and balanced review of the research product. As mentioned above, BSEE has the option to hire a contractor to select peer reviewers. Selection of peer reviewers for contractor-led peer reviews is addressed at the end of this section.

Step 3.2.1: Identify Peer Review Candidates

A first step in selecting peer reviewers is to identify several potential candidates who meet the expertise and experience requirements specified in the Peer Review Plan, and who are independent and likely free of COI. The Peer Review Leader should also ensure that the final group of peer reviewers includes a balance of perspectives on the review. These peer reviewer identification and screening criteria are discussed further in this subsection.

The **EERE Peer Review Guide** provides the following best practice for organizing the peer reviewer selection process:

"A matrix might be drawn up that indicates the various [areas of expertise] needed for the areas being reviewed across the top, and various perspectives or characteristics desired down the side…Reviewers meeting the qualifying standards for individual reviewers are then chosen because they fill a need for the panel as a whole. For example, reviewers would be selected who represent diversity in backgrounds and experience sufficient so the panel collectively covers the range of expertise required."

Peer Reviewer Candidate Identification and Screening Criteria

Expertise and Experience

The qualifications for peer reviewers should have been determined, at least at a high level, during the planning phase. At this point in the process, the Peer Review Leader should begin to search for peer reviewer candidates who have the necessary expertise and experience. The OMB Bulletin clearly states that, "The most important factor in selecting reviewers is expertise: ensuring that the selected reviewer has the knowledge, experience, and skills necessary to perform the review." When identifying potential peer reviewers, it is important to identify several candidates with expertise in each relevant technical area (if possible) to ensure that all areas are represented.

When evaluating potential candidates, expertise may be demonstrated in several ways:

- Educational qualifications (e.g., a PhD in Geophysics preferred, followed by a geology-related discipline)
- Experience or knowledge of a particular technical area (e.g., minimum years of relevant experience, authorship of relevant publications, specific modeling experience)
- Certifications (e.g., Professional Engineer)
- Recognition as an expert (e.g., technical leadership or participation in scientific societies, participation in government or industry panels, recommendations from colleagues, nominated by the public)

Candidates can be screened for these requirements through Internet searches, as many academics and professionals have biosketches and even curricula vitae (CVs) posted online.

Balance

The final set of peer reviewer candidates must represent a range of scientific perspectives relevant to the research product topic(s). For research products addressing a limited technical area, determining the necessary range of perspectives that should be represented in the group may be relatively straightforward. Outlining the various perspectives for a research product that addresses many technical disciplines may present more of a challenge; in these cases, the OMB Bulletin guidance states that the Peer Review Leader must ensure that the collective expertise of the peer reviewers represents "the necessary spectrum of knowledge."

The Peer Review Leader might consider identifying a set of peer reviewers with diverse experiences in addition to diverse perspectives. For example, a peer review generally should not include two reviewers from the same academic or professional affiliation.

Independence

"Independence," in the context of peer reviewer identification, refers to the separation of the peer reviewer from the development of the research product. An independent peer reviewer will likely be free of COI. This subsection will describe the process for screening candidate peer reviewers for COI issues relating to involvement with the research product undergoing review. See Step 3.2.2 for guidance on conducting a more thorough evaluation of COI.

The considerations outlined in Table 3-1 must be taken into account when screening for the independence of candidate peer reviewers for an external peer review.

TABLE 3-1: CONSIDERATIONS WHEN SCREENING FOR PEER REVIEWER INDEPENDENCE

Consideration	Specific Guidance
Level of involvement in the research product being reviewed	• Peer reviewers must not have participated in the development of the research product that will be reviewed. • For highly influential scientific assessments, peer reviewers must not be BSEE employees, with one exception (see below text). • Peer reviewers should not be affiliated with the organizations involved in the development of the research product. • Peer reviewers should have no obvious scientific collaborations or relationships with the research product authors (e.g., the candidate peer reviewer should not have co-authorship of a paper with the research product authors).
Level of BSEE involvement in the candidate reviewer's previous work	• If BSEE awards a research grant based on an "investigator-initiated, competitive, peer-reviewed proposal," the scientist receiving the award is generally considered to be "independent" for the purposes of peer reviews of other BSEE research products. • For other types of BSEE research grants, the level of independence of the scientists/authors will depend on the level of BSEE involvement in the research product. • If BSEE works with the scientist to design or implement the research, the scientist would be considered less independent for the purposes of peer reviewer selection.
Funding of the candidate reviewer's work	• The Peer Review Leader should consider a candidate peer reviewer's consulting or contractual arrangement with BSEE or the specific office sponsoring the peer review. • In general, it is best to choose peer reviewers whose independence is not clouded by monetary arrangements with BSEE. • BSEE staff should inform candidate reviewers that their names will be disclosed in order to discourage candidates with Real COI from participating in the peer review.
Participation in previous BSEE peer reviews	• For highly influential scientific assessments, BSEE must avoid using the same peer reviewer more than once unless the individual's expertise is essential to the assessments being reviewed and this expertise would otherwise be unavailable. • For influential scientific assessments, per the OMB Bulletin, BSEE must "make an effort to rotate peer review responsibilities across the available pool of qualified reviewers, recognizing that in some cases repeated service by the same reviewer is needed because of essential expertise." This rotation can help provide process independence and a diversity of perspectives on BSEE research products."

In addition, the Peer Review Leader should consider additional levels of independence beyond independence from the research product. In some cases, peer reviewers must be seen as independent from BSEE altogether.

When identifying **internal reviewers**, the Peer Review Leader should select BSEE staff who are not only independent of the development of the research product (either directly or through the chain of command) but are independent of both the research program that developed the research product and the Office or Division facilitating any associated BSEE rulemakings or decisions. With one exception (see Appendix F for related OMB Bulletin text), for peer reviews of highly influential scientific assessments, peer reviewers must not be BSEE employees unless they are special government employees employed solely for the purpose of the peer review.

Categories of Peer Review Candidates and Compensation

For external panel reviews, external letter reviews, and internal peer reviews, all peer reviewers fall under one of the following three categories:

- **Special Government Employees (SGEs):** An SGE is "an officer or employee who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for not more than 130 days during any period of 365 consecutive days."[6] BSEE may hire external experts as SGEs for the purpose of serving as peer reviewers.
- **Regular Government Employees (RGEs):** RGEs are "all executive branch employees who are not (1) SGEs under 18 U.S.C. § 202(a), (2) covered non-career employees under 5 C.F.R. § 2636.303(a), nor (3) employees appointed by the President to a full-time non-career position described under 5 C.F.R. § 2635.804(c)(2)."[7] RGEs may serve as peer reviewers for both internal and external BSEE peer reviews.
- **Contracted peer reviewers:** Contracted peer reviewers are external experts (not SGEs or RGEs) whose services are acquired either by BSEE or by a contractor in the case of contractor-led peer reviews.
    - For peer reviews led by BSEE staff, BSEE hires contracted peer reviewers through call orders issued under BSEE Blanket Purchase Agreements established for the management of external peer reviews.
    - For contractor-led peer reviews, contracted peer reviewers are hired as subcontractors to the contractor that is leading the peer review.

Each category of peer reviewers has separate considerations for compensation and is subject to different COI standards (see COI discussion in Step 3.2.2).

Compensation

Due to the technical complexity and cutting-edge nature of BSEE's research products, BSEE hires experts as peer reviewers who are highly trained and qualified and often have very specialized expertise. In order to attract these experts to participate in BSEE peer reviews, BSEE will typically provide compensation (including a fee or honoraria for services, travel reimbursement, and per diem, as appropriate) for contracted peer reviewers and SGEs participating in external peer reviewers. BSEE does not provide compensation to RGEs for their service as peer reviewers, but may in certain cases provide for travel and per diem expenses for these individuals.

The Peer Review Leader and Decision Maker are ultimately responsible for determining the appropriate level of compensation for peer reviewers. Several factors may influence the amount of peer reviewer compensation, including technical complexity of the research product and reviewer availability.

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[6] See discussion provided by the Office of Government Ethics for additional information: http://www.oge.gov/Topics/Selected-Employee-Categories/Special-Government-Employees/.

[7] See discussion provided by the Office of Government Ethics for additional information: http://www.oge.gov/OGE-Advisories/Legal-Advisories/08x3a--Book-Deals-Involving-Regular-Employees-and-Special-Government-Employees/

There are several exceptional circumstances in which additional guidance is needed to determine if and how much to compensate peer reviewers:

- **Volunteer reviewers:** There may be instances in which peer reviewers are interested in volunteering to serve as peer reviewers. In these cases, peer reviewers must sign a form committing that they do not expect to be compensated for their services.
- **Foreign peer reviewers:** Peer reviewers who are not citizens of the United States may or may not be able to be compensated for service as peer reviewers.
- **State and local government employees:** Some state and local government employees may not be able to be compensated for service as peer reviewers.

In these circumstances, Peer Review Leaders and Decision Makers should refer to their General Counsel to ensure compliance with applicable federal requirements.

There may be instances in which a peer review candidate is interested in negotiating the level of compensation. These negotiations may take place at the discretion of the Peer Review Leader and Decision Maker and should be informed by the available budget for the peer review and the necessity of the candidate reviewer's expertise. The process for determining peer reviewer compensation can be iterative as necessary.

In addition to determining the appropriate level of compensation, the Peer Review Leader and Decision Maker should determine the desired timing and format for compensation. Peer reviewers may be compensated during or after the review and, depending on the category of peer reviewer, either with a one-time payment or as invoiced by the hour per the peer reviewer.

Methods and Sources for Identifying Peer Reviewer Candidates

The OMB Bulletin allows agencies broad discretion in the methods and sources used to select peer reviewers. The Peer Review Leader is responsible for coordinating the selection of peer reviewers and should obtain Decision Maker approval of the final list of reviewers.

BSEE staff may conduct searches for qualified candidates, solicit nominations for candidates from qualified individuals or organizations, or both.

Possible sources for **BSEE staff searches for qualified candidates** include:

- Academic and scholarly literature
- Conference and workshop presenters or panelists (e.g. International Oil Spill Conference (IOSC), Offshore Technology Conference (OTC))
- State or local government agencies
- Native American tribes
- Federal agencies (e.g., Bureau of Ocean Energy Management (BOEM), US Coast Guard (USCG), US Environmental Protection Agency (EPA), Department of Energy (DOE))
- Laboratories, non-profit research organizations, or consulting firms
- Internet and commercial expertise databases

Potential sources for **candidate peer reviewer nominations** include:

- Scientific and professional societies (e.g. National Emergency Management Association, Society of Petroleum Engineers)
- Public nominations solicited by BSEE
- BSEE staff
- External experts or authors of relevant scientific and scholarly products
- Industry groups (e.g. American Petroleum Institute)

A sufficient amount of candidate peer reviewers may be identified using only a few of these sources, or, in some cases, a more expansive search may be warranted.

Initial Contact with Peer Review Candidates

After identifying a list of potential peer review candidates, the Peer Review Leader should contact each candidate (usually via email) to describe the peer review and gauge the candidate's interest level and availability. The communication to the candidate peer reviewer should include the following information:

- Description of the research product and the goals for the peer review (including, where possible, the names of the research product authors and any organizations involved in its development)
- The sought-after expertise, experience, or skills for peer reviewers
- Request for an updated resume or CV
- Request to complete the BSEE Peer Review COI Form (see Appendix D), or, at a minimum, to review the form and notify the Peer Review Leader of any potential COI issues that may apply
- Expected timeframe for the peer review (i.e., when the peer review would start and the amount of time the reviewers will have to perform their review) and a request for candidate availability for the peer review
- Expected compensation for peer reviewers who are not RGEs
- Optional request to provide names of additional qualified reviewers
- BSEE point of contact information and a due date for the response
- Any other requests for information that would help the Peer Review Leader select the peer reviewers
- Information regarding disclosure of peer reviewer information (e.g. names, affiliations) and comments

Step 3.2.2: Evaluate Candidates and Select the Final Group of Peer Reviewers

The Peer Review Leader should evaluate each candidate's response, including the resumes/CVs and COI forms, in order to select peer reviewers with the necessary expertise, independence, and group balance.

Conflict of Interest

Evaluating COI is one of the most important, and challenging, aspects of conducting a peer review, and the Peer Review Leader should allocate enough time for a thorough review of potential COIs for all peer review candidates. This subsection will address COI considerations for internal peer reviews, external letter reviews, and external panel reviews. Peer reviews conducted by a Federal Advisory Committee or by the National Academy of Sciences (NAS) are subject to additional requirements.

Applicable Requirements

As mentioned above, COI standards and requirements vary by category of peer reviewer candidate:

- **Federal employees (SGEs and RGEs):** Per the OMB Bulletin, BSEE staff must ensure that "those reviewers serving as Federal employees (including special government employees) comply with applicable federal ethics requirements."
- **Contracted peer reviewers:** For non-federal reviewers, BSEE staff must "adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating the potential for conflicts."[8]
- **DOI staff:** All BSEE and U.S. Department of the Interior (DOI) employees are subject to BSEE-specific and DOI-specific standards for COI,[9] and all such employees involved in the peer review process should strictly adhere to these standards. For internal peer review candidates, BSEE staff should refer to conflict of interest guidance in the BSEE Director Ethics Memorandum, "Policy Regarding Interference with the Performance of Official Duties and Potential Conflicts of Interest" dated April 28, 2014.

A more in-depth treatment of federal and NAS COI requirements is included in Appendix E. BSEE staff should refer to their General Counsel, the BSEE Ethics Office, or the U.S. Department of the Interior Designated Agency Ethics Official (DOI DAEO) with any questions about federal COI requirements and to ensure that all applicable requirements are met.

The remainder of the discussion on COI is focused on peer reviews conducted by BSEE staff; for contractor-led peer reviews, the contractor is responsible for ensuring that COI is adequately addressed. Additional guidance on contractor-led peer reviews is included at the end of this section.

There are special COI considerations for peer review candidates who are SGEs or Federal Advisory Committee members when a Federal Advisory Committee is used for peer review. These are discussed in Appendix E. In addition, BSEE staff should consult the General Counsel, the BSEE Ethics Office, and the DOI DAEO when evaluating a non-U.S. citizen as a peer review candidate.

[8] http://www.nationalacademies.org/coi/index.html

[9] See the "BSEE Code of Ethics" and the "Ethics Guide for DOI Employees" available here: http://www.bsee.gov/Regulations-and-Guidance/Internal-Guidance-and-Directives/Ethics/BSEE-Ethics-Emphasis/.

Real COI and Apparent COI

When evaluating a peer reviewer candidate for conflict of interest, the Peer Review Leader must consider Real COI and Apparent COI:

- **Real Conflict of Interest:** In essence, a Real COI could be any financial interest held by an individual (or certain related persons[10]) that could be affected by their participation in the peer review. In many cases, it will be very evident if a peer reviewer has a Real COI. For circumstances that are more challenging, the Peer Review Leader should consult the guidance in Appendix E and speak with the U.S. Department of the Interior Designated Agency Ethics Official (DOI DAEO).
- **Apparent Conflict of Interest:** An Apparent COI could be any circumstance related to an individual (or certain related persons[11]) that may cause "a reasonable person with knowledge of the relevant facts" to question the individual's impartiality in participating in the peer review (i.e. "an appearance of loss of impartiality"[12]). Determining whether a peer reviewer has an Apparent COI can be more challenging than determining a Real COI. The BSEE Peer Review COI Form addresses many situations that may raise concerns of an Apparent COI. The Peer Review Leader should address any possible Apparent COI or Real COIs raised by the candidate reviewers' responses to the BSEE Peer Review COI Form. For challenging cases of potential Apparent COI, the Peer Review Leader should speak with the DOI DAEO.

[10] For any federal government employee, the financial interests of following individuals must also be considered as required under 18 U.S.C. § 208: "spouse, minor child, general partner, organization in which he is serving as officer, director, trustee, general partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment."

[11] The following individuals related to a peer review candidate should be considered when evaluating Apparent COI, in addition to any other relationships that may cause an appearance of loss of impartiality: members of the individuals household, "a person with whom the employee has or seeks a business, contractual, or other financial relationship; a person who is a member of the employee's household or is a relative with whom the employee has a close personal relationship; a person for whom the employee's spouse, parent, or dependent child serves or seeks to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee; any person for whom the employee has within the last year served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee; any organization (other than a political party) in which the employee is an active participant." (See: http://www.oge.gov/Topics/Financial-Conflicts-of-Interest-and-Impartiality/Current-Government-Employees/.)

[12] See 5 C.F.R. Part 2635.

Identifying COI

The OMB requirements for examining COI are as follows:

- Examine prospective reviewers' potential financial conflicts, including significant investments, consulting arrangements, employer affiliations, and grants/contracts.
- Scrutinize financial ties of potential reviewers to regulated entities (e.g., businesses), other stakeholders, and regulatory agencies when the information being reviewed is likely to be relevant to regulatory policy.
- Inquire into financial investments and business relationships, including work as an expert witness, consulting arrangements, honoraria, and sources of grants and contracts.

The BSEE Peer Review COI Form (see Appendix D) addresses all of the major affiliations and activities that could lead to a COI issue for a peer review candidate. As mentioned above, in the initial contact with candidate peer reviewers, the Peer Review Leader should have requested that all peer review candidates complete the BSEE Peer Review COI Form, or, at a minimum, review the form and notify the Peer Review Leader of any potential COI issues that may apply. At this point, the Peer Review Leader should contact each peer review candidate for whom there is a potential Real or Apparent COI (per the candidate's disclosure on the BSEE Peer Review Form or any subsequent contact) to obtain additional information.

In addition to the responses received from the peer reviewers, BSEE staff should conduct Internet searches on the peer review candidates to identify any public statements, affiliations, or experiences that may raise concern about the candidate's objectivity or independence with regard to the peer review.

Graphic 6 depicts the types of affiliations that could lead to a COI during a peer review. Involvement with the research product, located at the center of the graphic, is the activity most likely to lead to a real COI. Other affiliations or activities, grouped by professional history, financial interest, relationships, and public statements, may have a less direct implication for COI, but should be investigated nonetheless.

GRAPHIC 6: ACTIVITIES AND AFFILIATIONS THAT COULD LEAD TO COI

Reconciling, Documenting, and Monitoring COI

After determining if a peer reviewer has a Real COI or Apparent COI, the Decision Maker and Peer Review Leader must follow the requirements outlined in this subsection and in Appendix E for reconciling, documenting, and monitoring the COI.

Real COI

Peer review candidates with an identified Real COI must never participate in peer reviews of highly influential scientific assessments. The Decision Maker and Peer Review Leader are responsible for decisions regarding the participation of a peer review candidate with a Real or Apparent COI in a peer review for influential scientific information. A peer review candidate who has a Real COI must only participate in a peer review of influential scientific information if the Decision Maker and Peer Review Leader determine that the conflict is unavoidable and, for federal government employees, "not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee."[13] The Decision Maker and Peer Review Leader must reference specific guidance in Appendix E on assessing Real COIs to ensure compliance with all applicable federal and NAS requirements. Federal government employees with Real COIs will need a waiver from the Office of Government Ethics (OGE) to participate in a peer review for influential scientific information. The Decision Maker and Peer Review Leader must reference guidance on waivers in Appendix E in these cases.

[13] Ibid.

Apparent COI

In cases of Apparent COI, the Decision Maker and Peer Review Leader may only allow a candidate to participate in the peer 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."

For peer reviewers with either Real or Apparent COI, the COI will need to both be disclosed by the reviewer and documented by the Peer Review Leader in the Peer Review Record.

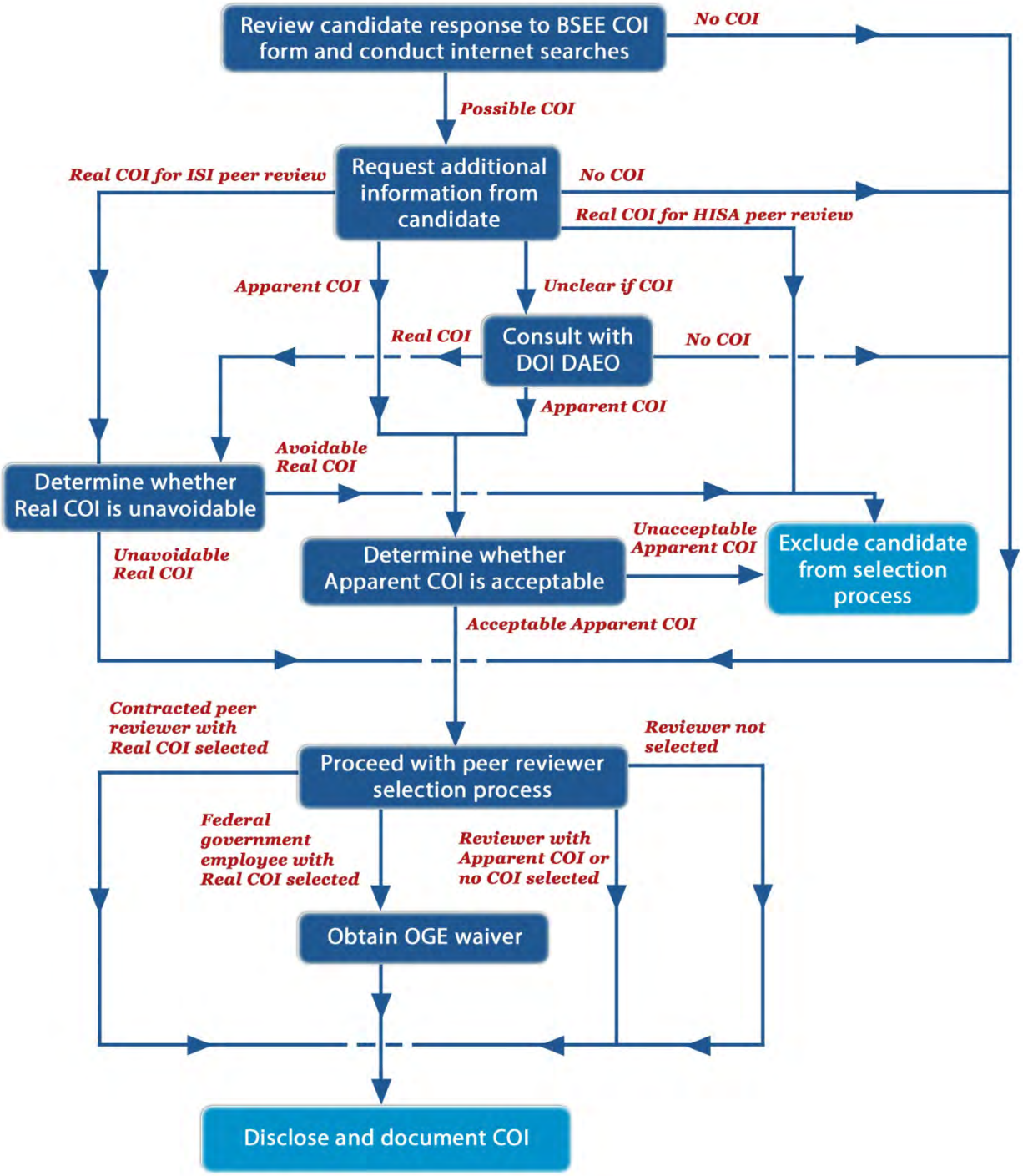
It may be possible to exclude a peer reviewer with a COI from the portion of the peer review with which they have a COI. The Peer Review Leader and Decision Maker should discuss this option where applicable.

The BSEE Peer Review COI Form and Peer Review Charge ask peer review candidates to agree to make the Peer Review Leader aware of any COIs that come up before or during the peer review. The Peer Review Leader and Decision Maker should evaluate these situations on a case-by-case basis to ensure that the objectivity and independence of the peer review process are upheld.

As mentioned above, the Peer Review Leader will need to document any COI issues for participating peer reviewers and the actions taken to reconcile those COIs in the Peer Review Record. The Peer Review Leader must ensure that all information included in the Peer Review Record conforms to the requirements regarding BSEE recordkeeping and privacy of reviewer information discussed in Steps 4.2 and 4.4 of this Manual. The same requirements apply to BSEE Peer Review COI Forms collected from the peer review candidates.

Graphic 7 depicts a process to help BSEE staff identify potential COIs discovered during the peer reviewer selection process and resolve any identified COI issues before the start of the peer review.

GRAPHIC 7: IDENTIFYING AND RESOLVING COI



HISA = highly influential scientific assessment; ISI = influential scientific information.

Balance

Once candidate peer reviewers have been evaluated for relevant expertise and COI, the Peer Review Leader should evaluate candidates while considering the balance of the selected group of reviewers as a whole. The OMB Bulletin states that the selection of individual reviewers must be based on expertise, experience and skills, and, as necessary, include specialists from multiple disciplines. Further, the Bulletin states that the group must be "sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge." The goal of checking for balance at this stage in the review process is to ensure that the group of potential reviewers adequately represents a range of diverse and representative perspectives for each of the relevant technical topics.

Timeline and Availability

When selecting peer reviewers, the Peer Review Leader should take into account both the rough timeframe for peer review devised by BSEE in the planning process and the availability of individual peer reviewer candidates.

The process of selecting a final group of peer reviewers may be iterative in several ways. As mentioned below, if the Peer Review Leader is notified of potential conflicts of interest surrounding a particular candidate reviewer, the Peer Review Leader may need to obtain additional information on the COI from the candidate, and, based on the results, the Peer Review Leader may need to eliminate that candidate from further consideration. Similarly, after considering peer reviewer availability and balance, the Peer Review Leader may realize that it is necessary to solicit additional peer review candidates to ensure that the review consists of a balanced group of reviewers. BSEE staff should allow ample time (2-3 weeks is usually sufficient) for this iterative peer review selection process. After determining a final list of peer reviewers, the Peer Review Leader should submit the list to the Decision Maker for final approval.

Specific Guidance on Selecting Peer Reviewers under Contractor-Led Peer Reviews

If BSEE is using a contractor to implement the peer review, the requirements for peer reviewer expertise and experience should have been included in the SOW to guide the contractor in the selection of reviewers. In a contractor-led peer review, contractors have ultimate responsibility for selecting peer reviewers. The contractor will conduct all interactions with peer review candidates during the selection process. The Peer Review Leader may provide the contractor with an alphabetized list of example individuals that BSEE believes meet the peer reviewer expertise requirements, but BSEE must make clear that the contractor is not limited to the list provided and is not required to select any particular reviewer. The contractor should select the peer reviewers based on the requirements specified in the SOW and according to the guidance in this section (where applicable), including a thorough evaluation of expertise, Real or Apparent COIs, and balance.

The SOW also should include any information that would help the contractor identify and address Real or Apparent COI. In addition, the SOW should stipulate that the contractor submit to BSEE a summary of its COI inquiries. The Peer Review Leader may provide the contractor with the BSEE COI Form in Appendix D. The contractor should provide the list of selected peer reviewers to BSEE for review. The Peer Review Leader and Decision Maker should confirm that the contractor has complied with the SOW and any applicable guidance in this Manual in their selection of reviewers. If the contractor has fulfilled its responsibilities, the Peer Reviewer Leader should convey approval of the list but not provide any additional input on reviewer selection (unless unique or unforeseen circumstances have arisen). If the contractor's selections do not align with the requirements in the SOW, then the Peer Review Leader should refine or clarify the expertise requirements to ensure that the contractor selects a qualified and balanced peer review panel.

Step 3.3: Finalize the Peer Review Schedule

While the schedule should have been considered during the planning phase, the schedule cannot be finalized until all reviewers are selected. This step helps the Peer Review Leader and Decision Maker prepare to conduct the peer review by providing guidance on finalizing the peer review schedule and notifying the selected reviewers.

Step 3.3.1: Finalize the Schedule

The Peer Review Leader and Decision Maker should develop the final schedule, taking into account the following considerations, as discussed in Step 2.1: schedule for associated rulemakings, schedule for development of the research product, internal and external deadlines, budget, public participation, and reviewer availability. The Peer Review Leader also should make sure to factor in additional considerations discussed in Step 2.1 for highly influential scientific assessments and research products that are used in support of rulemakings. Finally, the schedule also should take into account considerations regarding space rental, contractor logistics, and availability of key BSEE staff.

To finalize the schedule, the Peer Review Leader and Decision Maker should assign specific dates (or range of dates) for each of the following phase of the peer review implementation process:

- Compiling and sending out materials
- Hosting any meetings or panels
- Collecting comments
- Synthesizing comments
- Developing a Comment Response Document (where applicable)
- Completing the Peer Review Report and Peer Review Record

Step 3.3.2: Notify Selected Reviewers

Once the schedule is finalized, the Peer Review Leader should contact the selected peer reviewers to notify them that they have been selected and to give them advance notice of the final peer review schedule. The Peer Review Leader should request a response from all peer reviewers confirming their participation in the peer review.

At this time, the Peer Review Leader also should send those reviewers who have not completed and signed the BSEE Peer Review COI Form a copy of the Form, with a request to return the completed form as soon as possible. The Peer Review Leader should also send reviewers a confidential business information (CBI) non-disclosure form where applicable (see Step 2.1). Along with these forms, the Peer Review Leader should instruct reviewers that the review materials will not be sent until the completed and signed forms are returned to the Peer Review Leader. (Note that any COI issues should have been raised by the candidate reviewers earlier in the selection process, so the Peer Review Leader should not expect to receive additional information regarding COI issues at this time.)

As a courtesy, the Peer Review Leader also should notify any peer review candidates that were not selected for the peer review.

Specific Guidance for Finalizing the Peer Review Schedule under Contractor-Led Peer Reviews

For contractor-led peer reviews, the general schedule for the peer reviewers should have been stipulated to the contractor in the SOW. For example, BSEE may provide an expected or minimum amount of time (e.g., no less than 4 weeks, 40 hours, etc.) for peer reviewers to review the research product. However, the intricacies of scheduling the peer review should be the responsibility of the contractor. As mentioned above, in order to avoid becoming subject to FACA requirements, it is essential that the contractor manage the logistics of coordinating the peer review.

Step 3.4: Compile and Send the Peer Review Materials

The Peer Review Leader is responsible for preparing and sending the peer review materials to the peer reviewers. The materials should provide the peer reviewers with all of the necessary background and supplementary information to understand the research product and be able to provide a thorough review. This step provides guidance to the Peer Review Leader on compiling and sending the necessary materials to peer reviewers. Note that, per the OMB Bulletin, for highly influential scientific assessments, the Peer Review Leader must provide the peer reviewers "with sufficient information – including background information about key studies or models – to enable them to understand the data, analytic procedures, and assumptions used to support the key findings or conclusions of the draft assessment."

Before sending any materials to the peer reviewers, the Peer Review Leader must ensure that each peer reviewer has completed and signed a BSEE Peer Review COI Form, and where applicable, a CBI non-disclosure form.

Per the OMB Bulletin, all materials distributed for peer review must be marked with an appropriate and clear disclaimer on the information. The Peer Review Leader must ensure that the following disclaimer[14] is included in the information:

- "THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY BSEE. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY BSEE DETERMINATION OR POLICY."

[14] Per the OMB Bulletin, a similar disclaimer is required for draft influential scientific information presented at meetings or shared confidentially with colleagues for scientific input prior to peer review: "THE FINDINGS AND CONCLUSIONS IN THIS REPORT (PRESENTATION) HAVE NOT BEEN FORMALLY DISSEMINATED BY BSEE AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY." In addition, OMB guidance specifies that BSEE must discourage state, local, international and private organizations from using information in draft research products subject to peer review.

If the information being distributed for peer review is "highly relevant to specific policy or regulatory deliberations," per the OMB Bulletin, the disclaimer must be included on **every page**.

The Peer Review Leader should compile and send the following materials to the peer reviewers:

- Peer Review Charge, which includes:
    - Description of the research product, including problem statement, history, contributors, and goals of the research product
    - Schedule information
    - Information about meeting date(s)
    - Details on attribution and disclosure
    - Reiteration of compensation details
    - Per the OMB Bulletin, the Peer Review Leader must inform the peer reviewers of "applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality." This includes, but is not limited to, the DOI Information Quality Standards, DOI Department Manual "305 DM 3," Executive Order 12866, and the OMB Bulletin.
    - Information about how the reviewers' should complete the review, including logistics for submitting comments and confidentiality requirements
    - Details on evaluation criteria/rating systems
- Draft research product, background documents, and user guides
- Public comments received, where applicable
- Any other relevant information necessary for the peer review

For in-person panel meetings, the review material should be distributed several weeks in advance. For letter reviews, the review material should be distributed at least a few days before the review period starts. For efficiency, the materials should be sent in electronic format, and the Peer Review Leader should confirm peer reviewers' receipt of the materials.

Specific Guidance for Compiling and Sending Peer Review Materials under Contractor-Led Peer Reviews

The Peer Review Leader should provide the contractor with the research product, background documents, user guides, Peer Review Charge (if the contractor is not assisting in its development or finalization), evaluation criteria, public comments received, and any other information necessary for a technical review of the research product. The contractor may use an alternate COI form (if the use of BSEE forms is not stipulated in the SOW), but the Peer Review Leader should provide the necessary information on the research product (background, goals, contributors, etc.) to enable the contractor to develop this form. The contractor is responsible for distributing these materials to the peer reviewers and serving as the point of contact.

Step 3.5: Conduct the Peer Review

The logistics of conducting the peer review will vary depending on the peer review mechanism and the available resources for the peer review. BSEE staff should tailor the peer review logistics to the needs of the particular research product. This step provides general guidance to assist BSEE staff in conducting a peer review, including facilitating meetings and interactions, checking in with the peer reviewers, and collecting comments. Specific guidance for external letter reviews, external panel reviews, and internal reviews are also covered in this step.

Facilitating Meetings

All peer review mechanisms may feature meetings among the peer reviewers, BSEE staff, subject matter experts, and (depending on the research product being reviewed) members of the public. The Peer Review Leader should develop an agenda for any meetings that take place during the peer review process and distribute the agenda to attendees prior to the meeting.

For any meetings hosted during the course of a peer review, the Peer Review Leader has several responsibilities:

- **Facilitate interactions among reviewers:** The Peer Review Leader should ensure that each reviewer provides input during reviewer discussions. Whenever possible, the schedule should provide ample time for discussion among reviewers, which can improve the quality of reviewer feedback. Discussion among reviewers should be facilitated to elicit balanced participation (e.g., time to speak).
- **Facilitate interactions between reviewers and BSEE staff:** Whenever possible and useful, the Peer Review Leader should ensure that the meeting includes sufficient time for reviewer questions and official feedback/comments from reviewers. The research product authors and other BSEE staff may be present to give presentations or answer technical questions from peer reviewers about the research product. The Peer Review Leader should ensure that these discussions are on-topic and an effective use of peer reviewer time.
- **Manage the flow of the meeting:** The Peer Review Leader should keep track of the time allotted for each portion of the discussion and manage the flow of discussion as necessary.

After any meeting, the Peer Reviewer should create a meeting summary or meeting transcript, and this documentation should be completed as soon as possible (i.e., within a week after a kick-off meeting or within a month after a formal panel discussion) to allow for timely review of reviewer comments. The Peer Review Leader should distribute the draft meeting summary or transcript to the peer reviewers for approval before finalizing the document.

The Peer Review Leader should ensure that the meeting agenda and meeting transcript or summary is included in the Peer Review Record and is considered in the Peer Review Report.

External Letter Review

Conducting an external letter review can be completed in a few discrete steps. Table 3-2A provides BSEE's recommended practices for implementing external letter reviews.

TABLE 3-2A: CONDUCTING AN EXTERNAL LETTER REVIEW

Activity	Responsible Person(s)	When the Activity Takes Place	Best Practices
Send Peer Review Charge to peer reviewers	Peer Review Leader	On the pre-determined start date for the peer review	The Peer Review Leader should provide the Peer Review Charge to the peer reviewers, which should include an invitation to participate in a kick-off meeting and expectations for the submittal of written comments (e.g. format, due date).
Kick-off meeting	Peer Review Leader to schedule and lead, with attendance by all necessary parties (peer reviewers, SMEs, etc.)	0-2 weeks after the peer review materials are sent	• The kick-off meeting may be conducted as a conference call or a web-based meeting. • During the meeting, the Peer Review Leader should reinforce instructions to reviewers, provide any necessary background information, and answer reviewer questions. • The Peer Review Leader may invite SMEs and/or research product authors to answer questions and provide background information. • The kick-off meeting may be an informal discussion that does not need to follow a particular format.
Check in with peer reviewers	Peer Review Leader	1-2 weeks after the kick-off meeting	• The Peer Review Leader should check in with the peer reviewers to inquire whether they have any questions and ensure that they are on track to meet the specified due date for their comments. • The Peer Review Leader should also ensure that no COI issues have arisen during the completion of the review. (The BSEE Peer Review COI Form and the Peer Review Charge ask peer reviewers to make the Peer Review Leader aware of any COI issues that arise during the peer review.)
Mid-review conference call (optional)	Peer Review Leader to schedule and lead, with attendance by all necessary parties (peer reviewers, SMEs, etc.)	1-2 weeks after the kick-off meeting	• The Peer Review Leader may choose to host a mid-review conference call that would allow the reviewers to ask clarifying questions about the research product and the Peer Review Charge. • This mid-review conference call may be the Peer Review Leader's method for checking in with the peer reviewers (see above row).
Collect written comments	Peer Review Leader	On or before the specified due date (included in the Peer Review Charge)	• The Peer Review Leader should ensure that the comments are in the format required by the Peer Review Charge (e.g., Microsoft Word or PDF). • The Peer Review Leader should confirm receipt of the written comments.

External Panel Review

The OMB Bulletin affords reviewers flexibility in implementing a panel review. Table 3-2B provides BSEE's recommended practices for implementing external panel reviews.

TABLE 3-2B: CONDUCTING AN EXTERNAL PANEL REVIEW

Activity	Responsible Person(s)	When the Activity Takes Place	Best Practices
Send Peer Review Charge to peer reviewers	Peer Review Leader	2-3 weeks prior to panel discussion	The Peer Review Leader should provide the Peer Review Charge to the peer reviewers, which should include expectations for the peer reviewers' participation in the panel discussion and submittal of written comments by the start of the panel discussion.
Make introductions and provide overview of the peer review	Peer Review Leader	During the panel discussion	The Peer Review Leader should introduce the peer reviewers and provide an overview of the research product and peer review process.
Provide presentations on the research product, followed by Q&A	Various presenters, with facilitation by Peer Review Leader or support staff	During the panel discussion	Where applicable, the Peer Review Leader may ask individuals involved in the development of the research product, subject matter experts, or members of the public to present to the peer reviewers to inform the review of the research product. These presentations should be followed by a Q&A session with the peer reviewers.
Provide peer reviewer presentations, followed by Q&A	Peer reviewers, with facilitation by Peer Review Leader or support staff	During the panel discussion	Each peer reviewer should be asked to provide a brief presentation of their comments, followed by a Q&A session, during which other reviewers may ask questions of the peer reviewer.
Engage in group discussion	Peer reviewers, with facilitation by Peer Review Leader or support staff	During the panel discussion	The peer reviewers should be encouraged to discuss their written comments, but not encouraged to reach a consensus (see Step 2.4).
Submit written comments	Peer reviewers	At the conclusion of panel discussion	The peer reviewers should submit their written comments to the Peer Review Leader.
Submit optional revised comments	Peer reviewers	2-4 weeks after the conclusion of panel discussion	If peer reviewers are interested in submitting revised written comments, they should submit these comments to the Peer Review Leader.
Circulate meeting summary	Peer Review Leader	2-4 weeks after the conclusion of the panel discussion	The Peer Review Leader should circulate the draft meeting summary to the peer reviewers for review and approval.

Internal Review

Internal peer reviews can be tailored to the research product and often are less formal in implementation. Where applicable and practical, the Peer Review Leader may generally follow the guidance provided for implementing external reviews when conducting an internal peer review.

Specific Guidance for Conducting Contractor-Led Peer Reviews

Under a contractor-led review, the role for BSEE staff will be limited to providing background and technical information to the peer reviewers, if requested by the contractor. The contractor will otherwise facilitate all aspects of the review and serve as the point of contact for peer reviewers throughout the peer review. It should be made clear to the peer reviewers that the contractor is managing the peer review process. BSEE staff should not directly interact with peer reviewers during the peer review process, unless requested and overseen by the contractor.

Step 4: Complete and Document the Peer Review

After collecting reviewer comments, the Peer Review Leader and Decision Maker are responsible for analyzing the peer reviewer comments, documenting them in the Peer Review Report, and incorporating them into the research product, as necessary. The Peer Review Leader is also responsible for documenting the peer review process as a whole. The thoroughness and openness with which reviewer comments are analyzed, documented, responded to, and incorporated will influence the transparency of the peer review process and will contribute to the credibility of the final research product. This step provides guidance to the Peer Review Leader and Decision Maker for analyzing reviewer comments, creating the peer review report, responding to and incorporating peer review comments, and documenting the peer review.

Peer reviewer comments should be reviewed and addressed as soon as practicable after the review, ideally within a month of receipt of the comments, or possibly even earlier for comments that will most likely result in changes to the final research product.

For a contractor-led peer review, the contractor may assist BSEE with completing and documenting the peer review, as outlined in the SOW (see Steps 2.1 and 2.3 for guidance on use of contractors and development of an SOW). Implementation details for contractor-led peer reviews are discussed at the end of each subsection.

Step 4.1: Analyze Peer Reviewer Comments

This section provides guidance to the Peer Review Leader and Decision Maker on conducting an initial review and analysis of the peer review comments. After receiving the peer reviewer comments, the Peer Review Leader should synthesize and conduct a preliminary analysis of the comments. To do so, the Peer Review Leader should carefully read all of the comments received during the peer review, including written comments and oral comments received and documented during a peer review panel. Note that the analysis of oral comments will depend greatly on comprehensive and accurate meeting notes taken by BSEE staff or support staff.

Because the Peer Review Leader may not be the staff person responsible for the finalization of the research product, the research product authors or other BSEE subject matter experts may need to be consulted in order to appropriately assess peer review comments.

The Peer Review Leader should analyze the comments and brief the Decision Maker and any other senior management on comments that may significantly impact the development of the research product (i.e., research product budget, time, or resource needs). The Peer Review Leader and Decision Maker will respond to and incorporate comments after drafting the Peer Review Report (see Step 4.3), but the purpose of this preliminary analysis is to begin to address any comments that would benefit from early or more extensive review.

At this point in the peer review process, the Peer Review Leader and Decision Maker also should determine if the peer review comments have adequately addressed the Peer Review Charge. In the event that the Peer Review Charge has not been adequately addressed, resources permitting, the Peer Review Leader and Decision Maker may revise the Peer Review Charge and ask the same set of peer reviewers to respond to the revised charge. Or, the Decision Maker may decide to begin a new peer review of the research product. Either way, the original peer review must be documented according to the guidance in this Manual.

Specific Guidance for Analyzing Peer Reviewer Comments under Contractor-Led Peer Reviews

Under contractor-led peer reviews, the contractor will perform the initial reading and synthesis of the peer review comments as a first step in developing the Peer Review Report (see Step 4.2). BSEE may require the contractor to elevate significant comments to the Peer Review Leader, but the corresponding evaluation criteria for what constitutes a “significant” comment should be stipulated in the SOW. Alternatively, the Peer Review Leader may require the contractor to submit the verbatim comments to the Peer Review Leader immediately upon receipt of the comments to enable the Peer Review Leader to perform such analyses.

Step 4.2: Create the Peer Review Report

The Peer Review Leader must develop the Peer Review Report for the peer review. A Peer Review Report is a written document that details the goals, process, and outcomes of the peer review. It helps the reader understand why the peer review was undertaken, who the peer reviewers are and how they were selected, as well as how the reviewers responded to the Peer Review Charge. This section provides guidance to the Peer Review Leader for compiling the Peer Review Report.

Information To Be Included in the Peer Review Report

Per the OMB Bulletin, the Peer Review Report must describe the nature and scope of the review, as well as peer reviewers' conclusions and findings. The Peer Review Report describes the research product, identifies the reviewers, and provides logistical information about the peer review.

The following items must be included in the Peer Review Report:[15]

- Description of the research product under review
- Reviewer names and organizational affiliations
- Short description of the credentials and relevant experiences of each peer reviewer
- Summary of the peer review selection process, including mention and resolution of any COI issues
- Logistical information, including information about any meetings held
- Synthesis of reviewer comments, either verbatim or in summary form (or both)
- Peer Review Charge

Peer Review Report Organization

The specific organization of the comments within the Peer Review Report is at the discretion of the Peer Review Leader. As long as the Peer Review Report includes the information listed above, the Peer Review Leader may choose from a variety of different organizational formats.

For an **external letter review**, the most logical approach may be to organize the peer reviewer responses according to the organization of the Peer Review Charge. For example, if the Peer Review Charge included ten questions, then responses could be organized according to those ten questions in the Peer Review Report. The Peer Review Leader may choose to summarize comments in the Peer Review Report (including a summary of the reviewers' overall assessment of the research product,

To avoid becoming subject to FACA requirements, "[w]hen referring to the recommendations of the individual reviewers," the Peer Review Leader, "should not characterize these recommendations using terms such as "collective" or "consensus.""

-EPA Handbook

[15] Although not all of these elements are required by OMB, BSEE follows the best practice of including all of the listed information in Peer Review Reports. See Appendix F for details on the requirements for influential scientific information and highly influential scientific information, respectively.

and any agreement, disagreement, or actionable recommendations) and feature the verbatim responses in an appendix.

For an **external panel review**, the Peer Review Leader may choose to organize the oral comments according to the Peer Review Charge or may follow the organization of the panel discussion. For example, if the panel discussion allowed time for individual reviewers' presentations followed by a group discussion, then the Peer Review Report could follow that format. Any written comments that are obtained from the peer reviewer panelists (including draft and revised comments) should be included in the Peer Review Report, either verbatim or summarized.

Treatment of Numerical Data

The benefit of using numerical data is to reduce the influence of personal opinions on the results of a Peer Review Report and to standardize peer reviewer feedback. Numerical scoring systems are assets to a review when comparing two or more research products or sections within a research product. When using a numerical scoring system to rate the research product, whether to rate the research product as whole or various elements, it is important to normalize the data. A database or spreadsheet can be used to standardize the scores to ensure that the reviewer's data is normalized both within their own rankings and against the rankings of other reviewers. Factors to take into account for normalizing data include the number of reviewers, the number of separate panels used, and questions/categories by which the reviewers are rating.

Disclosure of Reviewers

As mentioned above, the names and organizational affiliations of reviewers must be disclosed in the Peer Review Report. The extent of attribution of reviewer comments (i.e., whether the report will detail which reviewer provided which content) is at the discretion of the Peer Review Leader and the Decision Maker, as decided in the peer review planning phase (see Step 2.2). It is important to remember that higher transparency is achieved when comments are attributed to the reviewer who provided the comment. For research products of high importance to policy or regulatory decision-making, the Peer Review Leader and Decision Maker should consider the highest level of transparency.

"The public may not have confidence in the peer review process when the names and affiliations of the peer reviewers are unknown. Without access to the comments of reviewers, the public is incapable of determining whether the government has seriously considered the comments of reviewers and made appropriate revisions."

-OMB Bulletin

Regarding disclosure of information about peer reviewers, the Peer Review Leader and Peer Review Coordinator must ensure that disclosure meets the requirements of the OMB Bulletin, which states that:

- To the extent information about a reviewer (name, credentials, affiliation) will be disclosed along with his/her comments or analysis, the agency shall comply with the requirements of

the Privacy Act, 5 U.S.C. § 522a as amended, and OMB Circular A-130, Appendix I, 61 Fed. Reg. 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice.

- Information about a reviewer retrieved from a record filed by the reviewer's name or other identifier may be disclosed only as permitted by the conditions of disclosure enumerated in the Privacy Act, 5 U.S.C. § 552a as amended, and as interpreted in OMB implementing guidance, 40 Fed. Reg. 28,948 (July 9, 1975).[16]

Dissemination of Peer Review Report

Once complete, the Peer Review Leader must ensure that the Peer Review Report is incorporated into the Peer Review Record and posted to the BSEE Web site, per the requirements addressed below. The Peer Review Leader should provide the Peer Review Report to senior management for review before dissemination of the research product.

The Peer Review Leader may provide the Peer Review Report to the peer reviewers as a courtesy. In addition, if a highly influential scientific assessment is used to support a rulemaking initiative (including Advanced Notice of Proposed Rulemakings (ANPRMs), proposed rulemakings, and final rulemakings), the Peer Review Report must be posted to the Web site with enough time to allow for public consideration.

Specific Guidance for Creating the Peer Review Report under Contractor-Led Peer Reviews

Contractors may develop the Peer Review Report, if required by the SOW. The SOW should detail any requirements related to the development of the Peer Review Report such as the following: all information to be included in the Peer Review Report; any organizational or style requirements; and requirements relating to comment attribution and reviewer disclosure. BSEE may stipulate that the contractor provide an outline of the Peer Review Report to the Peer Review Leader for review and approval, followed by a complete draft which would be finalized after incorporating BSEE comments. BSEE's review should be limited to ensuring that the contractor's Peer Review Report meets the requirements detailed in the contractor's SOW, as well as the requirements of the OMB Bulletin and, where applicable, this Manual. BSEE should not provide comments on the conclusions drawn in the contractor's Peer Review Report. The contractor would submit the final Peer Review Report to the Peer Review Leader for dissemination.

[16] For example, barring certain exceptions, information about an individual covered under the Privacy Act should not be disclosed without the consent of the individual. For additional guidance on the Privacy Act, see: http://www.justice.gov/opcl/conditions-disclosure-third-parties.

Step 4.3: Respond to and Incorporate Peer Reviewer Comments

This section will provide guidance on incorporating peer reviewer comments into the research product and creating a Comment Response Document. Once the peer review comments have been analyzed and incorporated into the Peer Review Report, the Decision Maker with the Peer Review Leader should consult with the research product author(s) or other BSEE subject matter experts to determine BSEE responses to the comments, including any subsequent recommended revisions to the research product.

Per OMB guidance, all peer reviewer comments must "be given consideration and be incorporated where relevant and valid." In most cases, the research product author(s) would be primarily responsible for incorporating comments into the research product. If the research product was developed by an external organization, the incorporation of peer reviewer comments would be stipulated by the work order or agreement with that organization.

Either after or while incorporating comments, the Decision Maker with the Peer Review Leader should draft the Comment Response Document as required (see below).

Comment Response Document

BSEE's formal response to peer reviewer comments can be found in the Comment Response Document. The Comment Response Document is a standalone document separate from the Peer Review Report or Peer Review Record. A Comment Response Document is required for peer reviews of highly influential scientific assessments and peer reviews involving public panels. In order to increase transparency, BSEE staff should consider drafting such a response for peer reviews of all other research products.

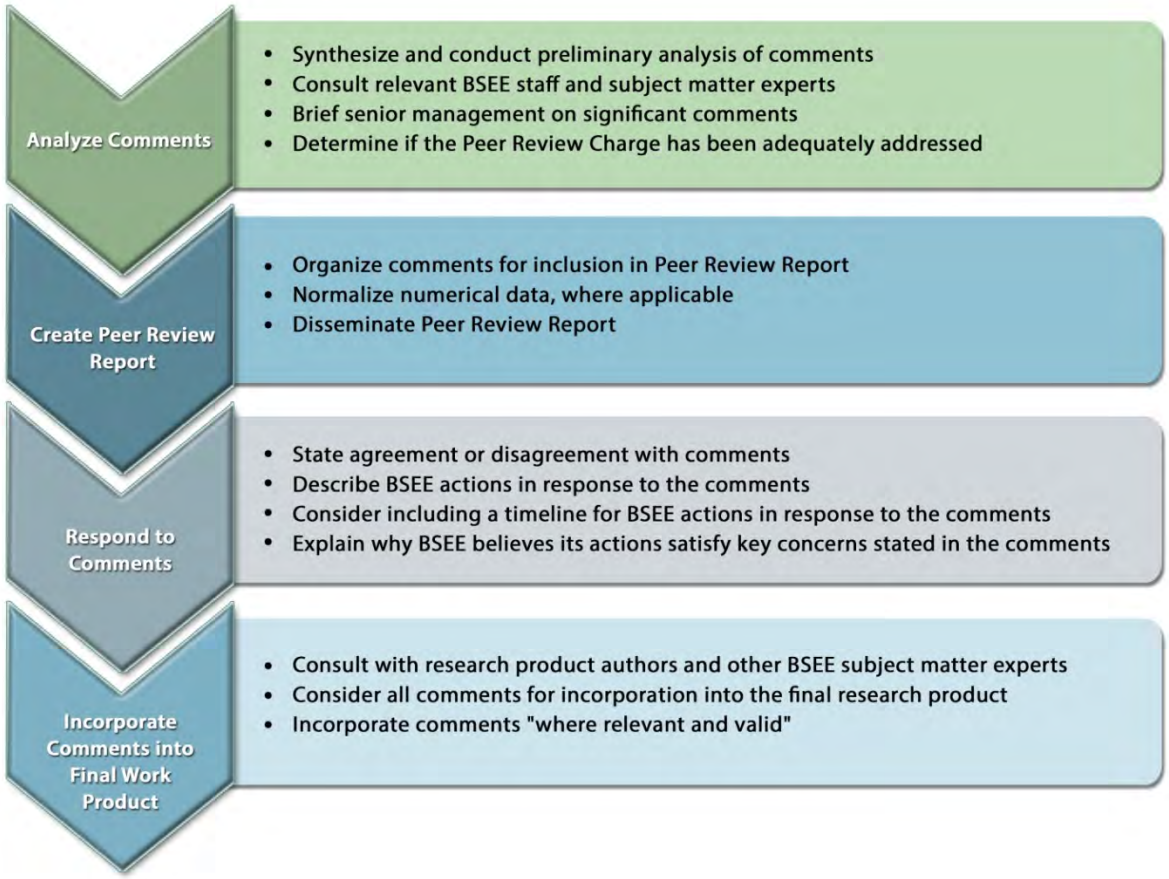
The Comment Response Document can be viewed as a written response to the Peer Review Report, and per the OMB Bulletin, it must address the following:

- Agreement or disagreement with views expressed in the Peer Review Report
- Actions BSEE has undertaken or will undertake in response to the Peer Review Report, and, optionally, a corresponding timeline for such actions
- Reasons those actions satisfy key concerns stated in the Peer Review Report (if applicable)

Particular attention should be paid to significant comments that were not accepted for incorporation into the research product, as well as actionable recommendations. Comment discussion should be comprehensive enough to give the reader a full view of the reasons why a comment was not accepted.

Graphic 8 provides an overview of the process for analyzing peer reviewer comments, responding to peer reviewer comments, and incorporating them into the revised research product.

GRAPHIC 8: ANALYZING, RESPONDING TO, AND INCORPORATING PEER REVIEWER COMMENTS



Specific Guidance for Responding to and Incorporating Peer Review Comments under Contractor-Led Peer Reviews

In a contractor-led peer review, the contractor should not assist BSEE in developing draft responses to peer review comments because they should be completely independent from the research product, and such responses involve an in-depth knowledge of the research project.

Step 4.4: Complete Documentation of the Peer Review

The Peer Review Leader and Peer Review Coordinator are responsible for ensuring that the peer review is appropriately documented in the Peer Review Record, any related BSEE regulatory actions, and in the research product itself. This step provides guidance to the Peer Review Leader and Peer Review Coordinator for compiling final documentation of the peer review.

Documentation in the Research Product

The revised research product should contain a summary of the peer review process and findings. The Peer Review Leader should coordinate with the research product author(s) to ensure that this description is incorporated into the revised research product.

Peer Review Record

The Peer Review Record will serve as the complete and formal record of the peer review process and results. The Peer Review Leader should have started compiling the Peer Review Record during the planning phase (see Step 2.3), and the completion of the Peer Review Record by the Peer Review Leader marks the end of the peer review process. The Peer Review Record should include sufficient information for readers to be able to understand what transpired during the peer review and the basis for any changes made to the research product or actions taken as a result of the review.

The Peer Review Record must include all relevant materials to the peer review, including but not limited to:

- Draft research product
- Peer Review Plan
- Materials provided to the reviewers
- Peer Review Report
- Comment Response Document, where applicable (see Step 4.3)
- Revised research product

The Peer Review Coordinator is responsible for ensuring that the Peer Review Record is stored in accordance with BSEE recordkeeping and forms management policies, and procedures and OMB requirements for handling information about peer reviewers (see Step 4.2). The Peer Review Coordinator (or other appropriate BSEE staff) should ensure that all guidelines for handling confidential business information (CBI) are followed and that the final documents are 508 compliant.[17]

The Peer Review Coordinator must post all items that are included in the Peer Review Record to the BSEE Web site. Additionally, the Peer Review Coordinator should post all items that are included in the Peer Review Record to the BSEE peer review database.

As a courtesy, the final research product may be sent to the peer reviewers.

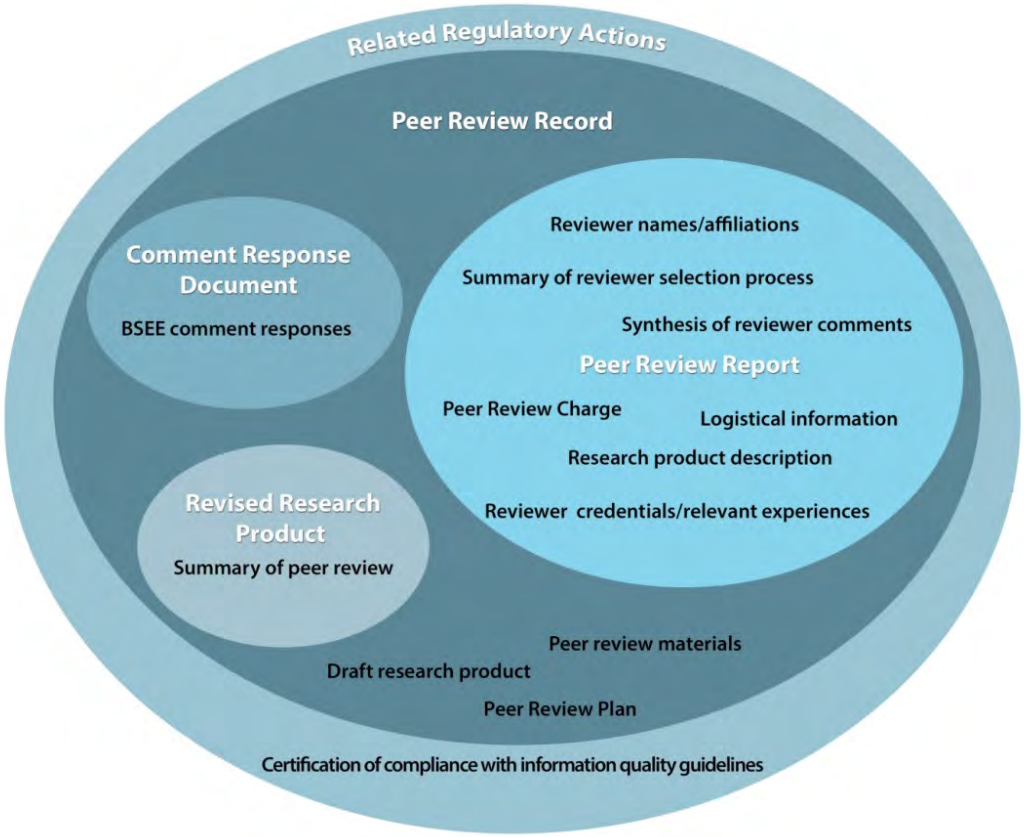
[17] Section 508 addresses accessibility of federal government information for individuals with disabilities. See the Section 508 Web site for additional information: http://www.section508.gov/.

Related Regulatory Actions

If influential scientific information or highly influential scientific assessments are relied upon to support a regulatory action, the administrative record for the action must include relevant peer review materials (including the Peer Review Record) and certification explaining how BSEE complied with the requirements of the OMB Bulletin and applicable information quality guidelines. In addition, per OMB requirements, the Peer Review Report must be discussed in the preamble to any related rulemaking.

Graphic 9 depicts the methods in which the information elements of a peer review (black phrases) are formally documented in certain repositories (colored circles). The graphic includes concentric circles representing the way in which a repository of information may be included in another repository. For example, there are several information elements that are documented in the Peer Review Report (e.g., reviewer names, Peer Review Charge, logistical information, comment synthesis, etc.), and that Peer Review Report is then included in the Peer Review Record, which is referenced for any associated regulatory action stemming from the peer review.

Graphic 9: Documenting a Peer Review



Annual Report

Annually, the Peer Review Coordinator must compile and submit a report to the OIRA by December 15 describing BSEE peer reviews over the course of the fiscal year. Per OMB requirements, the report must include:

- Number of BSEE peer reviews conducted subject to the OMB Bulletin (i.e., for influential scientific information and highly influential scientific assessments);
- Number of times alternative procedures were invoked;
- 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);
- 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 of the Interior pursuant to Section III(3)(c) (see Appendix F);
- Number of peer review panels that were conducted in public and the number that allowed public comment;
- Number of public comments provided on the agency's Peer Review Plans; and
- Number of peer reviewers that the agency used that were recommended by professional societies.

The Peer Review Coordinator should ensure compliance with any special requirements related to the Annual Report disseminated by DOI on an annual basis.

Lessons Learned

After completing a peer review, Peer Review Leaders are encouraged to reflect on and share any "lessons learned" with the Peer Review Coordinator, Decision Makers, and other Peer Review Leaders. As mentioned above, BSEE will refine and update this Manual through a process of continual improvement based on feedback from users.

Appendices

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Appendix A: Peer Review Checklist

Step 1: Determine When to Conduct a Peer Review				
Activity	**Step in Manual**	**To-Do**	**In Progress**	**Complete**
Ensure funding has been allocated for peer review	--			
Review requirements and guidance	1.1			
Check exemptions and review alternatives	1.2 and 1.3			
Notes:				

Step 2: Prepare for the Peer Review				
Activity	**Step in Manual**	**To-Do**	**In Progress**	**Complete**
Establish scope of peer review	2.1			
Consider desired level of transparency, including public involvement	2.1			
Consider Peer Review Charge questions	2.1			
Consider necessary qualifications of peer reviewers	2.1			
Consider treatment of confidential business information	2.1			
Determine timeline for peer review	2.1			
Determine peer review mechanism	2.2			
Determine method of selecting reviewers	2.2			
Determine disposition and attribution of comments	2.2			
Determine contractor involvement	2.2			
Develop Peer Review Plan (add to Peer Review Agenda , which is posted on the BSEE Web site)	2.3			
Begin the Peer Review Record	2.3			
Develop detailed budget	2.3			
Draft contractor Statement of Work (if applicable)	2.3			
Review legal aspects of peer review	2.4			
Notes:				

Step 3: Implement the Peer Review				
Activity	**Step in Manual**	**To-Do**	**In Progress**	**Complete**
Develop Peer Review Charge	3.1			
Identify and contact peer review candidates	3.2			
Evaluate candidate expertise, balance, availability, and COI concerns	3.2			
Finalize peer reviewers	3.2			
Finalize the schedule	3.3			
Notify selected peer reviewers (and those not selected)	3.3			
Compile and send peer review materials (after receiving COI form and non-disclosure form, if applicable)	3.4			
Confirm receipt of materials	3.4			
Conduct the peer review	3.5			
Facilitate and document meetings (if applicable)	3.5			
Collect reviewer's written comments	3.5			
Notes:				

Step 4: Complete and Document the Peer Review				
Activity	**Step in Manual**	**To-Do**	**In Progress**	**Complete**
Analyze peer reviewer comments	4.1			
Determine if charge was adequately addressed	4.1			
Brief management on significant comments	4.1			
Create and disseminate Peer Review Report	4.2			
Respond to peer reviewer comments, as applicable	4.3			
Incorporate peer reviewer comments into research product	4.3			
Finalize the Peer Review Record	4.4			
Document peer review in revised research product, related regulatory actions, and Annual Report	4.4			
Consider and share lessons learned	4.4			
Notes:				

Appendix B: Template for Creating an Effective Peer Review Charge

This appendix includes guidance to help BSEE staff develop an effective Peer Review Charge. The document is written in template form and, when complete, satisfies the requirements and best practices contained in this Manual. The Peer Review Leader should tailor the Peer Review Charge to suit the needs of a particular peer review.

Dear Mr./Mrs./Dr._____,

Thank you for agreeing to participate in the peer review of [insert title of research project]. This peer review is being undertaken to [insert objectives of the peer review].

[Insert several (1-5) paragraphs containing information on the research product. Items to consider for inclusion include: origin, purpose, and goals of the research; research development process; key hypotheses or conclusions; description of the format/layout of the product; individuals or organizations involved in the development of the research product; and any associated rulemakings.]

As a peer reviewer, you are asked to provide an overall assessment of the material, as well as respond to the technical questions included in the Enclosure. If the question requests a "yes/no" response or a numerical rating, you are instructed to provide support for your response. [Insert guidance on the evaluation criteria or rating classifications.] Your comments should be sufficiently clear and detailed to allow readers familiar with the subject to thoroughly understand their relevance to the material provided for review. You are not requested to and should not provide input or advice on BSEE's policies and decisions. Your review is not page-limited and should take as much space as you feel is necessary to complete your review.

Enclosed you will find the following materials to support your review:

1. [Insert a numbered list of items that are included in the package, including such things as: the research product being reviewed; background documents; technical instructions; and user guides.]

Please review the enclosed documentation and comply with the following activities:

- [Insert information about any required meeting attendance, including kick-off meetings and panel discussions. Include dates/times of the meetings and any call-in or logistical information.
- Include information about the peer review schedule and specific expectations for peer reviewers throughout the peer review, including what they are expected to contribute during meetings.
- Include information on and when and how written responses will be collected (e.g., at a panel discussion or via email, in electronic format (Microsoft Word or PDF)).]

As a peer reviewer, you should work independently when reviewing the research product. [Insert specific guidance for independent or collaborative work for a panel review.] You may not copy, quote, or

otherwise use, disclose, distribute, or publicize the content of the review materials. [Insert any specific non-disclosure guidance here.] In addition, you have a continuing obligation to identify and report to [insert contact name] any Real or Apparent conflicts of interest that may arise during completion of this peer review, or any other work related to this peer review.

You will be compensated with [insert type of payment, such as honoraria/fee/reimbursement] of [insert the agreed upon fee] upon [insert milestone for payment (e.g., submission of final written responses)]. Failure to complete the review according to these instructions and submit the required materials in accordance with the schedule may jeopardize payment in full.

Your name, affiliation, comments (verbatim or summary), [insert any other details about peer reviewers that BSEE intends to disclose (e.g. credentials, relevant experiences, etc.)], and BSEE responses to your comments will be included in a Peer Review Record. In this record, BSEE [will/may] attribute your comments to your name. The Peer Review Record will be made available to the public on the Internet. In addition, BSEE [may/will] publish a response to your comments with the Peer Review Record. [Insert any other information regarding how the findings of the peer review will be used.]

[Insert any other information relevant to the peer review, including requirements related to information access and quality.]

If you have any questions about the review process or have any issues with completing the review, please contact [insert name/ phone number/ email address]. Again, thank you for agreeing to participate in the peer review of [insert title of research project].

Sincerely,

[Insert name and contact information]

Enclosure: Technical questions to be addressed by peer reviewers. [Insert list of questions. For example questions, see the following page].

Example Questions for inclusion in a Peer Review Charge. The following example questions are intended to help BSEE staff generate ideas when drafting a Peer Review Charge and should not be considered an exhaustive or final list of questions. Each BSEE peer review will necessitate questions that are tailored to the particular research product.

Instructions: Please answer each question by entering a numerical rating between 1 and 5 in the column to the right. For example, if your rating is "3," input a "3" in the "Numerical Rating" column. In the box below each question, please provide comments supporting your numerical rating (use more pages as necessary).

For purposes of selecting a numerical rating, use the following categorical indicators:

1 = Unacceptable **2 = Inadequate** **3 = Mixed** **4 = Good** **5 = Excellent**

	Overall Questions	**Numerical Rating (1 – 5)**
1	Was the research product written objectively and transparently?	
Comments Supporting Rating (Required):		
2	Did the research product address the stated goals and objectives?	
Comments Supporting Rating (Required):		
3	Are there any apparent weaknesses or gaps in the research product?	
Comments Supporting Rating (Required):		
4	Are limitations and uncertainties clearly identified and adequately characterized?	
Comments Supporting Rating (Required):		
5	Is the research product easy to navigate and analyze?	
Comments Supporting Rating (Required):		

6	Are there ways in which the research product could be improved with regard to ease of use?	
Comments Supporting Rating (Required):		
Objectives/Assumptions		**Numerical Rating (1 – 5)**
7	Are the assumptions clearly defined?	
Comments Supporting Rating (Required):		
8	Are the assumptions appropriate?	
Comments Supporting Rating (Required):		
Research Design and Methodology		**Numerical Rating (1 – 5)**
9	Are there strengths of the analytical methods used?	
Comments Supporting Rating (Required):		
10	Are there weaknesses of the analytical methods used?	
Comments Supporting Rating (Required):		
11	Are variables clearly identified and characterized?	
Comments Supporting Rating (Required):		

12	Are data collection methods and inputs presented in a transparent manner?	
Comments Supporting Rating (Required):		
13	Were the analytical instruments appropriate and accurate and sensitive enough to produce relevant data?	
Comments Supporting Rating (Required):		
14	Was the data analysis appropriate?	
Comments Supporting Rating (Required):		
15	Should other techniques or analytic platforms have been considered?	
Comments Supporting Rating (Required):		
16	If modeling or extrapolation was used, were the methods appropriate?	
Comments Supporting Rating (Required):		
17	Are there any additional studies or sources of information/data that should have been consulted by the research product authors?	
Comments Supporting Rating (Required):		
	Conclusions	**Numerical Rating (1 – 5)**
18	Are the conclusions logical and appropriate based on the results?	
Comments Supporting Rating (Required):		

19	Can the conclusions be easily and accurately interpreted by the general public?	
Comments Supporting Rating (Required):		
20	Can BSEE be confident in the conclusions drawn from the research product?	
Comments Supporting Rating (Required):		
21	Are there any additional conclusions that could be drawn?	
Comments Supporting Rating (Required):		
Overall Assessment		**Numerical Rating (1 – 5)**
22	What is your overall assessment of the research product?	
Comments Supporting Rating (Required):		

Appendix C: Template for Statement of Work for Contractor-Led Peer Review

This appendix includes guidance to help BSEE staff develop an effective Statement of Work (SOW) for a contractor-led peer review. It is written as a call order award under a Blanket Purchase Agreement (BPA). The document is written in template form, and, when complete, satisfies the requirements and best practices contained in this Manual. The Peer Review Leader should tailor the SOW to suit the needs of a particular peer review.

STATEMENT OF WORK

Bureau of Safety and Environmental Enforcement (BSEE) Peer Review

Background

[Insert several (1-5) paragraphs containing background information on the research product. Items to consider for inclusion include: origin, purpose, and goals of the research; research development process; key hypotheses or conclusions; description of the format/layout of the product; individuals or organizations involved in the development of the research product; discussion of sensitivities surrounding the research product, and any associated rulemakings].

Purpose and Scope of Work

This call order is intended to support BSEE by conducting an independent review of [insert title of research product]. The peer review shall be carried out as a [letter review/peer review panel], and [insert number] of peer reviewers shall be chosen to review the research product.

The selected peer reviewers should have the following areas of expertise, experience, and skills:

- [Insert bulleted list of all necessary expertise, experience, and skills]

In addition to the submission of a written review of the research product, peer reviewers shall [Insert information about any required meeting attendance, including kick-off meetings and panel discussions].

The contractor shall implement the peer review as specified below:

Task 1: Kick-Off Meeting and Task Management

The contractor shall have a kick-off meeting with the BSEE Contracting Officer (CO) or Contracting Officer Representative (COR) and any other required BSEE staff within [X days/weeks] after call order award. The purpose of the meeting is to clarify outstanding questions and confirm the schedule and specific tasks. The contractor shall develop and distribute an agenda prior to the meeting, and shall deliver a meeting summary.

The contractor shall arrange [insert requirement for teleconference meetings or written progress report] with the BSEE COR [insert frequency] to summarize progress made to date. The contractor shall indicate progress achieved, technical issues encountered, solutions to issues (proposed or attempted), and projected activity. The contractor shall report potential issues or circumstances that may cause delays in the review process and notify the BSEE CO or COR if the project is beginning to exceed the hours or dollars allocated to this call order.

Task 2: Peer Review Selection

The contractor is responsible for acquiring the services of [X number] independent subject matter experts to conduct the requested peer review. The selected peer reviewers, when grouped, shall cover all technical aspects of the research product.

In selecting reviewers, the contractor shall avoid any reviewer with Real or Apparent conflict(s) of interest that would preclude an independent review. The contractor shall refer to the BSEE Peer Review Process Manual for guidance regarding peer reviewer independence and identifying, evaluating, disclosing, and monitoring Real or Apparent conflicts of interest among potential or selected peer reviewers. [Insert any additional COI requirements, including requirement to use BSEE COI form, submit written certification of disclosure and resolution of COI, and continuing obligation to report COI to the BSEE COR throughout the peer review.]

Selected peer reviewers shall have the expertise, experience, and/or skills. The contractor shall identify qualified candidate peer reviewers from [insert potential sources, including industry, government and/or academia] using several methods and sources. [Optional: Attach an appendix to the SOW that includes an alphabetized list of example subject matter experts who are anticipated to meet the minimum qualifications for the peer review. The SOW should state that the list shall not limit the contractor in the identification of potential reviewers, but should serve as a reference for identifying subject matter experts.]

Except for peer reviewers who are federal government employees, BSEE would expect that each peer reviewer would be provided with an honorarium in an appropriate amount for their services. Peer review compensation will be funded from the total allocated for this call order. The contractor shall assume, for the purpose of estimating costs, that peer review material comprises roughly [X] pages in length and that each peer reviewer will spend approximately [X-X] hours in reviewing the material, [insert other requirements such as meeting attendance], and writing comments.

Within [X days/weeks] of receipt of the call order award, the contractor shall provide the BSEE COR with a memorandum identifying the peer reviewers, their affiliations, copies of their resumes, and a target start date for the peer review.

The BSEE COR will provide written comments or approval of the peer reviewer list within [X weeks] of the list being received. A final list of peer reviewers is due within [X weeks] of receipt of BSEE comments. If BSEE disagrees with a chosen peer reviewer and believes that a substitute is needed, the contractor shall identify an alternate peer reviewer who has the necessary qualifications.

Task 3: Facilitate the Peer Review

The BSEE COR will provide the contractor with the peer review materials, including [insert project-specific list of peer review materials, as well as any information regarding whether the contractor is expected to assist with the development of the Peer Review Charge, including any draft questions or charge elements in an appendix]. The contractor shall distribute the peer review materials, including any instructions to reviewers on how to complete the peer review. The contractor shall assume that the peer review materials will be electronic and may be distributed by e-mail or FTP site.

After the distribution of the above documents to each of the peer reviewers, the contractor shall arrange a teleconference between the reviewers, the BSEE COR, and BSEE technical staff to permit BSEE to respond to questions from individual reviewers on the material that was provided for review. BSEE staff will provide additional technical and/or background material, as needed or if requested.

[Insert project-specific details for conducting the peer review, depending on whether the review is a letter review or a panel review].

For a panel review, insert specific information on requirements, such as the following:

- Approximate date for the meeting
- Desired location of the meeting
- Anticipated length of the meeting
- Stipulations regarding the contractor's required activities for the meeting, including the following:
    - Meeting space rental and logistics
    - Suggested attendees
    - Agenda development
    - Meeting facilitation
    - Collection of written response to Peer Review Charge
        - Format
        - Instructions to forward verbatim comments to BSEE COR
    - Meeting notes and meeting summaries
    - Audio/visual coordination

For a letter review, insert specific information on requirements, such as the following:

- Approximate start date and length for peer review
- Mid-review conference call
- Collection of written response to the Peer Review Charge, including format and any instructions to forward verbatim comments to the BSEE COR]

Task 4: Draft and Final Peer Review Report

The contractor shall develop both a draft and final Peer Review Report, which details the work completed in Tasks 1 through 3, including any issues encountered.

The Peer Review Report shall including the following information:

- Description of the research product under review
- Reviewer names and organizational affiliations
- Short description of the credentials and relevant experiences of each peer reviewer
- Summary of the peer review selection process, including an explanation and resolution of any COI issues
- Logistical information, including information about any meetings held
- Synthesis of reviewer comments, either verbatim or in summary form (or both)
- Peer Review Charge

[Insert other project-specific requirements for compilation of Peer Review Report, including style requirements and requirements for comment attribution.]

The draft Peer Review Report shall be delivered to BSEE within [X week(s)] of receipt of peer reviewer comments [or panel discussion]. The contractor shall provide BSEE with a final Peer Review Report addressing BSEE comments within [X week(s)] of receiving comments on the Peer Review Report.

Work Requirements

In performing this work, the contractor shall comply with the guidance specified in the BSEE Peer Review Process Manual, OMB Bulletin entitled "Final Information Quality Bulletin for Peer Review" (December 2004), DOI Information Quality Guidelines, and any other relevant requirements. The contractor shall manage the peer review process to ensure that each peer reviewer has sufficient time to complete his or her review and that each reviewer can adhere to the deadlines set forth in the deliverables schedule below.

At all times, contractor personnel shall identify themselves as Contractor employees and shall not present themselves as BSEE employees. Furthermore, they shall not represent the views of the U.S. Government, BSEE, or its employees. In addition, the Contractor shall not engage in inherently governmental activities, including but not limited to actual determination of BSEE policy and preparation of documents on BSEE letterhead.

[Insert any other work project specific requirements, including requirements for peer reviewer disclosure and required format of deliverables.]

Schedule of Deliverables

Task deliverables and due dates are summarized below.

Deliverable by Task	Distribution	Due Date
Task 1: Kick-Off Meeting and Task Management		
Arrange kick-off meeting		Within [X days/weeks] after call order award
Meeting agenda	Via email to CO and COR	Within [X days] of meeting
Meeting summary	Via email to CO and COR	Within [X days] after meeting
Progress report [or meetings]	Via email to CO and COR	[insert frequency]
Task 2: Peer Review Selection		
Peer Reviewer Selection Memo	Via email to CO and COR	Within [X weeks] after call order award
Finalize Peer Reviewer Selection Memo	Via email to CO and COR	Within [X days] of BSEE comments or approval of list
Submit COI certification form [if required]	Via email to CO and COR	Within [X days] of BSEE comments or approval of list

Task 3: Facilitate the Peer Review		
Draft Peer Review Charge [if required]	Via email to CO and COR	Within [X days/weeks] after call order award
Final Peer Review Charge [if required]	Via email to CO and COR	Within [X days] of BSEE comments or approval
Send peer review materials	Via email or FTP to peer reviewers	Within [X days/weeks] of BSEE approval of peer reviewers
Arrange peer reviewer teleconference		Within [X days] of delivery of peer review materials
Arrange/facilitate panel review [if required]		Within [X weeks] of delivery of peer review materials
Summary/minutes of panel review [if required]	Via email to CO, COR, and peer reviewers	Within [X days/weeks] of panel discussion
Collect written comments [and forward to BSEE, if required]	Via email to CO and COR	[Insert due date, depending on letter review or panel review]
Task 4: Draft and Final Peer Review Report		
Draft Peer Review Report	Via email to CO and COR	Within [X weeks] of receipt of peer review comments
Final Peer Review Report	Via email to CO and COR	Within [X weeks] of BSEE comments

Appendix D: BSEE Peer Review Conflict of Interest Form

BSEE Peer Review Conflict of Interest Form

Date:
BSEE Acquisition Number and Title:
Peer Reviewer Name/Affiliation:
Expected Role of Peer Reviewer: [Insert peer reviewer name] at [insert affiliation, if applicable] is a recognized expert in [insert area of expertise]. For this acquisition, [insert peer reviewer name] is expected to provide an independent, unbiased technical review of [insert name of research product]. The review entails [insert details of review, including peer review format/mechanism, any required meetings, and any expectations for reviewer comments].

Research Product Background: [Insert several (1-5) paragraphs containing background information on the research product. Items to consider for inclusion include: origin, purpose, and goals of the research; research development process; key hypotheses or conclusions; description of the format/layout of the product; individuals or organizations involved in the development of the research product (including authors, developers, or directors); discussion of sensitivities surrounding the research product, and any associated rulemakings.]

Information Relating to Conflict of Interest: In order to fulfill your duties as a peer reviewer, you are required to review and sign this conflict of interest (COI) disclosure and certification form and attach any additional information on related activities and associations as appropriate. Your BSEE point of contact may follow up with you for additional information regarding any potential COIs.

If you are selected and agree to serve as a peer reviewer, you will need to disclose any Real or Apparent COI (as explained below) on this form. Any disclosure of information provided in this completed form will be in compliance with the Privacy Act, 5 U.S.C. § 522a as amended; OMB implementing guidance, 40 Fed. Reg. 28,948 (July 9, 1975); and OMB Circular A-130, Appendix I, 61 Fed. Reg. 6428 (February 20, 1996). [Insert information about the extent of disclosure of COI information for the peer review. For example, "Peer reviewers with COIs will be asked to disclose their COIs at the beginning of panel meetings, and a brief summary of any COIs for selected peer reviewers will be included in the Peer Review Record, which will be published on the BSEE Web site."]

This Manual includes the following definitions for Real and Apparent COI:

- **Real COI:** A Real COI could be any financial interest held by an individual (or certain related persons[18]) that could be affected by their participation in the peer review.
- **Apparent COI:** An Apparent COI could be any circumstance related to an individual (or certain related persons[19]) that may cause "a reasonable person with knowledge of the relevant facts" to

[18] For any federal government employee, the financial interests of following individuals must also be considered as required under 18 U.S.C. § 208: "spouse, minor child, general partner, organization in which he is serving as officer, director, trustee, general partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment."

[19] The following individuals related to a peer review candidate should be considered when evaluating Apparent COI, in addition to any other relationships that may cause an appearance of loss of impartiality: members of the individuals household, "a person with whom the employee has or seeks a business, contractual, or other financial

question the individual's impartiality in participating in the peer review (i.e., "an appearance of loss of impartiality"[20]).

To preserve the independence of the BSEE peer review process, BSEE may decide not to allow individuals with Real or Apparent COIs to participate in BSEE peer reviews. For the purposes of filling out the form below, "you" or "your" should be read as applying to both you and any relevant individuals for the purposes of evaluating COI (see footnotes to definitions of Apparent and Real COI above).

Please consider carefully whether you might have a Real or Apparent COI or if any other interests, activities, or relationships would cause your impartiality as a peer reviewer to be questioned. Please provide relevant information on these topics as well as the information specified below. Information is considered to be relevant if the information may cause "a reasonable person with knowledge of the relevant facts" to question your impartiality in participating in the peer review.[21] State any necessary details, including, but not limited to, specific names and funding sources. Potential COIs may be related to, but are not limited to, relationships to the research product, professional history, financial interests, public statements, or other relationships.

Relationship to the Research Product. Relationships to the research product undergoing peer review that may lead to COI may include, but are not limited to, the following:

- Any involvement with the research product under review (including, but not limited to, methods, data, assumptions, conclusions)
- A business or personal relationship with the research product authors/developers/directors
- A business relationship with the organization(s) that developed the research product
- Professional relationship with BSEE, including any work under research contracts or grants and previous peer reviews

Please disclose any potential relevant information regarding your involvement with the research product under review or its authors, developers, directors, or sponsors:

relationship; a person who is a member of the employee's household or is a relative with whom the employee has a close personal relationship; a person for whom the employee's spouse, parent, or dependent child serves or seeks to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee; any person for whom the employee has within the last year served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee; any organization (other than a political party) in which the employee is an active participant." (See: http://www.oge.gov/Topics/Financial-Conflicts-of-Interest-and-Impartiality/Current-Government-Employees/.)

[20] See 5 C.F.R. Part 2635.

[21] Ibid.

Professional History. Professional history that may lead to COI may include, but is not limited to, the following:

- Relevant business (employee, owner, officer, consultant, client, trustee, etc.) and non-business (volunteer work, professional organizations, trade associations, etc.) relationships
- Government service (full- or part-time), including federal, state, and local government; military service; review panels; and advisory board membership
- Authorship of or collaboration on relevant research studies and their sources of funding
- Whether any part of this review would serve as a review of your work, or the work of your friends or colleagues

Please disclose any relevant information related to your professional history:

Financial Interests. Financial interests that may lead to COI may include, but are not limited to, the following:

- Relevant financial interests (public or private)
- Relevant property interests
- Whether this work would provide you with any financial or commercial competitive advantage

Please disclose any relevant information related to your financial interests:

Public Statements. Public statements that may lead to COI may include, but are not limited to, the following:

- Relevant public statements that you have made, including:
  - Testimony
  - Presentations
  - Speeches
  - Articles
  - Advocacy
- Professional obligations that require you to have a public opinion related to this project

Please disclose any relevant information related to your public statements:

Relationships. Relationships that may lead to COI may include, but are not limited to, the following:

- Relevant personal, financial, or other relationships
- Whether involvement in the peer review would provide access to a competitor's proprietary information or otherwise directly affect your competitor(s)

Please disclose any relevant information related to your relationships:

Please disclose any other relevant information regarding why you might be unable to provide impartial review of the research product:

I certify that the information I have provided on this form is true, complete, and correct to the best of my knowledge. During my period of service in connection with this peer review, I will promptly disclose any changes in this information.

_____ _____

Signature Date

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Appendix E: Additional Conflict of Interest Guidance

This Appendix provides additional guidance to BSEE staff for evaluating potential conflicts of interest (COIs) identified during the peer reviewer selection process. If, after reading this guidance, BSEE staff have questions or concerns about evaluating peer reviewer COI, they should consult the BSEE Ethics Office, the DOI DAEO, or Office of General Counsel, as appropriate.

As mentioned in Step 3 of this Manual, the specific OMB requirements for evaluating COI are as follows:

- Examine prospective reviewers' potential financial conflicts, including significant investments, consulting arrangements, employer affiliations, and grants/contracts.
- Scrutinize financial ties of potential reviewers to regulated entities (e.g., businesses), other stakeholders, and regulatory agencies when the information being reviewed is likely to be relevant to regulatory policy.
- Inquire into financial investments and business relationships, including work as an expert witness, consulting arrangements, honoraria, and sources of grants and contracts.

In addition to these requirements, which apply to all peer review candidates, the OMB Bulletin references separate standards and requirements for the evaluation of COI for both contracted peer reviewers and federal government employees (including Regular Government Employees (RGEs) and Special Government Employees (SGEs)) serving as peer reviewers:

> *To evaluate any real or perceived conflicts of interest with potential reviewers and questions regarding the independence of reviewers, agencies are referred to federal ethics requirements, applicable standards issued by the Office of Government Ethics, and the prevailing practices of the National Academy of Sciences (NAS).*

This Appendix will provide guidance on the additional standards and requirements that apply to each category of reviewer. First, the Appendix addresses COI requirements for contracted peer reviewers as adopted and adapted from the NAS. Next, the Appendix addresses COI requirements for federal government employee peer reviewers, including relevant statutory and regulatory requirements for financial COI and "appearance of loss of impartiality." The section on federal COI requirements also discusses exemptions, OGE waivers, and special cases.

COI Evaluation Requirements Applicable to Contracted Peer Reviewers

As defined in Step 3.2.1 of this Manual, "contracted peer reviewers" are external experts who are not federal government employees and whose services are acquired either by BSEE or by a contractor in the case of a contractor-led peer review. For peer review candidates that are not federal government employees, the OMB Bulletin requires agencies to "adopt or adapt the NAS [National Academy of Sciences] policy for committee selection with respect to evaluating conflicts of interest." In evaluating peer review candidates that would serve as contracted peer reviewers, BSEE staff will largely conform to the policies detailed in the NAS "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports" (hereafter referred to as the

"NAS COI Policy"). There are a few instances in which BSEE's COI evaluation policy for contracted peer reviewers will differ slightly from the NAS COI Policy. The full policy can be found here: http://www.nationalacademies.org/coi/index.html. This section will summarize the requirements found in this policy that are applicable to BSEE peer reviews.

Defining COI

The NAS COI Policy defines conflict of interest as "any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization." As used in the NAS COI Policy, the term typically refers to financial COIs, and this NAS definition closely parallels the definition of Real COI included in Section 3.2.1. The NAS definition of COI includes "interests of others with whom the individual has substantial common financial interests if these interests are relevant to the functions to be performed." According to the NAS COI Policy, interests of the following categories of persons must be evaluated:

- The individual's spouse and minor children;
- The individual's employer;
- The individual's business partners;
- Others with whom the individual has substantial common financial interests; and
- Interests of those for whom one is acting in a fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or non-profit, or serving as a trustee).

The following "general principles" are outlined in the NAS COI Policy and provide additional clarification on the definition of COI:

- The evaluation of COI should consider the perception of COI regardless of whether a COI would likely be realized. The guidance states that COI requirements "are objective and prophylactic" and "are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth."
- The definition of COI is limited to current interests (as opposed to past or future interests).

Evaluating COI

The NAS COI Policy specifies that the following financial interests should be evaluated where relevant:

- Employment relationships (including private and public sector employment and self-employment);
- Consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, and serving as an expert witness in litigation);
- Stocks, bonds, and other financial instruments and investments including partnerships;
- real estate investments;

- Patents, copyrights, and other intellectual property interests; commercial business ownership and investment interests;
- Services provided in exchange for honorariums and travel expense reimbursements; and
- Research funding and other forms of research support.

In addition, the NAS COI Policy provides the following guidance on evaluating candidates for COI:

- Peer reviewers should not be allowed access to proprietary information of a competitor or potential competitor without appropriate safeguards.
- Peer reviewers allowed access to confidential information that use/intend to use or disclose/intend to disclose information in a manner that could create a "direct and substantial economic benefit" for individuals or organizations will be considered to have a conflict of interest.
- Individuals should not serve as peer reviewers for peer reviews whose focus is "a critical review and evaluation of the individual's own work, or that of his or her immediate employer."
- Public statements or opinions on a topic relevant to the peer review may not constitute a conflict of interest except when "there is some significant, directly related interest or duty of the individual." (These public statements or opinions would still need to be evaluated with respect to panel balance and independence.)

The NAS Policy states that unless a candidate's conflict of interest is unavoidable and the agency "promptly and publicly discloses the conflict of interest," an individual with a COI cannot serve on a committee if the COI is relevant to the committee functions. BSEE adapts this guidance by requiring that the Peer Review Leader and Decision Maker only allow a contracted peer reviewer candidate with a Real COI to participate if the COI is unavoidable and by requiring documentation of the COI evaluation process in the Peer Review Record.

COI Evaluation Requirements Applicable to Federal Government Employee Peer Reviewers

BSEE employs as peer reviewers federal government employees, including Regular Government Employees (RGEs) and Special Government Employees (SGEs). As defined in Section 3.2.1 of this Manual, RGEs are "all executive branch employees who are not (1) SGEs under 18 U.S.C. § 202(a), (2) covered non-career employees under 5 C.F.R. § 2636.303(a), nor (3) employees appointed by the President to a full-time non-career position described under 5 C.F.R. § 2635.804(c)(2)."[22] An SGE is "an officer or employee who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for not more than 130 days during any period of 365 consecutive days."[23]

[22] See discussion provided by the Office of Government Ethics for additional information: http://www.oge.gov/OGE-Advisories/Legal-Advisories/08x3a--Book-Deals-Involving-Regular-Employees-and-Special-Government-Employees/

[23] See discussion provided by the Office of Government Ethics for additional information: http://www.oge.gov/Topics/Selected-Employee-Categories/Special-Government-Employees/.

The OMB Bulletin specifies that agencies must follow federal ethics requirements and applicable Office of Government Ethics standards when evaluating COI for peer review candidates who are federal government employees. In particular, the Bulletin states that, "peer reviewers who are federal employees (including special government employees) are subject to federal requirements governing conflicts of interest. See, e.g., 18 U.S.C. § 208; 5 C.F.R. Part 2635 (2004)." This section will address these requirements referenced in the OMB Bulletin, as well as a few other applicable requirements. In addition to the guidance provided in this section, BSEE staff should refer to the Office of Government Ethics Web site for additional details on all relevant conflict of interest requirements.

Financial Conflict of Interest and Impartiality Requirements

There are both statutory and regulatory requirements for evaluating financial COIs and any appearances of loss of impartiality for peer reviewers that are government employees.

Statutory Requirements - 18 U.S.C. § 208

The statutory basis for applicable Office of Government Ethics conflict of interest regulations and guidance is 18 U.S.C. § 208: "Acts affecting a personal financial interest." As applied to BSEE peer review, the statute would prohibit participation of a federal government employee in a peer review if the individual (or certain related persons[24]) had a financial interest that could be affected by their participation. Exemptions to this ban on participation for employees with a financial conflict of interest include: (1) individuals that notify the relevant Government official of the COI and receive approval for participation from that individual, (2) individuals whose COI is determined to be remote or inconsequential and falls under a blanket exemption as defined by the OGE, (3) individuals serving on a Federal Advisory Committee for which the relevant Government official approves their participation, (4) individuals with Native American or Alaska Native birthrights, under specified conditions. The subsections below will discuss regulations published by the Office of Government Ethics that provide specific guidance on these exemptions and implementing guidance on 18 U.S.C. § 208.

OGE Regulatory Requirements – 5 C.F.R. Part 2635 and 5 C.F.R. Part 2640

OGE published two major implementing regulations for 18 U.S.C. § 208: 5 C.F.R. Part 2635: "Standards of ethical conduct for employees of the executive branch" and 5 C.F.R. Part 2640: "Interpretation, Exemptions, Waiver Guidance Concerning 18 U.S.C. 208 (Acts Affecting a Personal Financial Interest)." In addition to this guidance, both 5 C.F.R. Part 2640 and 5 C.F.R. Part 2635 provide additional guidance on the financial conflict of interest prohibition in 18 U.S.C. § 208.[25] This section will address requirements regarding exemptions, waivers, and impartiality contained in these regulations.

[24] For any federal government employee, the financial interests of following individuals must also be considered under this statute: "spouse, minor child, general partner, organization in which he is serving as officer, director, trustee, general partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment."

[25] See the OGE Web site for summary descriptions and the regulatory text for 5 C.F.R. Part 2640 and 5 C.F.R. Part 2635: http://www.oge.gov/Laws-and-Regulations/OGE-Regulations/OGE-Regulations/.

Exemptions

In addition to the exemptions mentioned above, 5 C.F.R. Part 2640 includes a list of exemptions to the prohibition under 18 U.S.C. § 208 which OGE deems "are too remote or too inconsequential to affect the integrity of the services of the employees to which the prohibition applies." The broad categories of exemptions include:

- Exemptions for interests in mutual funds, unit investment trusts, and employee benefit plans
- Exemptions for interests in securities
- Miscellaneous exemptions, regarding:
    - Hiring decisions,
    - Employees on leave from institutions of higher education,
    - Multi-campus institutions of higher education,
    - Exemptions for financial interests arising from federal government employment or from Social Security or veterans' benefits,
    - Commercial discount and incentive programs,
    - Mutual insurance companies,
    - Exemption for employment interests of special government employees serving on advisory committees,
    - Directors of Federal Reserve Banks,
    - Medical products,
    - Nonvoting members of standing technical advisory committees established by the Food and Drug Administration,
    - Employees of the Tennessee Valley Authority,
    - Exemption for financial interests of non-federal government employers in the decennial census, and
    - Official participation in non-profit organizations.

Waivers

A peer review candidate may participate in a BSEE peer review with a financial COI as described in the section above if they obtain a waiver. Per 5 C.F.R. Part 2635, if the individual notifies and discloses the COI to the applicable BSEE official (usually the Decision Maker or Peer Review Leader), a waiver may be issued for the individual's participation if the official, "determines, in writing, that the employee's financial interest in the particular matter or matters is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee." Separate waiver considerations apply for FACA committee members.[26] BSEE officials are required to consult with OGE regarding such waivers whenever practical.

[26] See 5 C.F.R. 2636.402(d)(3).

BSEE also must provide a copy of any waivers to the Director of OGE. Additional guidance on waivers is included in Subpart C of 5 C.F.R. Part 2640, which "provides guidance to agencies on the factors to consider when issuing individual waivers under 18 U.S.C. 208 (b)(1) or (b)(3)."

Impartiality

In addition to the ban on participation of federal government employees with a financial conflict of interest in peer reviews, there are other cases where a federal government employee must not participate in a peer review due to impartiality concerns. Per 5 C.F.R. Part 2635, federal government employees should not participate in peer reviews if their participation may cause an appearance of loss of impartiality. The rule states that, "unless he receives prior authorization, an employee should not participate in a particular matter involving specific parties[27] which he knows is likely to affect the financial interests of a member of his household, or in which he knows a person with whom he has a covered relationship is or represents a party, if he determines that a reasonable person with knowledge of the relevant facts would question his impartiality in the matter."[28] The categories of individuals that fall under "covered relationship" are more extensive than the individuals whose interests must be evaluated for financial conflict of interest, as mentioned above. In addition to the impartiality concerns specifically referenced in 5 C.F.R. Part 2635, federal government employees are directed to evaluate any other circumstance which may cause an appearance of loss of impartiality using a process described in the regulation.

For impartiality concerns, a BSEE designee (usually the Decision Maker or Peer Review Leader) may determine whether "a reasonable person with knowledge of the relevant facts would be likely to question the employee's impartiality in the matter." If the BSEE designee determines that this would be the case, the BSEE designee may only allow the candidate to participate in the peer 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." The language regarding appearance of a loss of impartiality in 5 C.F.R. Part 2635 aligns with the definition and guidance provided in Step 3.2.2 of this Manual on Apparent COI. Under all federal requirements, employees are required to provide notification of any appearance of a loss of impartiality.

[27] OGE states that, "The term "particular matter involving specific parties" refers to a subset of all "particular matters," and includes Government matters such as a contract, grant, permit, license, or loan." http://www.oge.gov/Topics/Financial-Conflicts-of-Interest-and-Impartiality/Current-Government-Employees/ See 5 C.F.R. 2635.502(b) for a definition.

[28] See relevant definitions for "covered relationship," direct and predictable effect," and "particular matter involving specific parties" in 5 C.F.R. 2635.502(b).

Special Cases

In addition to the requirements mentioned above, the following categories of peer review candidates may be subject to differing COI evaluation requirements:

- **Special Government Employees:** SGEs are subject to a set of federal ethics requirements that differ from the requirements applicable to Regular Government Employees. The Office of Government Ethics provides extensive guidance on this topic, and BSEE staff should refer to the OGE Web site as a starting point for any questions on the evaluation of COI for SGEs.
- **FACA Committee Members:** In the event that a Federal Advisory Committee is used to conduct a peer review, there are additional requirements for evaluation of COI and selection of committee members. In addition, foreign peer reviewers may be subject to special considerations regarding the evaluation of COI and selection of peer reviewers. BSEE staff should refer to the BSEE Ethics Office, DOI DAEO, or General Counsel regarding these situations.
- **BSEE Peer Reviewers:** For internal peer review candidates, BSEE staff should refer to conflict of interest guidance in the BSEE Director Ethics Memorandum, "Policy Regarding Interference with the Performance of Official Duties and Potential Conflicts of Interest" dated April 28, 2014.

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Appendix F: OMB Bulletin Requirements by Step

This Appendix provides the OMB Bulletin requirements for each step of this Manual. The Manual fully complies with the guidance provided in the OMB Bulletin, and this Appendix provides the text of the relevant requirements for reference by BSEE staff. The OMB Bulletin includes a Preamble, and both the Preamble and Bulletin text are included below. The guidance in the Bulletin falls under three broad categories: guidance specific to peer reviews of influential scientific information (ISI), guidance specific to peer reviews of highly influential scientific assessments (HISA), and guidance applicable to all agencies subject to the Bulletin. We have used the convention "ISI," "HISA," or "All" to denote the applicability of the requirements below.

Bulletin Text	Preamble Text	Subsection	Applicability
Step 1: Determine When to Conduct a Peer Review			
"To the extent permitted by law, each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate."	"Section II requires each agency to subject "influential" scientific information to peer review prior to dissemination."	Step 1.1	ISI
"To the extent permitted by law, each agency shall conduct peer reviews on all information subject to this Section. The peer reviews shall satisfy the requirements of Section II of this Bulletin, as well as the additional requirements found in this Section."	"Whereas Section II leaves most of the considerations regarding the form of the peer review to the agency's discretion, Section III requires a more rigorous form of peer review for highly influential scientific assessments. The requirements of Section II of this Bulletin apply to Section III, but Section III has some additional requirements, which are discussed below."	Step 1.1	HISA
"Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed." [ISI] "Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this Section are generally presumed not to require additional peer review." [HISA]	"Section III (2) clarifies that the principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this Section are generally presumed not to require additional peer review." [HISA]	Step 1.1	ISI/HISA

Bulletin Text	Preamble Text	Subsection	Applicability
"As an alternative to complying with Sections II and III of this Bulletin, an agency may instead: (i) rely on the principal findings, conclusions and recommendations of a report produced by the National Academy of Sciences; (ii) commission the National Academy of Sciences to peer review an agency's draft scientific information; or (iii) employ an alternative scientific procedure or process, specifically approved by the Administrator in consultation with the Office of Science and Technology Policy (OSTP), that ensures the agency's scientific information satisfies applicable information quality standards. The alternative procedure(s) may be applied to a designated report or group of reports."	"The procedures of the NAS are generally quite rigorous, and thus agencies should presume that major findings, conclusions, and recommendations of NAS reports meet the performance standards of this Bulletin. As an alternative to complying with Sections II and III of this Bulletin, an agency may instead (1) rely on scientific information produced by the National Academy of Sciences, (2) commission the National Academy of Sciences to peer review an agency draft scientific information product, or (3) employ an alternative procedure or set of procedures, specifically approved by the OIRA Administrator in consultation with the Office of Science and Technology Policy (OSTP), that ensures that the scientific information product meets applicable information-quality standards."	Step 1.3	All
"For information subject to this section of the Bulletin, agencies need not have further peer review conducted on information that has already been subjected to adequate peer review."	"**…**As such, prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary."	Step 1.1	ISI
"In determining whether prior peer review is adequate, agencies shall give due consideration to the novelty and complexity of the science to be reviewed, the importance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review."	"In light of the broad range of information covered by Section II, agencies are directed to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review."	Step 1.1	ISI

Bulletin Text	Preamble Text	Subsection	Applicability
	"If information is disseminated pursuant to an exemption to this Bulletin, subsequent disseminations are not automatically exempted. For example, if influential scientific information is first disseminated in the course of an exempt agency adjudication, but is later disseminated in the context of a non-exempt rulemaking, the subsequent dissemination will be subject to the requirements of this Bulletin even though the first dissemination was not."	Step 1.2	All
"Agencies need not have peer review conducted on information that is: 1. related to certain national security, foreign affairs, or negotiations involving international trade or treaties where compliance with this Bulletin would interfere with the need for secrecy or promptness; 2. disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination), 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 (e.g., findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began); 4. an agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866, except for underlying data and	"There are a variety of situations where agencies need not conduct peer review under this Bulletin. These include, for example, disseminations of sensitive information related to certain national security, foreign affairs, or negotiations involving international treaties and trade where compliance with this Bulletin would interfere with the need for secrecy or promptness. This Bulletin does not cover official disseminations that arise in adjudications and permit proceedings, unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel (i.e., a major change in accepted practice) or likely to have precedent-setting influence on future adjudications or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities as well as site-specific activities. The determination as to whether peer review is practical and appropriate is left to the discretion of the agency. While this Bulletin is not broadly applicable to adjudications, agencies are encouraged to hold peer reviews of scientific assessments supporting adjudications to the same technical standards as peer reviews covered by the Bulletin, including transparency and disclosure of the data and models underlying the assessments. Protections apply to confidential business information. The Bulletin does not cover time-sensitive health and safety disseminations, for example, a dissemination based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began. For this purpose, "health" includes public health, or plant or animal infectious diseases. This Bulletin covers original data and formal analytic models used by agencies in Regulatory Impact Analyses (RIAs). However, the RIA documents themselves are already reviewed through an interagency	Step 1.2	All

Bulletin Text	Preamble Text	Subsection	Applicability
analytical models used; 5. routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (e.g., unemployment and poverty rates); 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; or 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."	review process under E.O. 12866 that involves application of the principles and methods defined in OMB Circular A-4. In that respect, RIAs are excluded from coverage by this Bulletin, although agencies are encouraged to have RIAs reviewed by peers within the government for adequacy and completeness. The Bulletin does not cover 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. Routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (e.g., unemployment and poverty rates) is excluded from this Bulletin. The Bulletin does not cover 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."		
"The agency head may waive or defer some or all of the peer review requirements of Sections II and III of this Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable."	"Section VIII also allows for a deferral or waiver of the requirements of the Bulletin where necessary. Specifically, the agency head may waive or defer some or all of the peer review requirements of Sections II or III of this Bulletin if there is a compelling rationale for waiver or deferral. Waivers will seldom be warranted under this provision because the Bulletin already provides significant safety valves, such as: the exemptions provided in Section IX, including the exemption for time-sensitive health and safety information; the authorization for alternative procedures in Section IV; and the overall flexibility provided for peer reviews of influential scientific information under Section II. Nonetheless, we have included this waiver and deferral provision to ensure needed flexibility in unusual and compelling situations not otherwise covered by the exemptions to the Bulletin, such as situations where unavoidable legal deadlines prevent full compliance with the Bulletin before information is disseminated. Deadlines found in consent decrees agreed to by agencies after the Bulletin is issued will not ordinarily warrant waiver of the Bulletin's requirements because those deadlines should be negotiated to permit time for all required procedures, including peer review. In	Step 1.2	All

Bulletin Text	Preamble Text	Subsection	Applicability
	addition, when an agency is unavoidably up against a deadline, deferral of some or all requirements of the Bulletin (as opposed to outright waiver of all of them) is the most appropriate accommodation between the need to satisfy immovable deadlines and the need to undertake proper peer review. If the agency head defers any of the peer review requirements prior to dissemination, peer review should be conducted as soon as practicable thereafter."		
Step 2: Plan the Peer Review			
"To ensure that public participation does not unduly delay agency activities, the agency shall clearly specify time limits for public participation throughout the peer review process."	"To avoid undue delay of agency activities, the agency shall specify time limits for public participation throughout the peer review process."	Step 2.1	HISA
"Agencies, however, should avoid open-ended comment periods, which may delay completion of peer reviews and complicate the completion of the final work product."		Step 2.1	ISI
	"Section III(5) addresses opportunity for public participation in peer review, and provides that the agency shall, wherever possible, provide for public participation."	Step 2.1	HISA
"Whenever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues."	"If an agency decides to make a draft assessment publicly available at the onset of a peer review process, the agency shall, whenever possible, provide a vehicle for the public to provide written comments, make an oral presentation before the peer reviewers, or both. When written public comments are received, the agency shall ensure that peer reviewers receive copies of comments that address significant scientific issues with ample time to consider them in their review."	Step 2.1	HISA

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"Agencies shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans. Agencies shall consider public comments on peer review plans."	"When new entries are added to the agenda of forthcoming reports and other information, the public should be provided with sufficient time to comment on the agency's peer review plan for that report or product. Agencies shall consider public comments on the peer review plan."	Step 2.1	All
"The choice of a peer review mechanism (for example, letter reviews or ad hoc panels) for influential scientific information shall be based on the novelty and complexity of the information to be reviewed, the importance of the information to decision making, the extent of prior peer review, and the expected benefits and costs of review, as well as the factors regarding transparency described in II(5)."	"Agencies are directed to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review."	Step 2.2	ISI
"Each peer review plan shall include: (i) a paragraph including 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; (ii) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (iii) the timing of the review (including deferrals); (iv) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be employed); (v) 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; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their	"Each entry on the agenda shall include a preliminary title of the planned report, a short paragraph describing the subject and purpose of the planned report, and an agency contact person. The agency shall provide its prediction regarding whether the dissemination will be "influential scientific information" or a "highly influential scientific assessment," as the designation can influence the type of peer review to be undertaken. The agency shall discuss the timing of the peer review, as well as the use of any deferrals. Agencies shall include entries in the agenda for influential scientific information, including highly influential scientific assessments, for which the Bulletin's requirements have been deferred or waived. If the agency, in consultation with the OIRA Administrator, has determined that it is appropriate to use a Section IV "alternative procedure" for a specific dissemination, a description of that alternative procedure shall be included in the agenda. …Each peer review plan shall include: (i) a paragraph including 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; (ii) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (iii) the timing of the review	Step 2.3	All

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review; (vii) the anticipated number of reviewers (3 or fewer; 4-10; or more than 10); (viii) a succinct description of the primary disciplines or expertise needed in the review; (ix) whether reviewers will be selected by the agency or by a designated outside organization; and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers."	(including deferrals); (iv) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be exercised); (v) 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; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; (vii) the anticipated number of reviewers (3 or fewer; 4-10; or more than 10); (viii) a succinct description of the primary disciplines or expertise needed in the review; (ix) whether reviewers will be selected by the agency or by a designated outside organization; and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers."		
"Each agency shall post on its website, and update at least every six months, an agenda of peer review plans. The agenda shall describe all planned and ongoing influential scientific information subject to this Bulletin. The agency shall provide a link from the agenda to each document that has been made public pursuant to this Bulletin. Agencies are encouraged to offer a listserve or similar mechanism to alert interested members of the public when entries are added or updated." "For each entry on the agenda the agency shall describe the peer review plan."	"…for each entry on the agenda, the agency shall describe the peer review plan." "The agency shall provide a link from the agenda to each document made public pursuant to this Bulletin. Agencies shall link their peer review agendas to the U.S. Government's official web portal: *firstgov* at http://www.FirstGov.gov [www.usa.gov]" "Agencies are encouraged to offer a listserve or similar mechanism for members of the public who would like to be notified by email each time an agency's peer review agenda has been updated."	Step 2.3	All
	"The National Academy of Public Administration suggests that the intensity of peer review should be commensurate with the significance of the information being disseminated and the likely implications for policy decisions… Furthermore, agencies need to consider tradeoffs between depth of peer review and timeliness."	Step 2.2	ISI

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"Reviewers shall be notified in advance regarding the extent of disclosure and attribution planned by the agency." [All]	"When deciding what type of peer review mechanism is appropriate for a specific information product, agencies will need to consider at least the following issues: individual versus panel review; timing; scope of the review; selection of reviewers; disclosure and attribution; public participation; disposition of reviewer comments; and adequacy of prior peer review." [ISI] "For agency-sponsored peer review conducted under Sections II and III, this Bulletin strikes a compromise by requiring disclosure of the identity of the reviewers, but not public attribution of specific comments to specific reviewers. The agency has considerable discretion in the implementation of this compromise (e.g., summarizing the views of reviewers as a group or disclosing individual reviewer comments without attribution). Whatever approach is employed, the agency must inform reviewers in advance of how it intends to address this issue." [ISI]	Steps 2.2/3.1/4.2	ISI
"Each agency shall post on its website, and update at least every six months, an agenda of peer review plans."	"Agencies should update their peer review agendas at least every six months. However, in some cases -- particularly for highly influential scientific assessments and other particularly important information -- more frequent updates of existing entries on the agenda, or the addition of new entries to the agenda, may be warranted."	Step 2.3	All
"The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin." [ISI] "The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin." [HISA]	"Section III(7) authorizes but does not require an agency to commission an entity independent of the agency to select peer reviewers and/or manage the peer review process in accordance with this Bulletin. The entity may be a scientific or professional society, a firm specializing in peer review, or a non-profit organization with experience in peer review." [HISA]	Step 2.2	ISI/HISA
Step 3: Implement the Peer Review			
	"The charge to the reviewers should be determined in advance of the selection of the reviewers."	Step 3.1	ISI

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"Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency."	"Furthermore, where appropriate, reviewers should be asked to provide advice on the reasonableness of judgments made from the scientific evidence. However, the charge should make clear that the reviewers are not to provide advice on the policy (e.g., the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis). Such considerations are the purview of the government." "The charge should ask that peer reviewers ensure that scientific uncertainties are clearly identified and characterized. Since not all uncertainties have an equal effect on the conclusions drawn, reviewers should be asked to ensure that the potential implications of the uncertainties for the technical conclusions drawn are clear."	Step 3.1	ISI
"Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge." "Agencies shall ensure that, in cases where the document being reviewed spans a variety of scientific disciplines or areas of technical expertise, reviewers who represent the necessary spectrum of knowledge are chosen." [ISI] "Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge." [HISA]	"While expertise is the primary consideration, reviewers should also be selected to represent a diversity of scientific perspectives relevant to the subject. On most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of the available literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review. Indeed, as a final layer of review, some organizations (e.g., the National Academy of Sciences) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports. The NAS policy on committee composition and balance[20] highlights important considerations associated with perspective, bias, and objectivity." [All] "With regard to the selection of reviewers, Section III(3)(a) emphasizes consideration of expertise and balance. As discussed in Section II, expertise refers to the required knowledge, experience and skills required to perform the review whereas balance refers to the need for diversity in scientific perspective and disciplines. We emphasize that the term "balance" here refers not to balancing of stakeholder or political interests but rather to a broad and diverse representation of respected perspectives and intellectual traditions within the scientific community, as discussed in the NAS policy on committee composition and balance…" [HISA]	Step 3.2	ISI/HISA

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"Peer reviewers shall not have participated in development of the work product. Agencies are encouraged to rotate membership on standing panels across the pool of qualified reviewers. Research grants that were awarded to scientists based on investigator-initiated, competitive, peer-reviewed proposals generally do not raise issues as to independence or conflicts." [ISI] "In addition to the requirements of Section II (3)(c), which shall apply to all reviews conducted under Section III, the agency -- or entity selecting the reviewers -- shall bar participation of scientists employed by the sponsoring agency unless the reviewer is employed only for the purpose of conducting the peer review (i.e., special government employees). The only exception to this bar would be the rare case where the agency determines, using the criteria developed by NAS for evaluating use of "employees of sponsors," that a premier government scientist is (a) not in a position of management or policy responsibility and (b) possesses essential expertise that cannot be obtained elsewhere. Furthermore, to be eligible for this exception, the scientist must be employed by a different agency of the Cabinet-level department than the agency that is disseminating the scientific information. The agency's determination shall be documented in writing and approved, on a non-delegable basis, by the	"A related issue is whether government-funded scientists in universities and consulting firms have sufficient independence from the federal agencies that support their work to be appropriate peer reviewers for those agencies.[23] This concern can be mitigated in situations where the scientist initiates the hypothesis to be tested or the method to be developed, which effectively creates a buffer between the scientist and the agency. When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects. This contrasts, for example, to a situation in which a scientist has a consulting or contractual arrangement with the agency or office sponsoring a peer review. Likewise, when the agency and a researcher work together (e.g., through a cooperative agreement) to design or implement a study, there is less independence from the agency. Furthermore, if a scientist has repeatedly served as a reviewer for the same agency, some may question whether that scientist is sufficiently independent from the agency to be employed as a peer reviewer on agency-sponsored projects. As the foregoing suggests, independence poses a complex set of questions that must be considered by agencies when peer reviewers are selected. In general, agencies shall make an effort to rotate peer review responsibilities across the available pool of qualified reviewers, recognizing that in some cases repeated service by the same reviewer is needed because of essential expertise." [ISI] "Section III(3)(c) instructs agencies to ensure that reviewers are independent of the agency sponsoring the review. Scientists employed by the sponsoring agency are not permitted to serve as reviewers for highly influential scientific assessments. This does not preclude Special Government Employees, such as academics appointed to advisory committees, from serving as peer reviewers. The only exception to this ban would be the rare situation in which a scientist from a different	Step 3.2	ISI/HISA

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Secretary or Deputy Secretary of the department prior to the scientist's appointment." [HISA] "Agencies shall avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential and cannot be obtained elsewhere." [HISA]	agency of a Cabinet-level department than the agency that is disseminating the scientific assessment has expertise, experience and skills that are essential but cannot be obtained elsewhere. In evaluating the need for this exception, agencies shall use the NAS criteria for assessing the appropriateness of using employees of sponsors (e.g., the government scientist must not have had any part in the development or prior review of the scientific information and must not hold a position of managerial or policy responsibility). We also considered whether a reviewer can be independent of the agency if that reviewer receives a substantial amount of research funding from the agency sponsoring the review. Research grants that were awarded to the scientist based on investigator-initiated, competitive, peer-reviewed proposals do not generally raise issues of independence. However, significant consulting and contractual relationships with the agency may raise issues of independence or conflict, depending upon the situation. Section III(3)(d) addresses concerns regarding repeated use of the same reviewer in multiple assessments. Such repeated use should be avoided unless a particular reviewer's expertise is essential. Agencies should rotate membership across the available pool of qualified reviewers. Similarly, when using standing panels of scientific advisors, it is suggested that the agency rotate membership among qualified scientists in order to obtain fresh perspectives and reinforce the reality and perception of independence from the agency." [HISA]		
"Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers." [ISI] "Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers." [HISA]	"Respect for the independence of reviewers may be enhanced if an agency collects names of potential reviewers (based on considerations of expertise and reputation for objectivity) from the public, including scientific or professional societies." "Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers." [ISI]	Step 3.2	ISI/HISA

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"The agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating the potential for conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income)." [ISI] "The agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences' policy for committee selection with respect to evaluating the potential for conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income)." [HISA]	"To evaluate any real or perceived conflicts of interest with potential reviewers and questions regarding the independence of reviewers, agencies are referred to federal ethics requirements, applicable standards issued by the Office of Government Ethics, and the prevailing practices of the National Academy of Sciences. Specifically, peer reviewers who are federal employees (including special government employees) are subject to federal requirements governing conflicts of interest. See, e.g., 18 U.S.C. § 208; 5 C.F.R. Part 2635 (2004). With respect to reviewers who are not federal employees, agencies shall adopt or adapt the NAS policy for committee selection with respect to evaluating conflicts of interest.[26] Both the NAS and the federal government recognize that under certain circumstances some conflict may be unavoidable in order to obtain the necessary expertise. See, e.g., 18 U.S.C. § 208(b)(3); 5 U.S.C. App. § 15 (governing NAS committees)." [ISI] ""Section III(3)(b) instructs agencies to consider barring participation by scientists with a conflict of interest. The conflict of interest standards for Sections II and III of the Bulletin are identical. As discussed under Section II, those peer reviewers who are federal employees, including Special Government Employees, are subject to applicable statutory and regulatory standards for federal employees. For non-government employees, agencies shall adopt or adapt the NAS policy for committee member selection with respect to evaluating conflicts of interest." [HISA]	Step 3.2	ISI/HISA
"For scientific information relevant to specific regulations, the agency shall examine a reviewer's financial ties to regulated entities (e.g., businesses), other stakeholders, and the agency." [ISI]	"Agencies shall make a special effort to examine prospective reviewers' potential financial conflicts, including significant investments, consulting arrangements, employer affiliations and grants/contracts. Financial ties of potential reviewers to regulated entities (e.g., businesses), other stakeholders, and regulatory agencies shall be scrutinized when the information being reviewed is likely to be relevant to regulatory policy.	Step 3.2	ISI/HISA

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"For scientific assessments relevant to specific regulations, a reviewer's financial ties to regulated entities (e.g., businesses), other stakeholders, and the agency shall be examined." [HISA]	The inquiry into potential conflicts goes beyond financial investments and business relationships and includes work as an expert witness, consulting arrangements, honoraria and sources of grants and contracts." [ISI]		
"The agency -- or entity managing the peer review -- shall provide the reviewers with sufficient information -- including background information about key studies or models -- to enable them to understand the data, analytic procedures, and assumptions used to support the key findings or conclusions of the draft assessment."	"Section III(4) requires agencies to provide reviewers with sufficient background information, including access to key studies, data and models, to perform their role as peer reviewers. In this respect, the peer review envisioned in Section III is more rigorous than some forms of journal peer review, where the reviewer is often not provided access to underlying data or models."	Step 3.4	HISA
"Peer review shall be conducted in a manner that respects (i) confidential business information and (ii) intellectual property."	"Furthermore, the peer review must be conducted in a manner that respects confidential business information as well as intellectual property."	Step 2.1/3.4	All
"Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality." [ISI]	"Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws." [HISA]	Step 3.4	ISI/HISA
	"To improve the transparency of the process, when an agency determines that it is necessary to use a reviewer with a real or perceived conflict of interest, the agency should consider publicly disclosing those conflicts. In such situations, the agency shall inform potential reviewers of such disclosure at the time they are recruited."	Step 3.2/4.2	ISI
Step 4: Complete and Document the Peer Review			
"The agency -- or entity managing the peer review -- shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions." [ISI]	"Section III(6) requires that agencies instruct reviewers to prepare a peer review report that describes the nature and scope of their review and their findings and conclusions." [HISA]	Step 4.2	ISI/HISA

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"The peer review report shall either (a) include a verbatim copy of each reviewer's comments (either with or without specific attributions) or (b) represent the views of the group as a whole, including any disparate and dissenting views. The agency shall disclose the names of the reviewers and their organizational affiliations in the report." [ISI] "In addition to the requirements specified in II(5), which shall apply to all reviews conducted under Section III, the peer review report shall include the charge to the reviewers and a short paragraph on both the credentials and relevant experiences of each peer reviewer." [HISA]	"The report shall disclose the name of each peer reviewer and a brief description of his or her organizational affiliation, credentials and relevant experiences. The peer review report should either summarize the views of the group as a whole (including any dissenting views) or include a verbatim copy of the comments of the individual reviewers (with or without attribution of specific views to specific names)." [HISA]	Step 4.2	ISI/HISA
"The agency shall disseminate the final peer review report on the agency's website along with all materials related to the peer review (any charge statement, the peer review report, and any agency response)." [ISI]	"The agency is required to disseminate the peer review report and the agency's response to the report on the agency's website, including all the materials related to the peer review such as the charge statement, peer review report, and agency response to the review." [HISA]	Step 4.2	ISI/HISA
	"If the scientific information is used to support a final rule then, where practicable, the peer review report shall be made available to the public with enough time for the public to consider the implications of the peer review report for the rule being considered."	Step 4.2	HISA
"The agency shall prepare a written response to the peer review report explaining (a) the agency's 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, and (c) the reasons the agency believes those actions satisfy the key concerns stated in the report (if	"All reviewer comments should be given consideration and be incorporated where relevant and valid." [ISI] "In addition, the credibility of the final scientific report is likely to be enhanced if the public understands how the agency addressed the specific concerns raised by the peer reviewers. Accordingly, agencies should consider preparing a written response to the peer review report explaining: the agency's agreement or disagreement, the actions the agency has undertaken or will undertake in response to the report, and (if applicable) the reasons the agency believes those actions satisfy any key	Step 4.3	ISI/HISA

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applicable). The agency shall disseminate its response to the peer review report on the agency's website with the related material specified in Section II(5).” [HISA]	concerns or recommendations in the report.” [ISI] “The agency shall also prepare a written response to the peer review report, indicating whether the agency agrees with the reviewers and what actions the agency has taken or plans to take to address the points made by reviewers.” [HISA]		
“The peer review report shall be discussed in the preamble to any related rulemaking and included in the administrative record for any related agency action.” [ISI] “If an agency relies on influential scientific information or a highly influential scientific assessment subject to this Bulletin to support a regulatory action, it shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this Bulletin and the applicable information quality guidelines. Relevant materials shall be placed in the administrative record.” [All]	“If an agency relies on influential scientific information or a highly influential scientific assessment subject to this Bulletin to support a regulatory action, it shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this Bulletin and the applicable information quality guidelines. Relevant materials shall be placed in the administrative record.” [All]	Step 4.4	All
“To the extent information about a reviewer (name, credentials, affiliation) will be disclosed along with his/her comments or analysis, the agency shall comply with the requirements of the Privacy Act, 5 U.S.C. § 522a as amended, and OMB Circular A-130, Appendix I, 61 Fed. Reg. 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice.” [All]	“Section VIII recognizes that individuals serving as peer reviewers have a privacy interest in information about themselves that the government maintains and retrieves by name or identifier from a system of records. To the extent information about a reviewer (name, credential, affiliation) will be disclosed along with his/her comments or analysis, the agency must comply with the requirements of the Privacy Act, 5 U.S.C. 552a, as amended, and OMB Circular A-130, Appendix I, 61 Fed. Reg. 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice. Furthermore, the peer review must be conducted in a manner that respects confidential business information as well as intellectual property.” [All] “Information about a reviewer retrieved from a record filed by the reviewer's name or other identifier may be disclosed only as permitted by the conditions of disclosure enumerated in the Privacy Act, 5 U.S.C. §	Step 4.2	ISI/All

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	552a as amended, and as interpreted in OMB implementing guidance, 40 Fed. Reg. 28,948 (July 9, 1975)." [ISI]		
"Each agency shall provide to OIRA, by December 15 of each year, a summary of the peer reviews conducted by the agency during the fiscal year. The report should include the following: 1) the number of peer reviews conducted subject to the Bulletin (i.e., for influential scientific information and highly influential scientific assessments); 2) the number of times alternative procedures were invoked; 3) 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); 4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin, including determinations by the Secretary pursuant to Section III(3)(c); 5) the number of peer review panels that were conducted in public and the number that allowed public comment; 6) the number of public comments provided on the agency's peer review plans; and 7) the number of peer reviewers that the agency used that were recommended by professional societies."	"Each agency shall prepare an annual report that summarizes key decisions made pursuant to this Bulletin. In particular, each agency should provide to OIRA the following: 1) the number of peer reviews conducted subject to the Bulletin (i.e., for influential scientific information and highly influential scientific assessments); 2) the number of times alternative procedures were invoked; 3) 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); 4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin, including determinations by the Secretary or Deputy Secretary pursuant to Section III (3) (c); 5) the number of peer review panels that were conducted in public and the number that allowed public comment; 6) the number of public comments provided on the agency's peer review plans; and 7) the number of peer reviewers that the agency used that were recommended by professional societies."	Step 4.4	All