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OMB Peer Review Bulletin Guidance

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SUMMARY OF REVISIONS:

OMB PEER REVIEW BULLETIN GUIDANCE
NOAA Fisheries Service
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I. BACKGROUND

The White House Office of Management and Budget (OMB) issued the final Peer Review Bulletin (PRB) in December 2004, pursuant to the Information Quality Act[1] (IQA) and OMB's general authorities. It went into effect on June 16, 2005, and establishes minimum peer review standards, a transparent process for public disclosure, and opportunity for public input. The PRB can be found at: http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf [2]

This document sets out guidance on the scope and applicability of the PRB as well as guidance for responding to data calls to update the NOAA peer review agenda.[3] The PRB requires agencies to update their peer review agendas at least every six months, therefore PRB data calls will be issued approximately every six months to obtain an updated list of peer review plans for any "highly influential scientific assessments" (HISA) and "influential scientific information" (ISI) that the agency intends to disseminate in the foreseeable future (i.e., within the next year). To ensure consistency nationally in responding to PRB data calls, the Office of Science and Technology anticipates updating this guidance as experience with the PRB grows.

II. BASICS OF THE PEER REVIEW BULLETIN

The PRB uses many of the same definitions found in the OMB (and NOAA) Information Quality Guidelines, issued under the IQA. As with the IQA, the PRB applies to federal agencies as that term is defined for purposes of the Paperwork Reduction Act, 44 U.S.C. § 3502(1). The PRB is triggered when agencies disseminate "influential scientific information." The term "dissemination" is modified slightly from the IQA definition to exclude information distributed to peer reviewers in compliance with the PRB. See the "PRB Exemptions and Exclusion" discussion below for additional detail.

Influential Scientific Information

The PRB defines the term "scientific information" as 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. This includes any communication or representation of knowledge such as facts or data, in any

[1] The Information Quality Act is Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 Public Law 106-554, codified at 44 U.S.C. § 3516 note.
[2] Note: the first 33 pages of the PRB are prefatory; the text of the PRB begins on pg. 34. See Appendix A of this document for the text of the PRB.
[3] The NOAA Peer Review Agenda is posted at:
http://www.cio.noaa.gov/Policy_Programs/prplans/PRsummaries.html

medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms.[4]

"Influential scientific information" (ISI) means 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. As noted in the NOAA Information Quality Guidelines, a clear and substantial impact is one that has a high probability of occurring. If it is merely arguable or a judgment call, then it would probably not be clear and substantial. In other words, if there is disagreement over whether an impact has a high probability of occurring, then the impact is probably not clear and substantial, and therefore not influential.

Even if information has a clear and substantial impact, it is not influential if the impact is not on "important public policies or private sector decisions." Scientific information that affects a broad range of parties (*e.g.*, an entire industry or a significant part of an industry, as opposed to a single company) is more likely to be influential than scientific information that affects a narrow range of parties.[5] In addition, scientific information that has a low cost or modest impact on affected parties is less likely to be influential than scientific information that can have a very costly or serious impact. There is a gray area where these two parameters, *i.e.*, the range of parties affected and the intensity of the impact, must be balanced against each other on a case by case basis. Given the subjective nature of the definition of ISI, staff should consult with their IQA point of contact and/or General Counsel if uncertain about whether a particular information product is subject to the PRB.

Peer review requirements for ISI are set out in Section II of the PRB. OMB estimates that, across the federal government, there will be approximately 1,200 ISIs issued annually.[6]

Highly Influential Scientific Assessments

Highly influential scientific assessments are a subset of influential scientific information. The PRB defines the term "scientific assessment" as "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.

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[4] The PRB definition of "Scientific information" mirrors the definition of "information" in the OMB Information Quality Guidelines, creating the (presumably) unintended consequence of defining the universe of scientific information as broadly as generic information. When NOAA recently revised its Information Quality Guidelines to incorporate a reference to the PRB and adopt key definitions from it, NOAA modified the definition of "scientific information" to limit its applicability to the fields of behavioral sciences, public health and medical sciences, life and earth sciences, engineering and physical sciences.

[5] *See, e.g.*, the Department of Agriculture's definition of "influential scientific, financial or statistical information." http://www.ocio.usda.gov/qi_guide/background.html.

[6] OMB Summary of Public and Agency Comments on Proposed Bulletin on Information Quality and Peer Review, pp. 13-14 (4/15/2004). Available at: http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/peer_review_comment.pdf

A highly influential scientific assessment (HISA) is a scientific assessment that: (i) has a potential impact of more than $500 million in any one year on either the public or private sector (the economic test); or (ii) is novel, controversial, or precedent-setting, or of significant interagency interest (the narrative test). Peer review requirements for HISAs are set out in Section III of the PRB.

The threshold for HISAs is fairly high, therefore it is anticipated that NOAA Fisheries Service (NMFS) would produce very few, if any, HISAs in any given year. OMB estimates that across the federal government, there might be 12-24 HISAs issued per year.[7] To date, the only NMFS-produced HISA listed on the NOAA peer review agenda is the proposed noise exposure criteria for marine mammals. Within other NOAA Line Offices, the HISAs identified to date are the synthesis and assessment reports produced by NOAA's Office of Oceanic and Atmospheric Research in coordination with other federal agencies as part of the U.S. Climate Change Science Program.

PRB Exemptions and Exclusions

Some disseminations of influential scientific information are exempt from the PRB, as specified in Section IX of the PRB. For example, information that is 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.

Agency regulatory impact analyses and regulatory flexibility analyses subject to interagency review under Executive Order 12866 are also exempt from the PRB, except for underlying data and analytical models used. See Section IX.5 of the PRB.

The PRB definition of "dissemination" contains several important exclusions, some of which mirror the IQA and some that are unique to the PRB. Under the PRB, dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act or similar law. The definition of dissemination also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes.

Unique to the PRB is an exclusion for information distributed to peer reviewers in compliance with the PRB, so long as the information includes a clear disclaimer as specified in Section I.3 of the PRB.[8] Dissemination also excludes 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 government support) if that information does not represent the views

[7] Id.

[8] The required disclaimer language is as follows: "THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY NOAA. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY."

of the agency. To qualify for this exemption, the information should contain a 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."

Determining if the PRB Applies

To determine if a particular information product is covered by the PRB, first ask if the scientific information will be disseminated by NMFS, as opposed to a third party such as a grantee. See the NOAA IQA Guidelines definitions of "agency initiated distribution of information" and "agency sponsored distribution of information" to assist in making this determination. If NMFS will be disseminating the scientific information, is it "influential scientific information," i.e., will the release of the scientific information have a clear and substantial impact on important public policies or private sector decision? Bear in mind that a clear and substantial impact is one that has a high probability of occurring. If in doubt, ask your IQA point of contact and/or consult with General Counsel.

If you determine that the scientific information is influential, next ask if this is a "highly influential scientific assessment" under either the economic test or the narrative test. As indicated above, the bar for HISAs is set very high. In any given year, NMFS anticipates releasing few, if any, HISAs.

If you have determined that the scientific information to be released is ISI or HISA, ask if any of the PRB exclusions or exemptions apply. For example, is this an inter-agency sharing of information or is the information being disseminated in the course of an agency adjudication or permit proceeding?

Finally, for ISI only, determine if the information has already been subjected to an adequate prior peer review. In determining whether the prior peer review was adequate, you must give due consideration to:

(i) the novelty and complexity of the science to be reviewed;
(ii) the importance of the information to decision making;
(iii) the extent of prior peer reviews; and
(iv) the expected benefits and costs of additional review.

See PRB Section II.2. In the preamble to the PRB, OMB states that publication in a refereed scientific journal may mean that the information has already been adequately peer reviewed, but goes on to caution that not all journal peer review rises to the level of an adequate prior peer review.[9] In each case, consideration must be given to the four factors listed above. If you determine that the prior peer review was adequate, prepare a memo for the administrative record supporting that conclusion. Be sure to address the four factors above.

If you are in the process of developing ISI, you must comply with the requirements of Section II of the PRB, i.e., paragraphs 3-6 of Section II. The adequate prior peer review provision applies mostly to information developed prior to the effective date of the PRB and to information developed by third parties. As a general rule, for NMFS-generated information, you should rely

[9] Peer Review Bulletin, pg. 21.

on the adequate prior peer review provision only if that information was developed prior to June 16, 2005, the effective date of the PRB.

III. AGENCY REQUIREMENTS UNDER THE PRB

Peer Review Agenda

Section V of the PRB requires agencies to post an agenda of peer review plans for information subject to the PRB and update the agenda at least every six months. Peer review plans must address ten elements, such as the title, subject and purpose of the information product; whether the information is ISI or HISA; timing and method of review (panel or letters); whether the public will be provided an opportunity to comment on the work to be peer reviewed; and a description of the primary disciplines or expertise needed in the review. See PRB Section V.2 for a complete list of required elements of a peer review plan.

Due to the requirement to update the peer review agenda every six months, NMFS will issue data calls at least twice annually for peer review plans to update the agenda. However, peer review plans will be accepted and the agenda updated on a rolling basis throughout the year. Staff should provide peer review plans for any ISI or HISA that the agency will disseminate in the foreseeable future, i.e., within the next year, so that the plan can be posted early enough to allow for public review and comment.

Annual Report to OMB

Agencies must provide an annual report to OMB by December 15th each year containing a summary of the agency's peer review activities in the preceding fiscal year. Section VI of the PRB sets forth the required elements for the report to OMB. NMFS will coordinate with the other NOAA Line Offices to prepare NOAA's annual report.

Certification in the Administrative Record

If the agency relies on ISI or HISA subject to the PRB to support a regulatory action, it must include a certification in the administrative record for that action explaining how the agency has complied with the requirements of the PRB and the agency's information quality guidelines. Relevant materials must be placed in the administrative record, e.g., in the Determinations section of a Decision Memo. Sample certification language is set forth below:

> Information Quality Act and OMB Peer Review Bulletin
> Pursuant to the Information Quality Act (44 U.S.C. § 3516 note), this information product has undergone a pre-dissemination review by [specify Office], completed on [date]. The signed Pre-dissemination Review and Documentation Form is on file in that Office.
>
> This information product was peer reviewed in accordance with the OMB Peer Review Bulletin. A peer review plan was posted on the agency's peer review agenda on [date _____]. The agency did/did not receive public comments on the plan. The information was peer reviewed by [specify letter, panel or other review process] between the dates of [specify, e.g., May 1 and May 15, 2007]. The charge to the peer reviewers, the peer

review report(s) and any agency response have been placed in the administrative record and posted on the agency's peer review agenda.

IV. CONDUCTING PEER REVIEW UNDER THE PRB

Peer Review of ISI

The determination as to whether an information product is subject to the PRB should be made early in the process of developing the information so that a peer review plan can be developed and posted well in advance of the release of the information.

Agencies have discretion in determining how to conduct peer review of ISI. The PRB instructs that "the choice of peer review mechanism (e.g., letter reviews or ad hoc panels) for ISI 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." See PRB Section II.4. Once the peer review plan is developed and on an agency's peer review agenda, the public will have the opportunity to comment on the adequacy of the peer review plan. The agency must consider comments on the peer review plan per Section V.3 of the PRB.

For review of ISI, the agency can select external peer reviewers or qualified agency scientists so long as they did not participate in the development of the work product to be reviewed. In selecting peer reviewers, the agency must select reviewers with the requisite expertise, experience and skills and must select a sufficiently broad and diverse group of reviewers to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Potential reviewers must be screened for conflicts of interest. Reviewers who are federal employees must comply with applicable federal ethics requirements. For screening potential reviewers who are not federal government employees, agencies must adopt or adapt the National Academy of Sciences (NAS) policy for evaluating potential conflicts of interest. NOAA has adapted the NAS conflict of interest policy; the NOAA Conflict of Interest Policy and related Disclosure Forms can be found at: http://www.cio.noaa.gov/Policy_Programs/info_quality.html

Peer reviewers must be informed of applicable access, objectivity, reproducibility and other quality standards under federal laws governing information access and quality. To comply with this requirement, the agency should provide reviewers with a copy of, or link to, the NOAA Information Quality Guidelines (http://www.cio.noaa.gov/Policy_Programs/IQ_Guidelines_110606.html). Reviewers must also be notified concerning the disclosure requirements (name and organizational affiliation of each reviewer) and extent of attribution planned by the agency (comments can be with or without attribution).[10]

The agency must prepare a peer review report to be posted on the NOAA peer review agenda. That report must either:

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

[10] PRB Section II.1.

Be aware, however, that a consensus report may trigger FACA requirements. To avoid FACA issues, the safer course of action is to request that the reviewers prepare individual reports. If you have questions concerning FACA, consult with General Counsel.

The peer review report must also disclose the names and organizational affiliations of the peer reviewers. In addition to posting the peer review report, the agency must also post the charge to the peer reviewers and the agency's response to the peer review report, if any. Note, however, that for ISI, the agency is not required to prepare a response. Finally, the peer review report must be discussed in the preamble to any related rulemaking and included in the administrative record for any related agency action. See Section III, above, for suggested language to certify compliance with the PRB.

Peer Review of HISA

For peer review of HISA, all of the requirements for review of ISI apply, as well as additional requirements set out in Section III of the PRB. As with ISI, principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed not to require additional peer review. For all other HISAs, the agency must set up a formal, external peer review. Agency scientists are barred from participating in the review, except in certain very limited circumstances.[11]

Agencies are encouraged, but not required, to make the draft HISA available for public comment at the same time it is submitted for peer review and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public.

In addition to providing reviewers with notice regarding applicable information access laws, disclosure requirements and the extent of attribution planned, the agency must 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.[12]

HISAs are subject to additional transparency requirements, in addition to those for ISI. For HISAs, the peer review report must include the charge to the peer reviewers and a short paragraph on the credentials and relevant experiences of each peer reviewer. The agency must also 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. The peer review report and agency response must be posted on the agency's peer review agenda.

[11] The only exception to the bar on agency scientists participating in the peer review would be the rare case where the agency determines 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. 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. See PRB Section III.3.c.

[12] PRB Section III.4.

Alternative Procedures

As an alternative to complying with Sections II and III of the PRB, agencies may instead:

(1) rely on the principal findings, conclusions and recommendations of a report produced by the National Academy of Sciences;
(2) commission the National Academy of Sciences to peer review the agency's draft scientific information; or
(3) employ an alternative scientific procedure or process, specifically approved by the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) in consultation with the White House Office of Science and Technology Policy (OSTP).

NMFS has not yet pursued approval of an alternative review procedure pursuant to (3) above and it is anticipated that NMFS would only do so in rare circumstances.

V. EXISTING PEER REVIEW PROCESSES FOR REVIEW OF NMFS SCIENCE

Fisheries Management Actions

The Councils, working with NMFS, have established regional processes of stock assessment review through the Stock Assessment Review Committee (New England and Mid-Atlantic), Southeast Data and Assessment Review (Southeast, Gulf of Mexico, and Caribbean), and the Stock Assessment Review (Pacific). Others have integrated their reviews into their SSC. With minor modifications, review by SSCs and/or these regional processes will likely satisfy the PRB requirements for peer review of influential scientific information.

To bring existing Council peer review processes into compliance with the PRB, NMFS has recommended that the Councils take the following steps. Adoption of these measures will satisfy the PRB requirements for peer review of ISI:

- Post biographical information for each SSC member on the Council website that describes the expertise, experience and organizational affiliations of the SSC membership;
- Adopt or adapt the National Academy of Sciences (NAS) policy for evaluating conflicts of interest, or simply adopt NOAA's adaptation of the NAS policy;
- Implement a system for recusal for those instances where an SSC member cannot meet the NAS conflict of interest standards;
- Adapt the SSC meeting minutes into a peer review report that satisfies the transparency requirements of the PRB (Section II.5);
- Provide a time and method for public comment prior to, during, or immediately following the panel review, include all comments in the peer review report, make any peer review materials available to the public and provide written responses to any public comments in the peer review report.
- Review upcoming actions on at least a semiannual basis to determine if the scientific information supporting that action must be peer reviewed in accordance with the requirements of the PRB.

The SSCs might take an important role in peer review arrangements by: 1) arranging for standard annual reviews by regional scientists to certify that the correct data and models are being used (and perhaps participating in those reviews); 2) for evaluations of models and assessment procedures, the SSC and CIE might each provide 50% of the reviewers for these regular assessments of methods and models, with the CIE concentrating on getting the best reviewers from across the country or internationally and the SSC concentrating on reviewers with both technical competence and region-specific knowledge; and 3) for expedited, controversial reviews there remains a requirement for independent outside reviewers such as through the CIE.

As discussed in Sections III and IV above, the requirement for a transparent peer review planning process is an important aspect of the PRB. To satisfy the PRB's transparency requirements, NMFS must coordinate with the Councils to identify influential scientific information subject to the OMB Bulletin, formulate and post a peer review plan on the agency's web site, and ensure that public comments on the peer review plan are addressed. This may also require coordination between Regional Offices and Science Centers to determine who is best positioned to develop, monitor and update the peer review plan.

Under the PRB, HISAs must be subjected to formal, external peer review; agency scientists are barred from participating in that peer review. Peer review by the CIE satisfies the PRB requirements for review of HISAs (as well as ISI). Therefore, such reviews will be conducted through the CIE and will be given high priority when determining which NMFS products will be submitted to the CIE for review.

1994 Policy on Peer Review in ESA Activities

The 1994 joint FWS/NMFS peer review policy for Endangered Species Act (ESA) activities (59 FR 34270, July 1, 1994) sets forth a process for peer review of science used in support of the agency's ESA activities, primarily listing decisions and recovery planning. Although there is some overlap with the requirements of the PRB, the PRB contains many additional requirements not found in the 1994 joint FWS/NMFS peer review policy (1994 joint policy). With some modifications, the 1994 joint policy can fulfill the PRB requirements for review of ISI (HISAs should be reviewed through the CIE).

The 1994 joint policy and the PRB have similar requirements for selecting peer reviewers who are independent and possess the requisite expertise and specialized knowledge to review the science at issue. Both also require the agency to include the comments of the peer reviewers in the administrative record for any related rulemaking.

The PRB requirements for a transparent peer review process and its conflict of interest provisions go beyond the 1994 joint policy. Specifically, the PRB requires the agency to develop and post a peer review plan on a publicly accessible website. The names and organizational affiliations of the reviewers must be disclosed, along with the comments of the reviewers, with or without attribution. Reviewers must also be notified in advance of the extent of disclosure and attribution planned by the agency. The peer review plan, the charge to the peer reviewers, the comments of the reviewers, and any agency response to the reviewer comments must be posted on the agency's peer review site.

The 1994 joint policy specifies that peer reviewers must be independent, but does not require the agency to screen potential reviewers for conflicts of interest. The PRB states that reviewers who are government employees must comply with applicable federal ethics requirements and that non-government employees must be screened using the conflict of interest policy adopted or adapted from the National Academy of Sciences.[13]

Finally, under the 1994 joint policy, peer review is typically conducted concurrent with the public comment period on a proposed rule or draft recovery plan. The PRB requires a specific disclaimer on every page of a draft document distributed for peer review in compliance with the PRB.[14]

In summary, for peer review of ISI, the 1994 joint policy satisfies some, but not all PRB requirements. The PRB imposes additional requirements on the peer review process. The transparency requirements, in particular, must be addressed early in the development of the information to be reviewed.

VI. EXAMPLES OF ISI

Given the subjective definition of ISI, it can be difficult to determine whether a particular NMFS information product is "influential scientific information" subject to the PRB. To assist in determining if a NMFS information product is "influential," the following is a list of categories of information products likely to be "influential" with some specific examples of ISI:

<u>Fisheries Management and Science</u>

- Stock Assessments
  - Benchmark assessments, i.e., an assessment prompted by a new fishery or protected resource management action
  - Assessments prompted by a major change in stock assessment model or data that will have a substantial impact on stock status determination and development of fisheries or protected species management strategies
  - Assessments using new and innovative analytical methods or assessment models
- Social, economic, and environmental impact assessments – underlying scientific data and analytical models.[15]

Specific examples include:

2011 Chesapeake Bay Blue Crab Stock Assessment
Acoustic-Trawl Survey Method for Coastal Pelagic Species
Atlantic Bluefin Tuna Status Report

[13] NOAA has adapted the NAS conflict of interest policy.
[14] PRB, Section I.3. See Footnote 7 for the required disclaimer language.
[15] Regulatory impact analyses and regulatory flexibility analyses subject to interagency review under Executive Order 12866 are exempt from the PRB, except for underlying data and analytical models used. PRB Section IX.4

Protected Resources Actions

- ESA listings
- ESA status reviews
- Critical habitat designations
- Biological Opinions
- Marine Mammal stock assessments

Specific examples include:

- Biological Review Team's status review for the Southern Resident Killer Whale listing determination
- Designation of Critical Habitat for Leatherback Sea Turtles Biological and Economic Reports
- Condition Report for Florida Keys National Marine Sanctuary

Examples of ISI falling outside the general categories provided above include:

- Science products developed in support of the hatchery Salmon listing policy
- Draft Report on treated timber effects on salmonids
- New juvenile fish passage model for the Columbia River power system

The general categories of information provided above highlight important NMFS information products that may rise to the level of ISI under the PRB. However, due to the variability of individual information products within these general categories, it is difficult, if not impossible to say that all information products in these general categories are influential. Therefore, each individual information product should be considered on a case-by-case basis. Further, the list of general categories provided is not intended to be an all-inclusive list. As experience with implementation of the PRB grows, this list can be expanded and refined.

VII. CONCLUSION

The PRB applies to "influential scientific information" and "highly influential scientific assessments" disseminated by federal agencies on or after June 16, 2005. NMFS staff will be asked semi-annually to submit peer review plans for forthcoming disseminations of ISI and HISAs. NOAA's peer review plans (collectively, the peer review agenda) are posted on the NOAA Information Quality web site at:
http://www.cio.noaa.gov/Policy_Programs/prplans/PRsummaries.html

As experience with PRB implementation grows, the list of NMFS information products subject to the PRB (as well as those exempt) will be further refined. However, due to the subjective nature of the definition of ISI and the variability of NMFS information products, it is difficult to set down a bright line test for influential vs. non-influential scientific information. If you have questions about whether a particular information product is subject to the PRB, contact your IQA point of contact and/or General Counsel for Fisheries.

APPENDIX A

Bulletin for Peer Review

I. Definitions.

For purposes of this Bulletin --
1. the term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA);
2. the term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. § 3502(1);
3. the term "dissemination" means agency initiated or sponsored distribution of information to the public (see 5 C.F.R. 1320.3(d) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act or similar law. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. The term "dissemination" also excludes information distributed for peer review in compliance with this Bulletin, provided that the distributing agency includes a clear disclaimer on the information as follows: "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 [THE AGENCY]. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY." For the purposes of this Bulletin, "dissemination" excludes 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 does not represent the views of an agency. To qualify for this exemption, the information should display 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";
4. the term "Information Quality Act" means Section 515 of Public Law 106-554 (Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000));
5. the term "scientific information" means 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. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes clear that what is being offered is someone's opinion rather than fact or the agency's views;
6. the term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions; and

7. the term “scientific assessment” means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

II. Peer Review of Influential Scientific Information.

1. In General: To the extent permitted by law, each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate. Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality.
2. Adequacy of Prior Peer Review: 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. 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. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.
3. Selection of Reviewers:

a. Expertise and Balance: 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 consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. Conflicts: 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). 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.

c. Independence: 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.

4. Choice of Peer Review Mechanism: 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).

5. Transparency: 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. 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. Reviewers shall be notified in advance regarding the extent of disclosure and attribution planned by the agency. 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). 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.

6. Management of Peer Review Process and Reviewer Selection: The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

III. Additional Peer Review Requirements for Highly Influential Scientific Assessments.

1. Applicability: This section applies to influential scientific information that the agency or the Administrator 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.

2. In General: 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. 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.

3. Selection of Reviewers:

a. Expertise and Balance: 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 consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. Conflicts: 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). 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.

c. Independence: 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 Secretary or Deputy Secretary of the department prior to the scientist's appointment.

d. Rotation: Agencies shall avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential and cannot be obtained elsewhere.

4. Information Access: 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.

5. Opportunity for Public Participation: 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. 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.

6. Transparency: 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. 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 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).

7. Management of Peer Review Process and Reviewer Selection: The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

IV. Alternative Procedures.

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.

V. Peer Review Planning.

1. Peer Review Agenda: 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.

2. Peer Review Plans: For each entry on the agenda the agency shall describe the peer review plan. 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 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.

3. Public Comment: 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.

VI. Annual Reports.

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.

VII. Certification in the Administrative Record.

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.

VIII. Safeguards, Deferrals, and Waivers.

1. Privacy: 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.
2. Confidentiality: Peer review shall be conducted in a manner that respects (i) confidential business information and (ii) intellectual property.
3. Deferral and Waiver: 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.

IX. Exemptions.

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 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.

X. Responsibilities of OIRA and OSTP.

OIRA, in consultation with OSTP, shall be responsible for overseeing implementation of this Bulletin. An interagency group, chaired by OSTP and OIRA, shall meet periodically to foster better understanding about peer review practices and to assess progress in implementing this Bulletin.

XI. Effective Date and Existing Law.

The requirements of this Bulletin, with the exception of those in Section V (Peer Review Planning), apply to information disseminated on or after six months following publication of this Bulletin, except that they do not apply to information for which an agency has already provided a draft report and an associated charge to peer reviewers. Any existing peer review mechanisms mandated by law shall be employed in a manner as consistent as possible with the practices and procedures laid out herein. The requirements in Section V apply to "highly influential scientific assessments," as designated in Section III of this Bulletin, within six months of publication of this Bulletin. The requirements in Section V apply to documents subject to Section II of this Bulletin one year after publication of this Bulletin.

XII. Judicial Review.

This Bulletin is intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.