Reclamation Manual

Policy

TEMPORARY RELEASE
(Expires 03/21/2011)

Subject: Peer Review of Scientific Information and Assessments

Purpose: The purpose of this Policy is to establish Bureau of Reclamation's policy for review of scientific information. The benefits of this Policy are establishment of peer review requirements; enhanced quality of scientific information produced, used, or disseminated by Reclamation; and increased credibility of decisions to which scientific information contributes; clarified application of Office of Management and Budget (OMB) Final Information Quality Bulletin for Peer Review (70 FR 2664-2677) (the OMB Bulletin), and implementation of the Information Quality Act (Pub. L. 106-554)

Authority: Information Quality Act (Pub. L. 106-554); Executive Order (EO) 12866, as amended by EO 13422; OMB Bulletin; OMB Guidelines (67 FR 8452-8460); Department of the Interior Information Quality Guidelines, 305 Departmental Manual (DM) Chapter 2; 318 DM Chapters 1-8

Approving Official: Commissioner

Contact: Director, Technical Resources, 86-60000

1. **Introduction**. The OMB Bulletin requires that important scientific information shall be peer reviewed by qualified specialists before the Federal Government disseminates the information.

2. **Applicability**. This Policy applies to all Reclamation employees who develop, review, produce, use, or disseminate scientific information.

3. **Definitions**. The following definitions apply to this Policy.

   A. **Dissemination.** Reclamation use or distribution of information (Reclamation-initiated or sponsored) to the public. Dissemination does not include:

      (1) distribution limited to government employees or contractors, cooperators, or grantees;

      (2) intra- or inter-agency use or sharing of government information;

      (3) responses to requests for records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act, or similar laws;

(4) correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes;

(5) information distributed for peer review in compliance with the OMB Bulletin and this Policy, or shared confidentially with scientific colleagues if Reclamation 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 Bureau of Reclamation. It does not represent and should not be construed to represent Reclamation's determination or policy;" and

(6) research produced by government-funded scientists (e.g., those supported extramurally or by Federal agencies or those working in state or local governments with Federal support) if the information:

(a) does not represent the views of Reclamation; and

(b) displays 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 Reclamation." However, regardless of who funded the work and the disclaimer displayed, once scientific information is used to inform a government decision, the agency is re-disseminating that information which makes it subject to Reclamation's Information Quality Requirements.

B. **Highly Influential Scientific Assessment.** A scientific assessment that the applicable Reclamation Director determines could have a potential impact of more than $500 million in any year, or is novel, controversial, or precedent setting or has significant interagency interest. Such an assessment contributes to "influential scientific information."

C. **Influential Scientific Information.** Scientific information that Reclamation can reasonably determine will or does have a clear and substantial impact on important public policies or private sector decisions.

D. **Independent Peers.** Persons who are not associated directly or indirectly with the information under review and whose background and expertise puts them on par technically and scientifically with the authors of the information.

E. **Peer Review.** A process in which the scientific merit of scientific information and the appropriateness of methods used and strength of the author's inferences are critically evaluated by independent peers.

F. **Peer Review Agenda.** A web-accessible listing of the peer review plans for all forthcoming disseminations of influential scientific information (including highly influential scientific assessments) that is regularly updated by Reclamation.

G. **Peer Review Plan.** A plan that documents the purpose of the peer review and the process that will be followed.

H. **Produce.** Conduct the data collection, analysis, and writing that generate scientific data, information, and conclusions.

I. **Scientific Assessment.** An evaluation of a body of scientific or technical knowledge that 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.

J. **Scientific Information.** 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 definition does not include opinions, where Reclamation's presentation makes clear that what is being offered is someone's opinion rather than fact or Reclamation's official position. Scientific information includes all of the following:

(1) 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;

(2) information that Reclamation disseminates from a web page, but does not include hyperlinked information that others disseminate; and

(3) the application of data, models, model outputs, and information to inform a decision being made by Reclamation.

4. **Responsibilities**.

A. **Commissione**r. The Commissioner is responsible for overseeing implementation of this Policy. The Commissioner may waive or defer some or all of the peer review requirements of the Sections II and III of the OMB Bulletin where warranted by a compelling rationale.

B. **Deputy Commissioner, Policy, Administration, and Budget.** The Deputy Commissioner, Policy, Administration, and Budget is responsible for evaluating the integrity and effectiveness of Reclamation's peer review process at least every 5 years.

C. **Chief Information Officer.** The Chief Information Officer is responsible for:

(1) placing this peer review Policy and other procedures on Reclamation's peer review website;

(2) establishing procedures for the posting of information undergoing peer review on Reclamation websites; and

(3) placing Reclamation's peer review agenda, as defined by the OMB Bulletin, on the peer review website.

D. **Directors**. Each Director that leads a directorate that develops, reviews, produces, uses, or disseminates scientific information is responsible for implementing this Policy by:

(1) Identifying a Peer Review Coordinator(s) responsible for ensuring that each of the provisions described in the OMB Bulletin and this Policy are followed. The Peer Review Coordinators must pay particular attention to OMB's directives on reviewer selection (expertise, balance, conflict of interest, and independence). [See OMB Bulletin section II (3) (a,b,c) and section III (3) (a,b,c).].

(2) Determining when disseminating or using scientific information or a scientific assessment requires a peer review.

(3) Designating the Peer Review Lead. This responsibility may be redelegated.

E. **Peer Review Coordinator.** The peer review coordinator is responsible for coordinating the peer review effort and reporting on peer review of influential information that occurs within their assigned directorate.

F. **Peer Review Lead.** For each peer review, the applicable Director, or delegated manager, must designate an official to have overall responsibility for conducting the peer review. The designated lead shall have training in peer review procedures. This responsibility includes:

(1) documenting whether peer review is required;

(2) establishing the objectives and structure of the review;

(3) determining whether the Federal Advisory Committee Act applies to the review;

(4) establishing timeframes for completing the review;

(5) selecting reviewers;

(6) providing review findings to authors;

(7) ensuring that comments are adequately and fairly addressed;

(8) ensuring that proper records are kept; and

(9) overseeing independent entities or contractors commissioned to manage the peer review process.

5. **Policy.**

A. **Peer Review.** All scientific information produced, used, or disseminated by each Reclamation organizational directorate must be reviewed pursuant to this Policy to determine whether and, if so, the type of peer review required. Such scientific information will be reviewed as follows:

(1) any scientific information that is determined to be "influential scientific information," including "highly influential scientific assessments," shall undergo peer review as specified in the OMB Bulletin; and

(2) all other scientific information will be analyzed to determine whether peer review would be sufficiently beneficial, and at what level.

B. **Scope.**

(1) This Policy applies to all scientific information produced, used, or disseminated by Reclamation. This includes scientific information that, along with other factors, informs a policy or management decision. For example, this Policy applies to scientific components of an environmental document prepared pursuant to the National Environmental Policy Act that present a scientific evaluation or are otherwise based upon scientific information.

(2) This Policy does not apply to:

(a) scientific information underlying past decisions, unless the relevant scientific information is being relied upon in making a new decision; and

(b) policy or management decisions notwithstanding whether these decisions are informed by scientific information.

6. **Criteria for Determining when Scientific Information Require Peer Review under the OMB Bulletin.**

A. **Influential Scientific Information.** Reclamation Directors, Peer Review Coordinators, and designated Peer Review Leads will decide on a case-by-case basis whether scientific information to be produced, used, or disseminated is "influential scientific information" or a "highly influential scientific assessment." Reclamation Directors, Peer Review Coordinators, and Peer Review Leads shall consider at least the factors in Paragraph 6.B (1) through 6.B (4) in establishing the criteria for making this determination.

B. **Highly Influential Scientific Assessments.** Each Director, Peer Review Coordinator, or designated Peer Review Lead shall consider at least the following factors when establishing criteria for identifying "highly influential scientific assessments:"

(1) the level of controversy associated with the scientific information or assessment;

(2) the potential for societal and resource impacts or implications associated with policy, management, or regulatory decisions that the scientific information might influence;

(3) the degree to which the scientific information contradicts prior findings and results or is likely to be novel or precedent-setting; and

(4) whether the level of interagency interest or crosscutting effects likely to result from the scientific information is "significant."

C. **Scientific Information That May Not Require Peer Review**. Scientific information that may not require peer review under this Policy includes the following:

(1) Items found in the list of exemptions under Section IX of the OMB Bulletin (Appendix A).

(2) Information published in a peer-reviewed journal. If the information (i.e., a specific study) is the principal basis for a decision, the peer review that was conducted must be determined to have been appropriate to the context in which the information will be used by Reclamation, or an additional peer review will be required.

(3) Routine statistical data used to compute standard indicators and trends that are gathered using methods based on well-established, peer-reviewed protocols and are interpreted and analyzed within the guidelines of the protocols.

(4) Information distributed for peer review in compliance with the OMB Bulletin and this Policy, or shared confidentially with scientific colleagues if Reclamation 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 Bureau of Reclamation. It does not represent and should not be construed to represent Reclamation's determination or policy."

(5) Research produced by government-funded scientists (e.g., those supported extramurally or by Federal agencies or those working in state or local governments with Federal support) if the information:

(a) does not represent the views of Reclamation; and

(b) displays 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 Reclamation." However, regardless of who funded the work and the disclaimer displayed, once scientific information is used to inform a government decision, the agency is re-disseminating that information which makes it subject to Reclamation's Information Quality Requirements.

7. **Peer Review Process.** The Peer review process shall be designed to: ensure that assumptions, findings, and conclusions of the scientific information are clearly stated and supported; identify oversights, omissions, and inconsistencies; and encourage authors to fully acknowledge limitations and uncertainties. Each Peer Review must follow the processes identified herein and consider the items identified below.

A. Determine the appropriate peer review mechanism, taking into consideration 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. Directors must consider these costs and benefits regardless of whether the peer review is required or elective under this Policy.

B. A Peer Review Plan shall be developed for each Peer Review that contains the following: (1) 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; (2) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (3) the timing of the review

(including deferrals); (4) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be employed); (5) 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; (6) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; (7) the anticipated number of reviewers (3 or fewer; 4-10; or more than 10); (8) a succinct description of the primary disciplines or expertise needed in the review; (9) whether reviewers will be selected by Reclamation or by a designated outside organization; and (10) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers.

C. The following additional items must be considered when planning a peer review:

(1) scope (including the importance of the 'charge' statement);

(2) selection of reviewers (expertise, balance, independence, and conflict of interest);

(3) disclosure and attribution;

(4) adequacy of prior peer review;

(5) disposition of reviewer comments (including agency response);

(6) compliance with the Federal Advisory Committee Act, when applicable;

(7) sections II and III of the OMB Bulletin which provide the specific requirements for peer review of influential scientific information, as well as, highly influential scientific assessments; and

(8) section IV of the OMB Bulletin, which discusses the availability of alternative procedures that may be considered.

8. **Deferral and Waiver**. The Commissioner may waive or defer some or all of the peer review requirements of the Sections II and III of the OMB Bulletin where warranted by a compelling rationale. Examples of compelling rationale include, but are not limited to, situations where unavoidable legal deadlines prevent full compliance with the OMB Bulletin. However, compliance with the Federal Advisory Committee Act, if applicable, cannot be waived. If the Commissioner defers the peer review requirements before dissemination, relevant peer review must be conducted as soon as practicable. Waivers will be administered using the process identified in RCD 03-03 *Request for Waiver from a Reclamation Manual Requirement and Approval or Disapproval of the Request*.