

Reclamation Manual

Policy

Subject:	Peer Review of Scientific Information and Assessments
Purpose:	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 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) (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, Series 5, 305 Departmental Manual (DM) Chapter 2; Series 7, 318 DM Chapters 1-3; and Reclamation Manual Policy, <i>Scientific Integrity</i> (CMP P13)
Approving Official:	Commissioner
Contact:	Scientific Integrity Officer (91-10000)

1. Introduction.

- A. The OMB Bulletin requires that influential scientific information including the subset of highly influential scientific assessments be peer reviewed by qualified specialists before it is disseminated by the Federal government. Agencies are granted broad discretion to weigh the benefits and costs of peer review mechanisms. Time-sensitive health and safety determinations are exempted from the OMB Bulletin. In complying with the OMB Bulletin, Reclamation, through this Policy, is establishing agency specific application and protocol of peer review for influential, highly influential, and other scientific information disseminated by Reclamation. This application is decision driven and scalable by the impact of the scientific information being disseminated.
 - B. Peer review must not be confused with public comment and other stakeholder processes. Notice and comment procedures are a separate process than peer review. Peer review is conducted to obtain evaluations of draft information that contains important scientific determinations, by participants with expertise and in consideration of independence and conflict of interest.
2. **Applicability.** This Policy applies to all Reclamation employees who disseminate scientific information.
3. **Definitions.** The following definitions apply to this Policy.
- A. **Decision.** An establishment of an official Reclamation position.

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- (1) A new decision is one that establishes a new official Reclamation position such as the issuance of a new characterizations of environmental impacts of proposed actions, or new records of decisions, or creation or alteration of standard operating procedures.
 - (2) Many decisions are carried out in fulfillment of previous Reclamation positions and are not considered new.
- B. Dissemination.** Reclamation's use of information or distribution of information to the public (Reclamation-initiated or sponsored). 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 informally 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, concurrence, or policy."; and
 - (6) information describing research produced by government-funded personnel (e.g., those supported externally 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) clearly displays the following disclaimer: "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 or the displayed disclaimers, once scientific information is used to inform a Reclamation decision, dissemination of that information is subject to peer review requirements within this Policy.
- C. Highly Influential Scientific Assessment.** A scientific assessment that the applicable Reclamation director determines does have an impact of more than \$500 million in any

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year, or is novel, controversial, or precedent setting or has significant interagency interest with respect to Reclamation or other known public policies or private sector decisions.

- D. **Independent Peers.** Persons who have not contributed directly or indirectly to the development of information under review and whose background and expertise puts them on par technically and scientifically with the authors of the information.
- E. **Influential Scientific Information.** Scientific information that the applicable Reclamation director can reasonably determine does have a clear and substantial impact on Reclamation or other known public policies or private sector decisions.
- F. **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 and documented by independent peers. Peer review does not constitute a recommendation or advice as to what uncertainty or precaution is appropriate to inform a decision.
- G. **Peer Review Agenda.** A Web-accessible listing of the peer review plans for all forthcoming disseminations of highly influential, influential, and discretionary peer review scientific information.
- H. **Peer Review Plan.** A plan that documents the purpose of the peer review and the peer review process that will be followed per Paragraph 8. of this Policy.
- I. **Quality Assurance/Quality Control or QA/QC.** The combination of quality assurance, the process or set of processes used to measure and assure the quality of a product, and quality control, the process of meeting products and services to expectations.
- J. **Scientific Assessment.** An evaluation of a body of scientific or technical information 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.
- K. **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:

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- (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 (if the link is to another Federal agency then that agency is the entity disseminating the information and is not considered within this Policy); and
- (3) the application of data, models, model outputs, and information to inform a decision being made by Reclamation.

4. Responsibilities.

- A. **Commissioner.** The Commissioner is responsible for overseeing implementation of this Policy.
- B. **Scientific Integrity Officer (SIO).** The SIO is responsible for:
 - (1) evaluating the integrity and effectiveness of Reclamation's peer review process at least every 5 years;
 - (2) making this peer review Policy and other procedures available on Reclamation's peer review Web site (<http://www.usbr.gov/main/qoi/peeragenda.html>); and
 - (3) working with directorates peer review coordinators to establish consistency and oversight of implementation of this Policy.
- C. **Director, Information Resources Office.** The Director, Information Resources Office is responsible for documenting peer review agendas and ensuring delivery of documentation to the Office of Information and Regulatory Affairs in OMB through the Department as part of Information Quality Act reporting.
- D. **Deputy Commissioner, External and Intergovernmental Affairs.** The Deputy Commissioner, External and Intergovernmental Affairs is responsible for:
 - (1) establishing procedures for the posting of and maintaining up to date information undergoing peer review on Reclamation Web sites; and
 - (2) ensuring Reclamation's peer review agendas, as defined by OMB Bulletin, are placed on the peer review Web site.
- E. **Directors.** Each director that leads a directorate that disseminates scientific information is responsible for implementing this Policy by:
 - (1) identifying a peer review coordinator(s) responsible for coordination and reporting of peer review activities within the directorate;

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- (2) determining when disseminating scientific information or a scientific assessment requires a peer review;
 - (3) determining if the information does not meet the criteria for Influential Scientific Information or a Highly Influential Scientific Assessment, as defined in Paragraphs 6.A. and 6.B., whether peer review would be cost effective and beneficial or otherwise desirable; and
 - (4) assigning a peer review lead for each peer review.
- F. **Peer Review Coordinator.** The peer review coordinator is required to have training in scientific integrity. The peer review coordinator is responsible for:
- (1) coordinating and reporting the directorate's peer review efforts;
 - (2) conducting regular outreach to individuals and organizations within the directorate to ensure that they are aware of and understand the policy, and are provided information on ways to achieve compliance;
 - (3) ensuring a peer review lead has been identified for each peer review being conducted; and
 - (4) ensuring provisions described in the OMB Bulletin and this Policy are followed including OMB's directives on reviewer selection (expertise, balance, conflict of interest, and independence). [See OMB Bulletin Sections II (3) (a,b,c) and Sections III (3) (a,b,c).]
- G. **Peer Review Lead.** The designated peer review lead shall have training in scientific integrity. The peer review lead is responsible for:
- (1) documenting whether influential or highly influential peer review is required;
 - (2) if influential scientific information or highly influential scientific assessment peer review is required:
 - (a) establishing the objectives and structure of the review;
 - (b) working with the Office of the Solicitor to determine whether the Federal Advisory Committee Act applies to the review and, if so, following the requirements of that act;
 - (c) establishing timeframes for completing the review;
 - (d) selecting reviewers;
 - (e) providing review findings to authors;

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- (f) ensuring that comments are adequately and fairly addressed;
 - (g) ensure that the appropriate budget and timing have been incorporated into the project;
 - (h) ensuring that proper records are kept; and
 - (i) overseeing independent entities or contractors commissioned to manage the peer review process; and
- (3) ensuring that the peer review plan is posted on Reclamation's Peer Review Agenda Web site (<http://www.usbr.gov/main/qoi/peeragenda.html>).

5. Policy.

A. **Peer Review.** All scientific information disseminated by each Reclamation organizational directorate must be evaluated pursuant to this Policy to determine whether peer review is required and, if so, what kind. 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 have received peer review as specified in the OMB Bulletin before dissemination.
- (2) Where influential scientific information and highly influential scientific assessment peer review are not required, the directorate will determine whether discretionary peer review would be beneficial or otherwise desirable and cost-effective. Discretionary peer review must be performed in a manner that reflects the complexity and impact of the scientific information being disseminated. Less complex scientific information requires less complex review beginning with QA/QC, and more complex scientific information may need a peer review similar in scope to influential scientific assessments.

B. Scope.

- (1) This Policy applies to all scientific information and assessments, as defined in Paragraph 3.K. and 3.J., respectively, disseminated by Reclamation. This includes scientific information that, along with other factors, informs a policy or management decision. For example, this Policy applies to the scientific information in an environmental document prepared pursuant to the National Environmental Policy Act (NEPA). (It does not apply to the environmental document as a whole, see below.)
- (2) This Policy does not apply to:

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- (a) Scientific information underlying past decisions, unless the relevant scientific information is being relied upon in making a new decision.
- (b) Policy or management decisions and documents notwithstanding whether these decisions are informed by scientific information. For example, there is not a requirement under the OMB Bulletin for peer review of an entire NEPA document, as much of the NEPA document relates to agency policy and decision making. Only the underlying scientific information must be considered for sufficiency of existing review before its use and dissemination in the document.

6. **Factors for Determining when Scientific Information Requires Influential or Highly Influential Peer Review Under the OMB Bulletin.** Reclamation directors will decide on a case-by-case basis whether scientific information to be disseminated does not require peer review or requires peer review appropriate for influential or highly influential information.

- A. **Influential Scientific Information.** Each Reclamation director shall consider the following factor to identify “influential scientific information:” The degree to which scientific information may have substantial impact on Reclamation or other known public policies or private sector decisions.
- B. **Highly Influential Scientific Assessments.** Each Reclamation director shall consider the following factors to identify “highly influential scientific assessments:”
 - (1) the known Reclamation or other known public policies or private sector decisions influenced by the scientific assessment;
 - (2) whether the scientific assessment may have an impact of more than \$500 million in any year;
 - (3) the level of public and/or political debate associated with the scientific information or assessment;
 - (4) the potential for societal and resource impacts or implications associated with policy, management, or regulatory decisions that the scientific information might influence;
 - (5) the degree to which the scientific information contradicts prior findings and results or is likely to be novel or precedent-setting; and
 - (6) whether the level of interagency interest or crosscutting effects likely to result from the scientific information are “significant.”
- C. **Scientific Information That May Not Require Peer Review.** Scientific information that may not require peer review under this Policy, or which may already have met peer review requirements, include the following:

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- (1) Items found in the list of exemptions under Section IX of the OMB Bulletin.
 - (2) Information that has already been subjected to peer review (e.g., was published in a refereed journal). If the information in a specific study is the principal basis for a decision, the peer review that was conducted must be determined to have been adequate to the context in which the information will be used by Reclamation and the expected impact of use of the information. If it is determined that the peer review is not adequate, 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 informally 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 personnel (e.g., those employed by or supported extramurally or by Federal agencies or those working in state, local, or tribal governments with Federal support) if the information:
 - (a) Does not represent the official views of Reclamation.
 - (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 Reclamation decision, the agency is re-disseminating that information which makes it subject to Reclamation’s Information Quality Requirements and this Policy.
7. **Discretionary Peer Review.** Scientific information disseminated by Reclamation that does not meet the criteria for influential scientific information or highly influential scientific assessments will still be evaluated for whether peer review would be cost effective, beneficial, or otherwise desirable. This type of discretionary peer review may include QA/QC, technical sufficiency reviews, directorate specific peer review, and other Reclamation specific review practices. Where programs and offices have standardized discretionary peer review processes, links to those processes will be established on the peer review Web site. Otherwise, discretionary peer review will document the plan and be posted on the peer review Web site.

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8. **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. Peer review must be built into the project budget for which peer review is being conducted and reflect the timing and complexity of the review process as determined by the below. 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. Under the OMB Bulletin, agencies are granted broad discretion to weigh the benefits and costs of using a particular peer review mechanism including individual letters or panel reviews, public outreach, number of reviewers or alternative procedures for a specific information product. However, for review of highly influential scientific information, employees of Reclamation are not permitted to serve as reviewers – see Paragraph 8.C.
- B. A peer review plan shall be developed for each peer review and contain 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, with respect to dissemination, and length 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.

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- (9) Whether reviewers will be selected by Reclamation or by a designated outside organization.
 - (10) Whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers.
 - (11) Scope of the peer review and the charge to reviewers including clearly identifying that reviewers are not to provide advice on a policy or decision (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 Reclamation.
- C. The following additional items must be considered when planning a peer review:
- (1) selection of reviewers (expertise, balance, independence, and conflict of interest);
 - (2) disclosure and attribution;
 - (3) adequacy of prior peer review, if applicable;
 - (4) disposition of reviewer comments (including agency response);
 - (5) compliance with the Federal Advisory Committee Act, when applicable;
 - (6) 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
 - (7) Section IV of the OMB Bulletin, which discusses the availability of alternative procedures that may be considered.
- D. When the plan is completed, the peer review lead will work with the Deputy Commissioner, External and Intergovernmental Affairs to arrange for the plan to be posted on the Reclamation peer review Web site in a timely fashion.
9. **Deviation.** As provided in OMB Bulletin, Section VIII.(3), the Commissioner may deviate from or defer some or all of the peer review requirements of Sections II and III of the OMB Bulletin where warranted by compelling rationale. An example of compelling rationale includes, but is 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 deviated. If the Commissioner defers the peer review requirements before dissemination, relevant peer review must be conducted as soon as practicable and prior to a final Reclamation policy or decision. Deviations will be administered using the process identified in Reclamation Manual Directive and Standard, *Request for Deviation from a Reclamation Manual Requirement and Approval or Disapproval of the Request* (RCD 03-03). All deviations from this Policy are to be

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documented on the peer review Web site and will be submitted to the OIRA per OMB Bulletin requirements.

RECLAMATION MANUAL TRANSMITTAL SHEET

Effective Date: _____

Release No. _____

Ensure all employees needing this information are provided a copy of this release.

Reclamation Manual Release Number and Subject

Summary of Changes

NOTE: This Reclamation Manual release applies to all Reclamation employees. When an exclusive bargaining unit exists, changes to this release may be subject to the provisions of collective bargaining agreements.

Filing instructions

Remove Sheets

Insert Sheets

All Reclamation Manual releases are available at <http://www.usbr.gov/recman/>

Filed by: _____

Date: _____