

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; 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.

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3. Policy.

A. **Peer Review.** All scientific information disseminated by each Reclamation 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. The OMB Bulletin does not provide requirements for discretionary peer review. Programs and offices who generate and disseminate scientific information may develop and document their respective discretionary peer review processes and may publish those processes on the Peer Review Agenda website.

B. Scope.

- (1) This Policy applies to all scientific information and assessments, as defined in Paragraph 6.K. and 6.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 (e.g., factual inputs, data, models, analyses, technical information, or scientific assessment) used 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:
 - (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. Put another way, this Policy applies to the various scientific information items that inform such decisions and documents, but not the overarching decisions and documents themselves. For example, this Policy does not require peer review of an entire NEPA document and the associated decision of whether significant impacts were found; however, it does require that the scientific information informing that NEPA document and decision be evaluated relative to the peer review process requirements described herein before that scientific information informs the NEPA document and associated decision.

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4. **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. **Information Classification.** Reclamation directors, potentially in consultation with their peer review coordinator and peer review lead(s), will decide on a case-by-case basis whether scientific information to be disseminated has been reviewed adequately per the requirements of this Policy. To judge adequacy of prior review, the directors shall determine whether the information may be classified as a highly influential scientific assessment or influential scientific information, thus triggering mandatory review requirements per Paragraph 3.A.(1). For all other scientific information, directors may judge whether the information has been adequately reviewed and, if not, how to apply their directorate's documented discretionary review process.
 - (1) **Scientific Information That May Not Require Peer Review.** This includes information that may not require peer review or may already have met peer review requirements includes the following:
 - (a) Items found in the list of exemptions under Section IX of the OMB Bulletin.
 - (b) 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.
 - (c) 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.
 - (d) 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 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."
 - (e) Research produced by government-funded personnel (e.g., those employed by or supported extramurally or by Federal agencies or those working in

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state, local, or tribal governments with Federal support) if the information: (1) does not represent the official views of Reclamation; and (2) 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.

- (2) **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.
- (3) **Highly Influential Scientific Assessments.** Each Reclamation director shall consider the following factors to identify “highly influential scientific assessments”:
 - (a) the known Reclamation or other known public policies or private sector decisions influenced by the scientific assessment;
 - (b) whether the scientific assessment may have an impact of more than \$500 million in any year;
 - (c) the level of public and/or political debate associated with the scientific information or assessment;
 - (d) the potential for societal and resource impacts or implications associated with policy, management, or regulatory decisions that the scientific information might influence;
 - (e) the degree to which the scientific information contradicts prior findings and results or is likely to be novel or precedent-setting; and
 - (f) whether the level of interagency interest or crosscutting effects likely to result from the scientific information are “significant.”

B. **Implementation.** The following actions shall be taken for all peer reviews on Influential Scientific Information and Highly Influential Scientific Assessment, except where noted below. For discretionary peer reviews, except where noted below, the following actions may be considered as good practices.

- (1) The Reclamation director shall ensure that a peer review lead is assigned to coordinate with the directorates’ peer review coordinator on planning, implementation and reporting of the given review.

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- (2) The peer review lead shall do the following for review of influential scientific information, highly influential scientific assessment, and any discretionary review that the directorate elects to have disseminated via the Peer Review Agenda website:
 - (a) document how the scientific information was classified (e.g., influential scientific information, highly influential scientific assessment, or neither) and what peer review requirements apply;
 - (b) establish the objectives and structure of the review;
 - (c) establish timeframes for completing the review;
 - (d) in consultation with the directorate's peer review coordinator, 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.
 - (e) work with the Office of the Solicitor to determine whether the Federal Advisory Committee (FAC) Act applies to the review given the selected review mechanism (e.g., potentially with respect to whether the review involves open meetings, committee chartering, and public involvement); and, if so, follow the requirements of the FAC Act;
 - (f) provide review findings to authors;
 - (g) ensure that comments are adequately and fairly addressed;
 - (h) ensure that the appropriate budget and timing have been incorporated into the project;
 - (i) ensure that proper records are kept;
 - (j) consider disclosure and attribution of reviewer comments;
 - (k) consider disposition of reviewer comments (including agency response);
 - (l) select reviewers as warranted by the review mechanism selected, considering expertise, balance, independence, and conflict of interest;
 - (m) oversee independent entities or contractors commissioned to manage the peer review process;
 - (n) develop a peer review plan per requirements of Paragraph 4.B.(3); and

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- (o) ensure that the peer review plan is posted on Reclamation's Peer Review Agenda website (<http://www.usbr.gov/main/qoi/peeragenda.html>) in a timely fashion, working within the procedures established by the Deputy Commissioner for the posting of peer review agendas and up-to-date information undergoing peer review on the Peer Review Agenda website. [Exception: In some cases, per OMB Bulleting Section III(5), a peer review assessment may be so sensitive that it is critical for the agency's assessment to achieve a high level of scientific information quality before it is publicized. In those situations, a rigorous yet confidential peer review process may be appropriate, prior to public release of the peer review assessment.]
- (3) A peer review plan shall contain the following items if it is to be posted on Reclamation's Peer Review Agenda website, and may contain these items in other discretionary review cases:
 - (a) 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.
 - (b) Whether the dissemination is likely to be influential scientific information, highly influential scientific assessment, or scientific information undergoing discretionary review.
 - (c) The timing, with respect to dissemination, and length of the review (including deferrals).
 - (d) Whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be employed).
 - (e) Whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided.
 - (f) Whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review.
 - (g) The anticipated number of reviewers (3 or fewer; 4-10; or more than 10).
 - (h) A succinct description of the primary disciplines or expertise needed in the review.
 - (i) Whether reviewers will be selected by Reclamation or by a designated outside organization.

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- (j) Whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers.
 - (k) 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.
 - (l) Whether the peer review comments or response to comments will be made public.
- (4) Additional requirements for peer review of influential scientific information or highly influential scientific assessment:
- (a) The peer review lead shall ensure that requirements from Sections II and III of the OMB Bulletin are implemented, as they correspond to peer review of influential scientific information and highly influential scientific assessments, respectively.
 - (b) The peer review lead shall consider alternative procedures as outlined in Section IV of the OMB Bulletin.
 - (c) When determining the appropriate review mechanism, in addition to the requirements in Paragraph 4.B.(2)(d), consider guidance within the OMB Bulletin which grants agencies broad discretion to weigh the benefits and costs of using a candidate peer review mechanism including individual letters or panel reviews, public outreach, number of reviewers or alternative procedures for a specific information product.
 - (d) Per Section III of the OMB Bulletin, Reclamation employees are not permitted to serve as reviewers of highly influential scientific assessments.
- (5) Additional considerations for discretionary review of scientific information:
- (a) When a Reclamation director determines that a discretionary peer review is appropriate, the manner of review shall be consistent with the directorate's documented discretionary peer review process, which may include quality assurance/quality control (QA/QC), technical sufficiency reviews, directorate specific peer review, and other Reclamation specific review practices.
 - (b) Discretionary peer review should 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

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with QA/QC, and more complex scientific information may need a peer review similar in scope to influential scientific assessments.

- C. **Deviation.** As provided in OMB Bulletin, Section VIII(3), the Commissioner may deviate from or defer some or all peer review requirements of OMB Bulletin Sections II (Influential Scientific Information) and III (Highly Influential Scientific Assessment) where warranted by compelling rationale. This is consistent with SO 3369, which states that any decision based on scientific conclusions (i.e., Influential Scientific Information or Highly Influential Scientific Assessment) that are not supported by publicly available raw data, analysis, or methodology, have not been peer-reviewed (consistent with the OMB Bulletin), or are not readily reproducible should include rationale why such science is the best available information. 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 FAC 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 documented on the peer review website and will be submitted to the Office of Information and Regulatory Affairs (OIRA) per OMB Bulletin requirements.
5. **Program Management.** The following bureau-wide programmatic activities shall be conducted to support effective Policy implementation and compliance.
 - A. **Program Evaluation.** Reclamation's Scientific Integrity Officer (SIO) will evaluate bureau-wide peer review processes at least once every 5 years for integrity and effectiveness.
 - B. **Program Reporting.** The Director, Information Resources Office shall document peer review agendas and ensure delivery of documentation to OIRA in OMB through the Department as part of Information Quality Act reporting.
 - C. **Directorate-level Coordination.** Each director that disseminates scientific information shall identify a peer review coordinator who will:
 - (1) coordinate peer review activities within the directorate;
 - (2) conduct regular outreach to individuals and organizations within the directorate to ensure that they are aware of this Policy, understand it, and are provided information on ways to achieve compliance;
 - (3) ensure reporting on peer review activities within the directorate; and,

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- (4) ensure 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).]
- D. **Bureau-wide Consistency.** The SIO will make this Policy and other procedures, including each directorate's documented discretionary peer review processes, available on Reclamation's Peer Review Agenda website. The SIO will also work with each directorate's peer review coordinator to establish consistency and oversight of implementation of this Policy.
- E. **Bureau-wide Dissemination of Peer Review Plans and Scientific Information.** The Deputy Commissioner shall establish procedures for the posting of and maintaining up-to-date information undergoing peer review on Reclamation's Peer Review Agenda website; ensure that Reclamation's peer review plans, as defined by OMB Bulletin and this Policy, are published on the Peer Review Agenda website; and ensure that scientific information prior to review and revised after review are published on the Peer Review Agenda website as requested by the originating directorate.
- F. **Training.** Each peer review coordinator and peer review lead shall have training in scientific integrity.
- 6. **Definitions.** The following definitions apply to this Policy.
 - A. **Decision.** An establishment of an official Reclamation position. A decision is one that establishes an official Reclamation position such as the issuance of a new characterizations of environmental impacts of proposed actions, or records of decisions, or creation or alteration of standard operating procedures.
 - 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 FAC 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.

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- (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 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.”
 - (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 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, the appropriateness of methods used, and strength of the author’s inferences are critically

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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 4.B.(3) 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 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 (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.
7. **Review Period.** The originating office will review this release every 4 years.

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: _____