

GEOSCIENCES AND ENGINEERING DIVISION
QUALITY ASSURANCE PROCEDURE

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Title: **QAP-002 REVIEW OF DOCUMENTS, REPORTS, AND PAPERS**

EFFECTIVITY AND APPROVAL

Revision 13 of this procedure became effective December 30, 2010. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	12-30-10

Changes were made to (i) eliminate separate concurrence reviews, (ii) assign the previously defined responsibilities of the concurrence reviewer to the programmatic reviewer, (iii) clarify the scope of quality assurance reviews and (iv) identify the availability and location of applicable forms.

Supersedes Procedure No. QAP-002, Rev. 12, Chg. 0 dated 07/12/2010.

Prepared by	Date	Approved by	Date
<i>Errol W. Hawkins</i>	<i>12/22/2010</i>	<i>[Signature]</i>	<i>12/22/2010</i>

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QAP-002 REVIEW OF DOCUMENTS, REPORTS, AND PAPERS

1.0 PURPOSE

This procedure establishes the methods for planning, performing, and documenting reviews of Geosciences and Engineering Division (GED) reports, papers, plans, proposals, and other documents produced by the GED staff. The broad category of "papers" includes but is not limited to abstracts, posters, papers to be published in conference proceedings, and both peer-reviewed and non-peer-reviewed journal articles.

This procedure applies to all documents prepared by GED on behalf of its clients as well as documents related to activities funded within Southwest Research Institute® (SwRI®). It also describes how GED staff members are to document resolution of review comments provided by clients, peer-review journals, or other third-party reviewers. At the discretion of the client, this procedure may be applied to documents that are developed by client organizations with contributions from GED staff members. Application of this procedure is optional only for documents that (i) result from projects led by other divisions and that do not have a GED staff member as the first author or (ii) are not transmitted to a client or third-party organization as a GED deliverable. In such cases, the GED contributing author or the author from the client organization has the option to request a review from the responsible GED manager. If this option is not exercised, the review process of the client is considered sufficient. Regardless, all document reviews should be recorded and preserved in the GED QA record system.

For peer reviews conducted at the direction of GED or its clients, this procedure reflects the guidance in NUREG-1297, Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories. This procedure addresses applicable requirements of the GED Quality Assurance Manual (QAM), Section 3.

A number of forms are used in implementing this procedure. Current electronic versions are available on a shared drive.

2.0 RESPONSIBILITY

2.1 Managers and directors are responsible for implementing QAP-002 for documents prepared in their areas of authority.

2.2 Document authors are responsible for preparing documents for review, resolving review comments, and collecting and submitting review documentation required by QAP-002. Authors may prepare and submit Form QAP-2 to accompany the author-final draft.

2.3 Reviewers are responsible for performing their assigned reviews in accordance with QAP-002.

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3.0 REVIEW TYPES

3.1 Technical Review—A review performed by personnel independent of those who performed the work, but who have technical expertise at least equivalent to that required to perform the original work. Technical reviews are in-depth, critical reviews, analyses, and evaluations of documents, material, or data that require technical verification and/or validation for applicability, correctness, adequacy, and completeness. Technical reviews verify compliance to predetermined requirements, industry standards, or common scientific, engineering, or industry practice, and determine whether the methods conform to established practices, the application of the method is appropriate, and results are consistent with the applied method.

3.2 Peer Review—An in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria employed, and conclusions drawn in the original work. Peer reviews confirm the overall adequacy of work for the intended purpose.

Peer reviews may be directed by GED, its clients, or a third party such as a conference organizer or journal editor. GED-directed peer reviews shall be conducted as described in the following paragraphs of Section 3.2 and Section 4 of this procedure. Peer reviews not directed by GED shall be conducted in accordance with the procedures and practices of the third-party review organization.

Peer reviewers shall have technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) at least equivalent to that needed for the original work. Peer reviewers shall not have been involved as a participant, supervisor, technical reviewer, or advisor for the work being reviewed, and to the extent practical, shall have sufficient freedom from funding considerations to assure the work is impartially reviewed.

A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed. The group shall vary with the complexity of the work to be reviewed, its importance to establishing that safety or performance goals are met, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review. The collective technical expertise and qualifications of peer group members shall span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought. Technical areas more central to the work to be reviewed shall receive proportionally more representation on the peer review group.

3.3 Editorial Review—A review performed by a person knowledgeable of the Division Editorial Style Guide or other applicable editorial standards. Professional editors should be used for complex documents and when necessary based on the skills of the author.

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Editing shall consist of (i) review by the editor; (ii) discussion of the review results between the editor and author, as necessary; and (iii) appropriate modification of the document. Editorial reviews are recorded in marked-up documents. Resolution of editorial comments is at the option of the author. Editorial review results are not retained as QA records.

- 3.4 Quality Assurance (QA) Review—A review that evaluates whether (i) the requirements of the GED QAM and applicable procedures are met; (ii) any initial submissions or proposed changes reduce the organizational commitment to quality assurance and, if they do, such are documented and justified; and (iii) new procedures are identified where appropriate (e.g., when a new area of work is undertaken or work is not effectively controlled using existing procedures, such as QAP-001, Scientific Notebook Control) and any such procedures are appropriately categorized (i.e., AP, QAP, or TOP). QA reviews are conducted by QA staff knowledgeable of the applicable QA program and procedural requirements.
- 3.5 Programmatic Review—A review that (i) determines whether contractual requirements, objectives, policies, and programmatic requirements are correctly and consistently addressed; (ii) determines whether there is agreement with the overall approach and presentation of the work being reviewed; and (iii) provides a basis for assuring consistency among like products. Programmatic reviews shall be conducted by individuals knowledgeable of applicable requirements and the objectives of the work described or performed, generally the responsible group or program manager, director, vice president, or their designees, which may include institute engineers and scientists who have the necessary programmatic knowledge.

A programmatic review verifies the following, as appropriate for the type of document being reviewed:

- The document reads clearly, and the presentation is appropriate for the intended audience.
- The overall objectives of the work being planned or described are met by the document being reviewed.
- Approach, methods, and/or conclusions are consistent with acceptable methods and GED policy.
- The document satisfies the requirements of the scope of work or other specifications.
- Copyright restrictions are appropriately addressed.
- Appropriate measures are taken to protect client-provided and arising intellectual property.

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- Software used is controlled according to TOP-018, Development and Control of Scientific and Engineering Software, and validated software is used for regulatory or other appropriate reviews.
- Regulatory requirements are properly applied or incorporated.
- Classified, safeguards, sensitive unclassified, export controlled, and other types of information are identified appropriately and either access restrictions are applied or the material is otherwise excluded from the document.

3.6 **Format Review**—A review to assure that document organization and style requirements and internal and client document distribution requirements are met. Format reviews are performed by personnel who did not format the document under review and who are knowledgeable of document format requirements.

4.0 DOCUMENT PREPARATION AND REVIEW PROCESS

Managers have several evaluation, review, and approval responsibilities in the document preparation and review process. These responsibilities are assigned to specific managers, directors, or the vice president based on who has programmatic responsibility for the document being prepared.

4.1 Document Submittal for Review

4.1.1 The author shall submit a final draft of the item requiring review (hereafter referred to as the “author final draft”) to the responsible manager sufficiently in advance of the due date to allow for word processing, review, reproduction, and distribution. When the item includes information sourced from a GED scientific notebook(s), the author also shall provide copies of the relevant pages from the scientific notebook to facilitate the technical and programmatic reviews.

GED contract deliverable reports that include information sourced from scientific notebook(s) shall identify the scientific notebook(s) and relevant pages in the Acknowledgements portion of the report.

4.1.2 The manager shall evaluate the author final draft document and determine whether it is sufficiently complete to begin review. The manager shall verify that relevant programmatic objectives are satisfied by the document. The manager shall confirm that applicable software was controlled according to TOP-018. In general, TOP-018 control is required if the technical conclusions or programmatic findings presented in the document are used in regulatory reviews and environmental documentation, or directly support regulatory decisions, safety-related evaluations, monitoring of critical systems, and the like.

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4.2 Review Planning

4.2.1 To initiate reviews, Form QAP-6, Document Review Request and Transmittal Control, shall be completed, signed, and dated by the manager. Form completion includes:

- Select the document type from the review item categories identified in Table 1, Review Requirements Matrix.
- Check the required review types from Table 1 on the Form QAP-6.
- Specify any special markings (e.g., pre-decisional, export control, etc.) required for the document.
- Identify the scientific notebooks that provided data or analyses contributing to the document under review.
- List all authors and contributors to the document under review (note, do not use et al.).

4.2.2 The manager shall select the appropriate types of reviews using the criteria described in Section 3 and shall identify the reviewers on the Form QAP-6. In general, third party reviews (e.g., by clients, conference organizers, and journals) do not use this form. Documents are processed first through the GED review and then submitted for subsequent third-party review. The manager shall select the appropriate types of review for a subsequent GED review based on the significance and nature of changes that result from a third-party review process.

4.2.3 Not all reviews indicated in Table 1 may be required for revisions and changes to previously completed documents. Depending on the extent and nature of the changes, reviews may be omitted or limited. In such cases, the Form QAP-6 shall include a brief justification by the manager for any review scope less than that defined in the Review Requirements Matrix.

4.2.4 When a technical review is required by Table 1, assignments shall be made using the criteria in Section 3. The responsible manager will complete Form QAP-12, Instructions to Technical Reviewers. It may be appropriate to assign more than one technical reviewer. In such cases, different members of the review team may be assigned different sections of the document (i.e., less than the entire document) to review, as appropriate. Instructions to technical reviewers shall be approved by the responsible manager and a director.

4.2.5 When checks of calculations are specified in the instructions to technical reviewers, the verifications shall be performed in accordance with QAP-014, Documentation and Verification of Scientific and Engineering Calculations, and documented on Form QAP-19, Calculation Verification Worksheet.

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4.2.6 When a technical review is required by Table 1, a peer review also may be required if the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods cannot otherwise be established through testing, alternate calculations, or reference to previously established standards and practices. In general, the following conditions are indicative of situations in which a peer review may be required:

- Critical interpretations or decisions will be made in the face of significant uncertainty or subjective judgment, including the planning for data collection, research, or testing.
- Interpretations having significant impact on the results will be made.
- Novel or beyond state-of-the-art testing, plans, and procedures or analyses are or will be utilized.
- Detailed technical criteria or standard industry procedures do not exist or are being developed.
- Results of tests are not reproducible or repeatable.
- Data or interpretations are ambiguous.
- Data adequacy is questionable [e.g., data may not have been collected in conformance with an established QA program (see QAP-015, Qualification of Existing Data)].
- The adequacy of a critical body of information can be established by alternate means, but there is disagreement within the associated technical community regarding the applicability or appropriateness of the alternate means.

If a peer review is required, the responsible manager will complete Form QAP-13, Instructions to Peer Reviewers. Instructions to peer reviewers shall be approved by the responsible manager and a director. Peer reviews may be conducted on activities as well as documents. While the complete review process may not apply to reviewing an activity, peer reviews of activities shall be conducted in accordance with this procedure.

4.2.7 Deliverable items shall be edited to enhance and improve writing style, grammar, and punctuation and to assure that the writing is effective. NRC intermediate and major milestones shall be edited according to the Division Editorial Style Guide, as required by contract. Non-NRC deliverables should be edited according to the Division Editorial Style Guide to the extent appropriate to the client needs. The manager shall determine whether non-deliverable documents need to be edited.

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4.3 Reviews and Comment Resolution

Although the following instructions apply specifically to reviews directed by the division, the principles and concepts (e.g., obtaining written comments, responding to them in writing, documenting the results, etc.) apply to all technical and peer reviews. Reviews directed by clients may use this procedure and/or its associated forms, if elected by the client; otherwise the client review process is deemed sufficient. In general, reviews conducted by clients and other third parties will use their own process. For such reviews, the document lead author is responsible for obtaining and responding to review comments and including them in division records as specified in Section 5.

- 4.3.1 In general, documents should be routed to reviewers in the order listed on Form QAP-6. Exceptions may be made to the order of review or parallel reviews may be conducted with the approval of the responsible manager or a director. Peer reviews, when necessary, may be conducted after other reviews are completed.
- 4.3.2 If NRC or other client staff contributed to the report, their scientific notebooks or other quality-related documentation shall be obtained if possible and provided to technical reviewers, when appropriate.
- 4.3.3 Review comments (except for those from editorial reviews) shall be documented using Form QAP-3, Report Review/Comment Resolution Record. Editorial comments (not requiring resolution) may be made as marginalia on the review copy of the document. After comments are recorded, reviewers shall sign and date each page of Form QAP-3 in the "reviewer signature" block. In addition, technical reviewers shall initial Form QAP-12 to indicate that all review criteria identified have been addressed, and peer reviewers shall initial Form QAP-13 to indicate that all review criteria identified have been addressed.
- 4.3.4 Review comments and instructions for revision may be received from a client, symposium organizer, journal editor, or other external review organization. If possible, these should be recorded and resolved using the Form QAP-3. If comments or instructions for revision are conveyed by some other means, these shall be retained and included in our QA records. Regardless of the form in which third-party comments are received, comment resolution shall be documented and the associated records retained.
- 4.3.5 The author or other designated responder shall provide a response to each comment and shall sign the "responder signature" block on each page of Form QAP-3. In cases involving third-party reviews, the author shall respond to the comments in writing (e.g., by letter, email, and/or changes directly in the document text) and retain correspondence and other documentation as described in Section 5 of this procedure.
- 4.3.6 After comment response and changes to the document have been incorporated and checked by the author in response to the technical review, the revised document,

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comment resolution records, and the Form QAP-6 sheets shall be returned to the reviewer. If acceptable (i.e., when resolution is accomplished), the reviewer shall

- Verify that the comment resolutions have been incorporated.
- Sign and date the “response accepted by” block of each page of Form QAP-3.
- Initial and date the Form QAP-6 in the appropriate block along the right margin of the form.

4.3.7 After comment response and changes to the document have been incorporated and checked by the author in response to any GED-directed peer review, the revised document, reviewer comments, comment resolution records, and Form QAP-6, Document Review Request and Transmittal Control, sheets shall be returned to the reviewer. If acceptable (i.e., when resolution is accomplished), the reviewer shall

- Verify that the comment resolutions have been incorporated.
- Sign and date the “response accepted by” block of each page of Form QAP-3.
- Initial and date the Form QAP-6 in the appropriate block along the right margin of the form.

4.3.8 After comment resolution and changes to the document have been incorporated and checked by the author in response to any third-party peer review, the review organization will document approval by the process used by that organization. The actions and related forms identified in Section 4.3.7 may be used if preferred by the client or other third-party organization; otherwise, other appropriate written means shall be used to document acceptance of the responses. When Forms QAP-3 and QAP-13 are not used by third-party reviewers, the responsible assistant director or director shall confirm that the peer review process is complete and initial and date the Form QAP-6 in the appropriate block along the right margin of the form.

4.3.9 After the Form QAP-6 has been signed by all reviewers, a verification of compliance with QAP-002 shall be performed by QA staff or a person acting in that capacity (e.g., a responsible manager, director, or the vice president). Verification reviews of QA deliverables shall be performed by qualified individuals independent of the development of the deliverable. Verification of compliance with QAP-002 reviews shall determine the following:

- All required review types were selected, required reviews were performed, and comments have been resolved.
- The Form QAP-3, QAP-6, and QAP-12 sheets are complete.

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- Any required Form QAP-13 and Form QAP-19 worksheets are complete.
- Software used is properly controlled according to TOP-018, and validated software is used for regulatory reviews.

5. RECORDS

Items identified as review documentation within this procedure shall be maintained as QA records in accordance with QAP-012, Quality Assurance Records Control. Retained records shall include (i) reviewed items, (ii) Document Review Request and Transmittal Control forms, (iii) Instructions to Technical Reviewer forms, (iv) Instructions to Peer Reviewers forms, (v) Report Review/Comment Resolution Record forms, (vi) Calculation Verification Worksheet forms, (vii) GED directed peer review reports and responses to peer review, (viii) third-party peer review comments and responses to those comments, and (ix) other related correspondence. If comments or instructions for revision were provided by the client or other outside review organization, these comments and their resolution—regardless of form—shall be included in the review documentation.

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Table 1. Review Requirements Matrix

Document Type	Technical*	Editorial	QA	Programmatic	Format
Technical Documents					
Technical Reports, Software Requirements Descriptions, Software Validation Reports, Annual Reports	✓	✓†		✓	✓†
Papers/Presentations					
Journal Articles, Proceedings, Abstracts, Conference Papers, Presentations Posters	✓	✓†		✓	
Guidance Documents					
Technical Positions, Rulemakings, Regulatory Guides	✓	✓†		✓	✓
Quality Assurance Manual and Procedures					
QAM		✓†	✓	✓	✓
QAPs and APs	✓‡	✓†	✓	✓	✓
TOPs	✓	✓†	✓	✓	✓
Administrative/Fiscal Documents					
Operations Plans, Work Plans, Proposals	✓	✓†	✓	✓	✓
Project Plans, Test Plans, Software Validation Plans	✓	✓†	✓	✓	✓†
*Check criteria in Section 4.2.6 to determine if peer review is needed. †Mandatory if AI or milestone, otherwise optional per manager. ‡Required if QAP or AP has safety related, technical, or other content that would benefit from such review.					