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

EFFECTIVITY

Revision 10 of this procedure became effective on August 5, 2005. This procedure consists of the pages and changes listed below.

Page No.	Change No.	Date Effective
1	1	11/04/2005
2-3	0	08/05/2005
4-8	1	11/04/2005

Change 1:
Form numbers were changed: AP-6 to QAP-6, TOP-3 to QAP-3
Trip/Meeting reports added to Table 1.

Supersedes Procedure No. QAP-002, Rev 10, Chg 0, dated 8/5/2005

Prepared by	Date	Approved by	Date
Robert Buel	11/3/2005	[illegible]	11/3/2005

QAP–002 REVIEW OF DOCUMENTS, REPORTS, AND PAPERS

1. PURPOSE

The purpose of this procedure is to establish the methods for planning, performing, and documenting reviews of Geosciences and Engineering Division (Division) documents, reports, papers, plans, and proposals.

For peer reviewers, this procedure reflects the guidance in the "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG–1297. This procedure addresses the requirements of the applicable Division Quality Assurance Manual (QAM), Section 3.

2. RESPONSIBILITY

2.1 Managers are responsible for implementing this procedure for documents prepared in their areas of authority.

2.2 Document authors are responsible for preparing documents for review and for resolving reviewer comments.

2.3 Reviewers are responsible for performing their assigned reviews in accordance with this procedure.

3. REVIEW TYPES

3.1 Technical Review—A review performed by qualified 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.

3.2 Peer Review—A peer review is 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 adequacy of work.

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 should 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 should 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 should receive proportionally more representation on the peer review group.

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

3.4 Concurrence Review—A review that provides general concurrence with the overall approach and presentation of the work being reviewed and provides a basis for consistency among like products. Concurrence reviews are performed by individuals cognizant of the applicable requirements and of the objectives of the work described or performed.

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

- The document satisfies the requirements of the work, methods conform to established practices, and the application of the method is appropriate.
- 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.

3.5 Quality Assurance (QA) Review—A review that verifies the requirements of the QAM and applicable procedures are met and identifies training needs associated with new and revised procedures. QA reviews are conducted by QA staff cognizant of the applicable QA program and procedural requirements.

3.6 Programmatic Review—A review to verify that contractual requirements, objectives, policies, and programmatic requirements are correctly and consistently addressed by the document under review. Programmatic reviews shall be conducted by the cognizant Director, Assistant Director, CNWRA President, Division Vice President, or their designees.

Programmatic reviews verify the following:

- Contractual requirements are complied with.
- Objectives of applicable plans are satisfied.
- General approach, presentation, and clarity are satisfactory.
- Approach, methods, and/or conclusions are consistent with Division policy.
- Copyright restrictions are appropriately addressed.
- Software used is controlled according to TOP–018, Development and Control of Scientific and Engineering Software and validated software is used for regulatory reviews.
- Regulatory requirements are properly applied or incorporated.

3.7 Format Review—A review to verify document format requirements are complied with, 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 cognizant of document style, format, and distribution requirements.

4. DOCUMENT PREPARATION AND REVIEW PROCESS

4.1 Document Submittal for Review

4.1.1 The author shall submit a final draft of the item requiring review to the cognizant manager sufficiently in advance of the due date to allow for word processing, review, reproduction, and distribution.

4.1.2 The manager shall evaluate the final draft and determine whether it is sufficiently developed to begin review. The manager shall identify the technical areas to be covered by reviewers and verify that relevant programmatic objectives are satisfied by the document. The manager shall confirm that, when software was used in developing the report, the software was controlled according to TOP–018, and was validated if the document includes a regulatory review.

4.2 Review Planning

4.2.1 To initiate reviews, the "Document Review Request and Transmittal Control," Form QAP–6, shall be completed, signed, and dated by the manager.

- 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 QAP–6 form.
- Specify any special markings (e.g., predecisional) 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 (i.e., do not use et al.).

4.2.2 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. Other documents may be edited, as determined necessary by the manager.

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 QAP–6 form 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, a peer review may also 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 cognizant technical community regarding the applicability or appropriateness of the alternate means.

- Peer reviews may be conducted on activities as well as documents. While the complete review process will not apply to review of an activity, peer reviews of activities shall be conducted in accordance with Section 5.2 of this procedure.

4.2.5 The manager shall select technical, peer, and/or concurrence reviewers when required using the criteria described in Section 3 and shall identify the reviewers on the QAP–6 form.

4.3 Reviews and Comment Resolution

4.3.1 Documents should be routed to reviewers in the order listed on the QAP–6 form. 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 should be obtained 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. 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 QAP–3 form in the "reviewer signature" block.

4.3.4 The author or other designated responder shall provide a response to each comment and shall sign the "responder signature" block on each QAP–3 form.

4.3.5 After comment resolution and changes to the document have been incorporated and checked by the author, the revised document, comment resolution records, and the QAP–6 form shall be returned to the reviewer. If acceptable, the reviewer shall

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

4.3.6 After the QAP–6 form has been signed-off by all reviewers, a "verification of compliance with QAP–002" shall be performed by QA staff or a person acting in that capacity. 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.
- QAP–3 forms are complete.
- Software used is properly controlled according to TOP–018, and validated software is used for regulatory reviews.

5. SPECIFIC REVIEW METHODS

5.1 Technical Review

5.1.1 The manager shall identify the technical review criteria applicable to the work being reviewed by checking the appropriate blocks on Form QAP–12, "Instructions to Technical Reviewers." Instructions to technical reviewers shall be approved by the cognizant Assistant Director. When multiple reviewers are needed to cover the full scope of work, separate instructions should be prepared for each reviewer.

5.1.2 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 the QAP–3 form or shall be attached to it.

5.1.3 After completing the review, the technical reviewer shall indicate that all review criteria identified have been addressed by initialing the "Instructions to Technical Reviewers" form in the box adjacent to the selected review criteria under "Accomplished."

5.2 Peer Review

5.2.1 When a peer review is necessary, the manager shall identify those peer review issues applicable to the work being reviewed by checking the appropriate blocks of Form QAP–13, "Instructions to Peer Reviewers." Instructions to peer reviewers shall be approved by the responsible Assistant Director.

5.2.2 After completion of the peer review, reviewer comments; minutes of Peer Review Group meetings and telephone conference records, as applicable; and peer review report(s) shall be prepared and presented to the author of the work being reviewed. Responses to peer review comments shall be documented, and the document under review shall be revised as necessary. Appropriate resolution of peer review comments shall be verified by the cognizant director and documented by initialing and dating the QAP–6 form.

6. RECORDS

All items identified as review documentation within this procedure shall be maintained as QA records in accordance with QAP–012, Quality Assurance Records Control, including, (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) peer review reports, and (vii) peer review responses.

Table 1. Review Requirements Matrix

Document Type	Technical	Editorial	Concurrence	QA	Programmatic	Format
Technical Documents						
Technical Reports, Software Requirements Descriptions, Software Validation Reports, Annual Reports Trip/Meeting 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, APs		✓*	✓	✓	✓	✓
TOPs	✓	✓*		✓	✓	✓
Administrative/Fiscal Documents						
Operations Plans, Work Plans, Proposals	✓	✓*	✓	✓	✓	✓
Project Plans, Test Plans, Software Validation Plans	✓	✓*		✓	✓	✓*

*Mandatory if AI or milestone, otherwise optional per manager.