

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE		Proc. <u>QAP-002</u> Revision <u>9</u> Change <u>0</u> Page <u>1</u> of <u>9</u>	
Title: QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS, AND PAPERS			
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Approvals			
Written by	Date	Concurrence Review	Date
/s/Robert Brient	8/12/2004	/s/Budhi Sagar	8/13/2004
Quality Assurance	Date	Cognizant Director	Date
/s/Mark Ehnstrom	8/12/2004	/s/Patrick Mackin	8/12/2004

<p>CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES</p> <p>QUALITY ASSURANCE PROCEDURE</p>	<p>Proc. QAP-002</p> <p>Revision <u>9</u> Chg <u>0</u></p> <p>Page <u>2</u> of <u>9</u></p>
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QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS, AND PAPERS

1. PURPOSE

The purpose of this procedure is to establish the methods for planning, performing, and documenting reviews of Center for the Nuclear Waste Regulatory Analyses (CNWRA) documents, reports, papers, plans, and proposals. Deliverable documents, as well as revisions and changes to previously submitted documents, shall be reviewed in accordance with this procedure.

For peer reviewers, this procedure reflects the guidance in the "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, and implements CNWRA Quality Assurance Manual (CQAM), Section 3.

2. RESPONSIBILITY

- 2.1 Managers having responsibility for CNWRA documents and deliverables are responsible for implementing this procedure.
- 2.2 Reviewers are responsible for performing their assigned reviews in accordance with this procedure.
- 2.3 Document authors are responsible for preparing document packages for review and for resolving reviewer comments.

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.
- 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. In contrast to Peer Review, the term "Technical Review" refers to verification of compliance to predetermined requirements, industry standards, or common scientific, engineering, or industry practice.

Peer reviewers shall have technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree 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.

<p>CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES</p> <p>QUALITY ASSURANCE PROCEDURE</p>	<p>Proc. QAP-002</p> <p>Revision <u>9</u> Chg <u>0</u></p> <p>Page <u>3</u> of <u>9</u></p>
--	---

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 waste isolation 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 any 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 qualified persons knowledgeable of the CNWRA Editorial Style Guide. SwRI Publications 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 permanent 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 of the CNWRA. Concurrence reviews are performed by individuals cognizant of the applicable technical and procedural 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 technical 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 Review—A review that verifies the requirements of the CNWRA Quality Assurance Manual and applicable procedures are met. Quality Assurance Reviews are conducted by Quality Assurance staff cognizant of the applicable quality assurance program and procedural requirements.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-002

Revision 9 Chg 0

Page 4 of 9

- 3.6 CNWRA Programmatic Review—A review to verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review. CNWRA Programmatic Reviews are conducted by the cognizant CNWRA director, Deputy Technical Director for Systems Engineering and Integration, President, or their designees.

CNWRA Programmatic Reviews verify the following:

- Contractual requirements are complied with.
- Objectives of applicable CNWRA plans are satisfied.
- General approach, presentation, and clarity are satisfactory.
- Approach, methods, and/or conclusions are consistent with CNWRA policy.
- Copyright restrictions are appropriately addressed.
- Software used is controlled according to TOP-018, 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, internal and NRC document distribution requirements are met, and spelling is correct. 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 final drafts of items 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 each item to be reviewed 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, Development and Control of Scientific and Engineering Software, and was validated if the document includes a regulatory review.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-002

Revision 9 Chg 0

Page 5 of 9

4.2 Review Planning

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

- The document type shall be one of the review item categories identified in Table 1, Review Requirements Matrix.
- From the Review Requirements Matrix, the manager shall check the required review types on the AP-6 form.
- The manager shall specify any special markings (e.g., predecisional) required for the document.

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

4.2.3 In addition to a Technical Review, a Peer Review 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 Quality Assurance program (see QAP-015 "Qualification of Existing Data")].

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-002 Revision <u>9</u> Chg <u>0</u> Page <u>6</u> of <u>9</u>
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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	✓	✓			✓	✓
Papers/Presentations						
Journal Articles Proceedings Abstracts Conference Papers Posters	✓	✓*			✓	
Guidance Documents						
Technical Positions Rulemakings Regulatory Guides	✓	✓*			✓	✓
Quality Assurance Manual and Procedures						
CQAM, QAPs, APs		✓*	✓	✓	✓	✓
TOPs	✓	✓*		✓	✓	✓
Administrative/Fiscal Documents						
Operations Plans Work Plans Proposals	✓	✓*	✓	✓	✓	✓
Project Plans Test Plans Software Validation Plans	✓	✓*		✓	✓	✓

* Mandatory if a milestone, otherwise optional per the cognizant manager.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-002

Revision 9 Chg 0

Page 7 of 9

- 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.
- 4.2.4 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 AP-6 form.
- 4.2.6 As required by contract, Intermediate and Major Milestone deliverable items shall be edited according to the CNWRA Editorial Style Guide to enhance and improve writing style, grammar, and punctuation and to assure that the writing is effective. Other documents may be edited, as determined necessary by the manager.
- 4.2.7 A Quality Requirements Application Matrix (QRAM) shall be prepared in accordance with QAP-013, Quality Planning if the review involves an operations plan, project plan, or other contractual commitment to work. The QRAM shall be completed and approved prior to initiation of work activities.
- 4.3 Reviews and Comment Resolution
- 4.3.1 Documents should be routed to reviewers in the order of listing on the AP-6 form. Peer Reviews may be conducted after the other required reviews are completed.
- 4.3.2 If NRC staff contributed to the report, their scientific notebooks should be obtained and provided to reviewers, when appropriate.
- 4.3.3 Review comments (except for those from Editorial Reviews) shall be documented using the CNWRA Form TOP-3. Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document. After comments are recorded, reviewers shall sign and date each TOP-3 form in the "Reviewer Signature" block.
- 4.3.4 The author, or other designated responder, shall provide a resolution for each comment and shall confirm this action by signing the "responder signature" block on each TOP-3 form.
- 4.3.5 After comment resolution and changes to the document have been incorporated, the revised document, comment resolution records, and the AP-6 form shall be returned to the reviewers. If acceptable, the reviewers shall

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-002

Revision 9 Chg 0

Page 8 of 9

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

4.3.6 After the AP-6 form has been signed-off by all reviewers, compliance with the provisions of this procedure shall be verified by Quality Assurance 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.
- TOP-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 CNWRA Form QAP-12, "Instructions to Technical Reviewers." Instructions to Technical Reviewers shall be approved by the cognizant director. When multiple reviewers are needed to cover the full scope of work, separate instructions should be prepared for each reviewer, if appropriate.

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 and documented on the TOP-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 (Form QAP-12) 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 the CNWRA Form QAP-13, Instructions to Peer Reviewers. Instructions to Peer Reviewers shall be approved by the cognizant director. The basis of the evaluation shall be the reviewer's expert judgment.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-002

Revision 9 Chg 0

Page 9 of 9

5.2.2 Individual 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 AP-6 form.

6. RECORDS

All items identified as review documentation within this procedure shall be maintained as Quality Assurance Records in accordance with QAP-012, "Quality Assurance Records Control," including:

- Reviewed items
- Document Review Request and Transmittal Control Forms
- Instructions to Technical Reviewers
- Instructions to Peer Reviewers
- Report Review/Comment Resolution Record Forms
- Peer Review Reports
- Peer Review Responses



CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
DOCUMENT REVIEW REQUEST AND TRANSMITTAL CONTROL (REF. QAP-002)

I. DOCUMENT INFORMATION

a. TITLE: _____

b. DOCUMENT TYPE

<input type="checkbox"/> Technical Reports	<input type="checkbox"/> CQAM, QAPs, APs	<input type="checkbox"/> Abstracts*	<input type="checkbox"/> Posters*
<input type="checkbox"/> Guidance Documents	<input type="checkbox"/> TOPs	<input type="checkbox"/> Conference Papers*	<input type="checkbox"/> Presentations*
<input type="checkbox"/> Operations Plans, Proposals	<input type="checkbox"/> Project, Test, Validation Plans	<input type="checkbox"/> Journal Articles*	*Peer Reviewed Y <input type="checkbox"/> N <input type="checkbox"/>

* Conference/Journal Title/
Date/Location/Publisher/City, State: _____

Special Markings : Predecisional: Y ☐ N ☐ Proprietary: Y ☐ N ☐ Other: _____ Licensing Support Network: Y ☐ N ☐

Copyright Permission Required and Obtained: Y ☐ N ☐

c. PROJECT INFORMATION

Project No. _____ Milestone No. _____ Subject Code _____

CNWRA DOCUMENT NO. Y ☐ N ☐ Assigned No. _____ CNWRA 200X-XXX

d. SCHEDULE Today's Date _____ Scheduled Transmittal Date _____

II. RESPONSIBILITIES (Fill in names on each blank line in this section.)

Author(s) _____ Manager _____ Assigned Secretary _____

III. REVIEW (See QAP-002 table 1 for applicable review types.)

Review Types & Reviewers Determined by Manager

	(Manager Signature) <u>Req'd Date</u>	<u>Initials</u>	(Date) <u>Completed</u>
<input type="checkbox"/> TECHNICAL (Attach CNWRA form QAP-12.) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> PEER (Attach CNWRA form QAP-13.) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> EDITORIAL Reviewer: _____	_____	_____	_____
<input type="checkbox"/> CONCURRENCE Reviewer: _____	_____	_____	_____
<input type="checkbox"/> QUALITY ASSURANCE Reviewer: _____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC/COPYRIGHT PERMISSION VERIFIED Reviewer: _____	_____	_____	_____
<input type="checkbox"/> FORMAT Reviewer/Style: _____	_____	_____	_____
_____	_____	_____	_____
Verification of Compliance with QAP-002 _____	_____	_____	_____

CNWRA calculations and analyses supporting this report are documented in Scientific Notebook(s): _____

IV TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Use "Guidelines for Minimum Distribution of CNWRA Correspondence.")

_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES INSTRUCTIONS TO TECHNICAL REVIEWERS

Technical Review Items to Verify

REVIEWER: _____

TITLE: _____

Please perform a Technical Review of the subject document in accordance with CNWRA QAP-002, verifying the specific items identified below. Technical comments shall be documented on the attached Comment Resolution Record and presented to the author for resolution. Initial blanks on right side of page to show completion of assigned review.

Required review completion date: _____

TECHNICAL CORRECTNESS

ACCOMPLISHED

<input type="checkbox"/>	Assumptions are reasonable and documented in sufficient detail that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. (Do not assign if report does not contain data interpretation and analysis.)	<input type="checkbox"/>
<input type="checkbox"/>	Software versions used in analysis are controlled according to TOP-018.	<input type="checkbox"/>
<input type="checkbox"/>	Regulatory reviews are performed using software validated according to TOP-018. Software use is within the range of validation.	<input type="checkbox"/>
<input type="checkbox"/>	Appropriate techniques are used.	<input type="checkbox"/>
<input type="checkbox"/>	Data are appropriate and are properly referenced.	<input type="checkbox"/>
<input type="checkbox"/>	Conclusions are properly supported by correctly interpreted data.	<input type="checkbox"/>

Are there calculations?

YES

☐

NO

☐

If yes, are "over checks" required? If no "over checks" are required, explain why:

YES

☐

NO

☐

Identify the calculation tools used and over checks needed:

<input type="checkbox"/>	Controlled Software	Check input for accuracy and output for reasonableness.
<input type="checkbox"/>	Uncontrolled Software	Check inputs, perform check calculations (copy of code is required for QA records)
<input type="checkbox"/>	Commercial Off-the-Shelf Software	Check inputs and outputs, check formulae
<input type="checkbox"/>	Other Calculation(s)	Check inputs, perform check calculations

Document these reviews by a statement on TOP-3 form explaining which calculations were checked, and how they were checked. Attach verification calculation, in accordance with Section 3.2.5 of QAP-014.

<input type="checkbox"/>	Calculations are correct, documented and verified in accordance with QAP-014, Section 3.2.3.	<input type="checkbox"/>
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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES INSTRUCTIONS TO TECHNICAL REVIEWERS

Technical Review Items to Verify

READABILITY

ACCOMPLISHED

<input type="checkbox"/>	Document is written for the intended audience, with correct grammar and syntax.	<input type="checkbox"/>
<input type="checkbox"/>	Illustrations and tables clearly present basic information and emphasize relationships.	<input type="checkbox"/>

CONTENT AND FORMAT

ACCOMPLISHED

<input type="checkbox"/>	Title reflects the objectives of the document.	<input type="checkbox"/>
<input type="checkbox"/>	Abstract states purpose, describes study, and summarizes the pertinent results and conclusions.	<input type="checkbox"/>
<input type="checkbox"/>	Introduction states the objectives and scope of the work and presents background information.	<input type="checkbox"/>
<input type="checkbox"/>	Body of the manuscript is logically organized and presents the basic information.	<input type="checkbox"/>
<input type="checkbox"/>	Conclusions and results summarize the principal findings and address each of the objectives of the work.	<input type="checkbox"/>
<input type="checkbox"/>	References are cited in the text and in the references section.	<input type="checkbox"/>
<input type="checkbox"/>	Costs and financial tables are included and agree with text.	<input type="checkbox"/>
MANAGER	DATE	COGNIZANT DIRECTOR
		DATE

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES



INSTRUCTIONS TO PEER REVIEWERS

TO: _____
Reviewer

SUBJECT: Review of: _____

Reference: QAP-002

ISSUES TO EVALUATE

- _____ The validity of assumptions.
- _____ Appropriateness and limitations of methodology and procedures.
- _____ Adequacy and appropriateness of application.
- _____ Uncertainty of results, and consequences if the results are incorrect.
- _____ Alternate interpretations (of the results).
- _____ Validity of conditions.

Manager

Date

Technical Director

Date

CNWRA REPORT REVIEW / COMMENT RESOLUTION RECORD		PAGE	OF	PAGES
PROJECT NUMBER		DOCUMENT DATE		DOCUMENT NUMBER
TITLE:				
The comments shown below address questions and concerns of a technical and/or programmatic nature which arose in this review. Because of possible implications, they require action and response.		RESPONSE: (Write "accept" and note briefly how comment was incorporated, or give justification if rejected.)		
REVIEWER SIGNATURE:		RESPONDER SIGNATURE:		
DATE:		DATE:		
Response accepted by:		If resolution cannot be achieved, the matter shall be elevated to the next level of authority.		
Signature		Distribution: This completed form shall be maintained in a record file.		
Date				