

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 0

QUALITY ASSURANCE PROCEDURE

Page 1 of 16

Title

REVIEW OF CNWRA DOCUMENTS, REPORTS, PAPERS AND PRESENTATION MATERIALS

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 4-24-90. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	0	4-24-90

SUPERSEDED

Revised by QAP-002-Change 1

Supersedes Procedure No. TOP-002

Approvals

Written By Robert D. Brient <i>Robert D. Brient</i>	Date <i>3/12/90</i>	Technical Review R. E. Engelhardt <i>R. E. Engelhardt</i>	Date <i>3/22/90</i>
Quality Assurance Bruce Habrigo <i>Bruce Habrigo</i>	Date <i>4/5/90</i>	Cognizant Director Henry R. Garcia <i>Henry R. Garcia</i>	Date <i>4/24/90</i>

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 2 of 16

REVIEW OF CNWRA DOCUMENTS, REPORTS, PAPERS AND PRESENTATION MATERIALS

1. PURPOSE

The purpose of this procedure is to establish the methods for planning, performing, and documenting the various types of reviews required for Center documents, reports, papers, and presentation materials. This procedure is developed in conformance with the "Generic Technical Position On Peer Review For High-Level Nuclear Waste Repositories", NUREG-1297.

2. RESPONSIBILITIES

- 2.1 Element Managers are responsible for establishing review routing of documents and for performing Technical and Peer Review planning functions.
- 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 reviewers' comments.

3. DEFINITIONS

- 3.1 Peer - A peer is a person having 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.
- 3.2 Peer Review Group - A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.
- 3.3 Peer Review - A peer review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 3 of 16

A peer review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of 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, and industry practice.

- 3.4 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4. PROCEDURE

4.1 REVIEW REQUIREMENT MATRIX

The Center produces a wide variety of documents, reports, papers, and presentation materials which require specific reviews of their technical, quality assurance, and/or programmatic content and format to applicable criteria. Table 1 provides a listing of items, required reviews, and reference to the applicable paragraph within this procedure prescribing the review method.

4.2 TYPES OF REVIEW

4.2.1 Center Programmatic Review

Center programmatic reviews, performed by Center management, verify that Center contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the report.

4.2.2 QA Programmatic Review

Performed by the Center QA staff, QA reviews verify that the requirements of this procedure, the CQAM and other applicable procedures are met.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 4 of 16

TABLE 1. REVIEW REQUIREMENTS MATRIX

<u>Review Type</u>	<u>Center Programmatic</u>	<u>QA</u>	<u>Technical/ Peer</u>	<u>Concurrence</u>	<u>Format</u>
Reference Paragraph No.	4.3	4.4	4.5	4.6	4.7
<u>Review Item</u>					
<u>Technical Documents:</u>					
Final Reports on Research and Technical Assistance, NUREGS/CRs	X	X	X		X
Letter Reports	X			X	X
<u>Papers/Presentations:</u>					
Journal Articles, Proceedings, Conference Presentation Materials	X		X		
<u>Guidance Documents:</u>					
Draft Technical Positions, Rulemakings, and Regulatory Guides	X	X	X		X
Quarterly Reports: Research	X	X	X		X
<u>QA Program Documents:</u>					
CQAM, QAPs	X	X		X	X
TOPs	X	X	X		X
<u>Administrative/Fiscal Documents:</u>					
Operations Plans	X	X		X	X
Project Plans	X	X	X		X
Administrative Procedures	X			X	X
Program Manager's Periodic Reports	X			X	X

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 5 of 16

4.2.3 Technical Review

Formally planned and fully documented Technical Reviews are performed by individuals technically capable of performing the original work, verifying the technical correctness of the work against established practices.

4.2.4 Peer Review

Conducted by individuals technically capable of performing the original work. Peer Reviews are planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.

4.2.5 Concurrence Review

Concurrence reviews are performed by technically capable individuals cognizant of the applicable technical requirements and objectives of the work being described or being prescribed. These reviews provide general concurrence with the author for the overall approach and presentation of the work being reviewed.

4.2.6 Format Review

Performed by clerical personnel cognizant of correspondence, report, and other document requirements, format reviews verify spelling, grammar, format, and that distribution requirements are met.

4.3 CENTER PROGRAMMATIC REVIEW

4.3.1 Review Planning

No formal planning for Center Programmatic Reviews is required. The document package (item to be reviewed and supporting documentation) shall be routed to the reviewer by the cognizant Element Manager.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 6 of 16

4.3.2 Reviewer Requirements

Center Programmatic reviews shall be conducted by the cognizant Director, Technical Director, or President.

4.3.3 Review Scope

Center Programmatic reviews shall verify the following:

- a) General compliance to contractual requirements.
- b) Review item satisfies the objectives of all applicable Center plans.
- c) The general approach, presentation and clarity of the review item are satisfactory.
- d) The approach, methods and/or conclusions are consistent with Center policy.

4.3.4 Comment Resolution

The reviewer shall present any comments requiring resolution to the author, and shall verify that the review item is revised based on the resolution.

4.3.5 Review Documentation

Center Programmatic Reviews shall be documented by signature of the reviewer on the review package routing label and in the signature block of the finalized document.

4.4 QA PROGRAMMATIC REVIEW

4.4.1 Review Planning

Items requiring QA Programmatic Review shall have routing of the entire review package by the cognizant Element Manager to the Center QA Director. QA reviews shall be conducted after required Technical, Peer, Concurrence, and/or Format reviews have been completed.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 7 of 16

4.4.2 Reviewer Requirements

QA reviews shall be conducted by Center QA staff cognizant of the applicable QA program and procedural requirements.

4.4.3 Review Scope

QA reviews shall verify the following:

- a) Required reviews are conducted in accordance with applicable CQAM, TOP, and QAP requirements; reviewers are properly qualified and review documentation provides objective evidence of proper review performance and resolution of comments.
- b) The review item and supporting documentation provide objective evidence that the work was performed in accordance with applicable CQAM, Operations Plan, Project Plan, TOPs, and QAP requirements.
- c) The review item satisfies applicable content and format requirements.

4.4.4 Comment Resolution

QA review comments requiring resolution shall be documented on CNWRA Form QAP-6, QA Document Review (Quality Implications), and forwarded to the author. The author shall provide responses to the comments, and the reviewer shall indicate concurrence with the responses by signature in the lower right hand block of the form. The reviewer shall verify revision of the review item based on resolution of his comments, if necessary. In cases when satisfactory resolution is not obtained, the Center President shall be final arbiter.

4.4.5 Review Documentation

Documentation of QA reviews shall be by the QA Document Review form and by signature of the Center Director of QA in the appropriate signature block on the final document.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 8 of 16

4.5 TECHNICAL AND PEER REVIEW

4.5.1 Review Planning

Documents requiring Technical/Peer review shall be presented to the cognizant Element Manager, who shall plan for the review, accomplishing the following:

- a) Determine whether a Peer Review is necessary (in addition to the Technical Review), based on the criteria identified in Table 2 and the requirements of applicable Work, Operations, and Project Plans, and the state-of-the-art of methods, measurement precision and accuracy, and data quality within the discipline.
- b) Select reviewers based on the requirements of paragraph 4.5.2.
- c) Provide instructions to reviewers regarding the scope and depth of their reviews.
- d) Schedule the reviews, including, as necessary, peer review group meetings and teleconferences.
- e) Provide to each reviewer the review item and pertinent supporting documentation (review package).

4.5.2 Reviewer Requirements

- a) Individuals performing Technical and Peer Reviews shall have technical qualifications at least equivalent to that required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Peer reviewers additionally cannot have been involved as participants, supervisors, technical reviewers, or advisors in the work being reviewed. Reviewers shall be qualified in accordance with CQAM Section 2.
- b) Peer Reviews shall be conducted by an individual or by a Peer Review Group of sufficient size and composition to span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought, as appropriate. Technical areas more central to

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 9 of 16

TABLE 2. CRITERIA FOR APPLICABILITY OF PEER REVIEWS

- A. A Peer Review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing cannot otherwise be established through testing, alternate calculations, or reference to previously established standards and practices.
- B. In general, the following conditions are indicative of situations in which a Peer Review is required:
- o Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
 - o Decisions or interpretations having significant impact on performance assessment conclusions will be made.
 - o Novel or beyond state-of-the-art testing, plans, and procedures or analyses are or will be utilized.
 - o Detailed technical criteria or standard industry procedures do not exist or are being developed.
 - o Results of tests are not reproducible or repeatable.
 - o Data or interpretations are ambiguous.
 - o Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program.
- C. A Peer Review shall also be used when 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.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 10 of 16

the work to be reviewed should receive proportionally more representation on the Peer Review group.

4.5.3 Technical Review Scope

The Element Manager shall identify those Technical Review items applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12, Instructions to Technical Reviewers (Figure 1). The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practice.

4.5.4. Technical Review Comment Resolution

Technical Review comments requiring resolution shall be identified on CNWRA Form TOP-3, CNWRA Report Review/Comment Resolution Record. In addition, the reviewer shall indicate the status of each of the review items identified in the "Instructions to Technical Reviewers". Editorial comments of a minor nature may be made as marginalia on the reviewer's copy of the report.

The author shall respond to the reviewer's comments, and the reviewer shall indicate concurrence with the responses by signature in the appropriate block in the lower right hand portion of the form. If resolution between the author and reviewer cannot be reached, the Center Technical Director or President shall serve as final arbiter.

4.5.5 Technical Review Documentation

Documentation of Technical Reviews shall include the following:

- a) Review planning documents, including Instructions to Reviewers.
- b) CNWRA Report Review/Comment Resolution Record.
- c) Reviewer qualification documentation.
- d) As applicable, documentation of arbitration of unresolved comments.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 11 of 16

4.5.6 Peer Review Scope

The Element Manager shall identify those Peer Review issues applicable to the work being reviewed by checking the appropriate blocks of CNWRA Form QAP-13, Instructions to Peer Reviewers (Figure 2). The basis of the evaluation shall be the reviewer's expert judgement.

4.5.7 Peer Review Comment Resolution

- a) Individual reviewer's comments, minutes of Peer Review Group meetings and telephone conference records, as applicable, shall be compiled into a Peer Review Report and presented to the author of the work being reviewed. The report shall include a clear description of the work or issue that was peer reviewed, conclusions reached by the peer review process for each of the issues identified in the "Instructions to Peer Reviewers", and individual statements by Peer Review Group members reflecting dissenting views or additional comments, as appropriate.
- b) The author shall respond in writing to each comment requiring resolution. The Peer Review Group shall document concurrence with the resolutions by written memoranda, letters, or teleconference records. If concurrence between the Peer Review Group and author cannot be reached, the Center Technical Director or President shall serve as final arbiter.

The Peer Review Group Chairman shall verify that resolved comments have been incorporated into the finalized document and sign the document in the appropriate signature block.

4.5.8 Technical/Peer Review Documentation

Documentation of Technical and Peer Reviews shall include the following, as applicable:

- a) Review planning documents, including instructions to reviewers.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 12 of 16

- b) Peer Review Reports and supporting documentation (memos, letters, minutes, etc.).
- c) Peer Review comment resolution documentation.
- d) Reviewer qualification documentation.
- e) As applicable, documentation of arbitration of unresolved comments.

4.6 CONCURRENCE REVIEW

4.6.1 Review Planning

Concurrence reviews shall be planned through routing of a review copy of the document to the reviewer by the Element Manager. Beyond those included in this procedure, no specific instructions to the reviewer are required.

4.6.2 Reviewer Qualification

Concurrence reviews shall be conducted by individuals familiar with the technical and programmatic requirements and objectives of the work being planned or described.

4.6.3 Review Scope

Concurrence reviews shall verify the following, as appropriate for the type of document being reviewed:

- a) The document satisfies the technical requirements of the work; methods conform to established practices and the application of the method is appropriate.
- b) The document reads clearly and the presentation is appropriate for the intended audience.
- c) The overall objectives of the work being planned or described are met by the document being reviewed.

4.6.4 Review Comment Resolution

The reviewer shall present any comments requiring resolution to the author, either in writing or verbally. The author

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 13 of 16

shall discuss comments and their resolution with the reviewer. As necessary, the Cognizant Director may be called upon to make the final resolution.

4.6.5 Review Documentation

Concurrence Reviews shall be documented by signature of the reviewer on the final document, indicating concurrence with the approach of the document and with the resolution of comments.

4.7 **FORMAT REVIEW**

4.7.1 Review Planning

Format reviews shall be performed during the preparation of documents, and shall be planned by the individual (clerical personnel) preparing the document. No additional planning is required.

4.7.2 Reviewer Requirements

Format Reviews shall be performed by Center clerical personnel other than the individual preparing the document, familiar with format and distribution requirements of Center documents and correspondence.

4.7.3 Review Scope

Format Reviews shall verify the following:

- a) Spelling, grammar, and general clarity and readability;
- b) Conformance to applicable document format requirements;
- c) Internal and NRC document distribution requirements are met.

5. **RECORDS**

All items identified as review documentation within this procedure shall be classified as QA Records in accordance with CQAM Section 17 and retained in CNWRA files for six years, including:

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 14 of 16

- a) Document Review Package.
- b) QA Document Review Forms.
- c) Review planning documents.
- d) Instructions to Technical Reviewers.
- e) Instructions to Peer Reviewers.
- f) Report Review/Comment Resolution Record Forms.
- g) Peer Review Reports, minutes and teleconference records.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 0

Page 15 of 16

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

INSTRUCTIONS TO TECHNICAL REVIEWERS
Technical Review Items to Verify

TO: _____
Reviewer

Technical Correctness

- Assumptions are reasonable and clearly stated.
- Appropriate techniques are used.*
- Computations are correct, computer programs are verified and documented.
- Conclusions are properly supported by correctly interpreted data.*

* Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.

Readability

- Document is written for the intended audience, with correct grammar, syntax, and a minimum of scientific jargon.
- Illustrations and tables clearly present basic information and emphasize relationships.

Content and Format

- Title reflects the objectives of the document.
- Abstract states purpose, describes study, and summarizes pertinent results and conclusions.
- Introduction states the objectives and scope of the work and presents background information.
- Body of the manuscript is logically organized and presents the basic information.
- Conclusions and results summarize the principal findings and answer each of the objectives of the work.
- References are cited in the text and in the references section.

Element Manager

Date

Cognizant Director

Date

Figure 1

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

Proc. QAP-002
Revision 0
Page 16 of 16

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

TO: _____
Reviewer

**INSTRUCTIONS TO PEER REVIEWERS
Issues to Evaluate**

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

Element Manager

Date

Cognizant Director

Date

Figure 2

Superseded by Chg 1

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

Proc. QAP-002

Revision 1

Page 1 of 15

Title
QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS, PAPERS AND PRESENTATION MATERIALS

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on May 31, 1991. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	5/31/91

SUPERSEDED

Supersedes Procedure No. QAP-002 Rev. 0

Approvals

Written By <i>Robert Burt</i>	Date <i>5/28/91</i>	Technical Review <i>[Signature]</i>	Date <i>5/30/91</i>
Quality Assurance <i>[Signature]</i>	Date <i>5/31/91</i>	Cognizant Director <i>[Signature]</i>	Date <i>5/31/91</i>

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

Proc. QAP-002

Revision 1

Page 2 of 15

QAP-002 REVIEW OF CNWRA
DOCUMENTS, REPORTS, PAPERS AND PRESENTATION MATERIALS

1. PURPOSE

The purpose of this procedure is to establish the methods for planning, performing, and documenting the various types of reviews required for Center documents, reports, papers, and presentation materials. This procedure is developed in conformance with the "Generic Technical Position On Peer Review For High-Level Nuclear Waste Repositories", NUREG-1297 and implements CQAM Section 3.

2. RESPONSIBILITIES

- 2.1 Element Managers are responsible for implementation of 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 reviewers' comments.

3. DEFINITIONS

- 3.1 Concurrence Reviews - Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide a basis for consistency among like products of the Center. Concurrence reviews are performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed.
- 3.2 Peer - A peer is a person having 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.
- 3.3 Peer Review Group - A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 1

QUALITY ASSURANCE PROCEDURE

Page 3 of 15

3.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of 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, and industry practice.

3.5 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4. PROCEDURE

Center Technical Documents, Papers and Presentation Materials, Guidance Documents, QA Program Documents, and Administrative/Fiscal Documents shall receive, as applicable, Format, Technical/Peer, Concurrence, Programmatic, and QA Reviews in accordance with this procedure.

4.1 INITIATION OF REVIEWS

(a) Authors/Analysts shall submit completed items requiring review to the cognizant Element Manager, along with any supporting documentation needed to perform the review (Scientific Notebooks, calculation verifications, etc.).

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 1

Page 4 of 15

- (b) The author shall also provide information for initiating the "Document Review and Transmittal Control", Form AP-6, (Figure 1). The Document type shall be one of the review item categories identified in Table 1, Review Requirements Matrix.
- (c) From the Review Requirements Matrix, the Element Manager shall check the required review types on the AP-6 form.
- (d) A Peer Review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is required:
- Critical interpretations or decisions will be made in the face of significant uncertainty or subjective judgement, including the planning for data collection, research, or testing;
 - Interpretations having significant impact on licensing decisions 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;

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

Proc. QAP-002
Revision 1
Page 5 of 15

TABLE 1. REVIEW REQUIREMENTS MATRIX

Review Type	<u>Format</u> 4.2	Technical/ <u>Peer</u> 4.3/4.4	<u>Concurrence</u> 4.5	Center <u>Programmatic</u> 4.6	<u>QA</u> 4.7
<u>Technical Documents:</u>					
Final Reports on Research and Technical Assistance, NUREGS/CRs	X	X		X	X
Research Quarterly Reports:	X	X		X	X
Letter Reports	X		X	X	
PADB Documents		X	X		X
<u>Papers/Presentations:</u>					
Journal Articles, Proceedings, Conference Presentation Materials		X		X	
<u>Guidance Documents:</u>					
Draft Technical Positions, Rulemakings, and Regulatory Guides	X	X		X	X
<u>QA Program Documents:</u>					
CQAM, QAPs	X		X	X	X
TOPs	X	X		X	X
<u>Administrative/Fiscal Documents:</u>					
Operations Plans	X		X	X	X
Project Plans	X	X		X	X
Administrative Procedures	X		X	X	
Program Manager's Periodic Reports	X		X	X	

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

Proc. QAP-002

Revision 1

Page 6 of 15

• Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program (see QAP-014 "Qualification of Existing Data").

- (e) A Peer Review shall also be used when 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.
- (f) If Technical, Peer, or Concurrence reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 4.3.2 and 4.4.2, and identify them on the AP-6 form.
- (g) If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 4.3(c) and 4.4(c). Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.
- (h) Review items, the AP-6 form, and supporting documentation shall be routed for reviews in the order of listing on the AP-6 form, however, Technical, Concurrence, and Programmatic reviews may be conducted simultaneously. Instructions to reviewers shall also be provided to Technical and Peer Reviewers, as applicable. Any comments shall be resolved as specified below, and the AP-6 form shall be initialled and dated by the reviewer before proceeding for the next specified review.

4.2 FORMAT REVIEWS

- (a) Format Reviews shall be performed by personnel cognizant of correspondence, report and other document requirements.

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

Proc. QAP-002

Revision 1

Page 7 of 15

(b) Format Reviews shall verify the following:

- Spelling, grammar, and general clarity and readability;
- Conformance to applicable document format requirements;
- Internal and NRC document distribution requirements, as applicable, are met.

4.3 TECHNICAL REVIEWS

- (a) Formally planned and fully documented Technical Reviews shall be performed to verify the technical correctness of the work against established practices.
- (b) Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with CQAM Section 2.
- (c) The Element Manager shall identify those Technical Review items applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12, Instructions to Technical Reviewers (Figure 2). Instructions to Technical Reviewers shall be approved by the cognizant Director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practice.
- (d) Technical Review comments requiring resolution and the status of each of the review items identified in the Instructions to Technical Reviewers shall be identified on CNWRA Form TOP-3, CNWRA Report Review/Comment Resolution Record, (Figure 3). Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 1

Page 8 of 15

- (e) 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 attached to it.
- (f) The author shall respond to the reviewer's comments, and the reviewer shall indicate concurrence with the responses by signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the Center Technical Director or President shall serve as final arbiter.

4.4 PEER REVIEWS

- (a) Peer Reviews shall be conducted by individuals technically capable of performing the original work. Peer Reviews shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.
- (b) In addition to having qualifications equivalent to Technical Reviewers (paragraph 4.3.2), Peer Reviewers cannot have been involved as participants, supervisors, technical reviewers, or advisors in the work being reviewed. Peer Reviews shall be conducted by an individual or by a Peer Review Group of sufficient size and composition to span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought, as appropriate. Technical areas more central to the work to be reviewed should receive proportionally more representation on the Peer Review group.
- (c) The Element Manager shall identify those Peer Review issues applicable to the work being reviewed by checking the appropriate blocks of CNWRA Form QAP-13, Instructions to Peer Reviewers (Figure 4). Instructions to Peer Reviewers shall be approved by the cognizant Director. The basis of the evaluation shall be the reviewer's expert judgement.

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

Proc. QAP-002
Revision 1
Page 9 of 15

- (d) Individual reviewer's comments, minutes of Peer Review Group meetings and telephone conference records, as applicable, shall be compiled into a Peer Review Report and presented to the author of the work being reviewed. The report shall include a clear description of the work or issue that was peer reviewed, conclusions reached by the Peer Review process for each of the issues identified in the Instructions to Peer Reviewers, and individual statements by Peer Review Group members reflecting dissenting views or additional comments, as appropriate.
- (e) The author shall respond in writing to each comment requiring resolution. The Peer Review Group shall document concurrence with the resolutions by written memoranda, letters, or teleconference records. If concurrence between the Peer Review Group and author cannot be reached, the Center Technical Director or President shall serve as final arbiter.
- (f) The Peer Review Group Chairman shall verify that resolved comments have been incorporated into the finalized document.

4.5 CONCURRENCE REVIEWS

- (a) Concurrence reviews shall be performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed. These reviews provide general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide a basis for consistency among like products of the Center.
- (b) Concurrence reviews shall verify 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;

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

Proc. QAP-002

Revision 1

Page 10 of 15

- 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.
- (c) Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, CNWRA Report Review/Comment Resolution Record. Editorial comments of a minor nature may be made as marginalia on the reviewer's copy of the report.
- (d) The author shall respond to the reviewer's comments, and the reviewer shall indicate concurrence with the responses by signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the Center Technical Director or President shall serve as final arbiter.

4.6 CENTER PROGRAMMATIC REVIEWS

- (a) Center programmatic reviews, performed by Center management, verify that Center contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the report.
- (b) Center Programmatic reviews shall be conducted by the cognizant Director, Technical Director, or President.
- (c) Center Programmatic reviews shall verify the following:
- General compliance to contractual requirements;
 - Review item satisfies the objectives of all applicable Center plans;
 - The general approach, presentation and clarity of the review item are satisfactory;
 - The approach, methods and/or conclusions are consistent with Center policy.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002
Revision 1
Page 11 of 15

- (d) The reviewer shall present any comments requiring resolution to the author, and shall verify that the review item is revised based on the resolution.

4.7 QA PROGRAMMATIC REVIEWS

- (a) Performed by the Center QA staff, QA reviews verify that the requirements of this procedure, the CQAM and other applicable procedures are met.
- (b) QA reviews shall be conducted by Center QA staff cognizant of the applicable QA program and procedural requirements.
- (c) QA reviews shall verify the following:
- Required reviews are conducted in accordance with applicable CQAM, TOP, and QAP requirements;
 - The review item and supporting documentation provide objective evidence that the work was performed in accordance with applicable CQAM, Operations Plan, Project Plan, TOPs, and QAP requirements;
 - The review item satisfies applicable content and format requirements.
- (d) QA review comments requiring resolution shall be documented on CNWRA Form QAP-6, QA Document Review (Figure 5), and forwarded to the author. The author shall provide responses to the comments, and the reviewer shall indicate concurrence with the responses by signature in the lower left hand block of the form. The reviewer shall verify revision of the review item based on resolution of his comments, if necessary. In cases when satisfactory resolution is not obtained, the Center President shall be final arbiter.

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

Proc. QAP-002

Revision 1

Page 12 of 15

5. RECORDS

All items identified as review documentation within this procedure shall be maintained as QA Records in accordance with CQAM Section 17 and retained for six years, including:

- Document Review Package;
- QA Document Review Forms;
- Document Review Request and Transmittal Control Forms;
- Instructions to Technical Reviewers;
- Instructions to Peer Reviewers;
- Report Review/Comment Resolution Record Forms;
- Peer Review Reports, minutes and teleconference records.

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

Proc. QAP-002
Revision 1
Page 13 of 15

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

ELEMENT MANAGER: **COMPLETE AS REQUIRED**

AUTHOR: _____

DOCUMENT TITLE: _____

DOCUMENT TYPE: _____

CONTROLLED UNCONTROLLED

PROJECT: _____ MILESTONE NUMBER: _____ SUBJECT CODE: _____

TODAY'S DATE: _____ SCHEDULED TRANSMITTAL DATE: _____

REVIEW TYPES: Check only those that are applicable.
Affix reviewer name(s) as required.

	Req'd Date	Review Complete	
		Initials	Date
<input type="checkbox"/> FORMAT	_____	_____	_____
<input type="checkbox"/> TECHNICAL (Attach CNWRA QAP Form 12-1)	_____	_____	_____
<input type="checkbox"/> PEER (Attach CNWRA QAP Form 13)	_____	_____	_____
_____	_____	_____	_____
<input type="checkbox"/> CONCURRENCE	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC	_____	_____	_____
<input type="checkbox"/> QA	_____	_____	_____

TRANSMITTAL
TO: _____ FROM: _____

COPIES TO: (Please add / delete names as required.)
 Standard Distribution (listed below).
 Sharon Mearse _____
 Jesse Funches _____
 Shirley Fortuna _____
 Barbara Stiltenspole _____
 Sharon Rowe _____
 John Latz _____
 CNWRA Directors _____
 CNWRA Element Managers _____

CNWRA FORM AP-6 (12/90)

Figure 1

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

Proc. QAP-002

Revision 1

Page 14 of 15



**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
INSTRUCTIONS TO TECHNICAL REVIEWERS
Technical Review Items to Verify**

TO: _____

SUBJECT: Review of _____

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 as specified by QAP-002, paragraph 4.5.4.

Required review completion date: _____

TECHNICAL CORRECTNESS

- Assumptions are reasonable and clearly stated.
- Appropriate techniques are used.*
- Computations are correct, calculations are documented and verified in accordance with QAP-014.
- Existing data are qualified (or exempted) in accordance with QAP-015.
- Conclusions are properly supported by correctly interpreted data.*

** Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.*

READABILITY

- Document is written for the intended audience, with correct grammar, syntax, and a minimum of scientific jargon.
- Illustrations and tables clearly present basic information and emphasize relationships.

CONTENT AND FORMAT

- Title reflects the objectives of the document.
- Abstract states purpose, describes study, and summarizes the pertinent results and conclusions.
- Introduction states the objectives and scope of the work and presents background information.
- Body of the manuscript is logically organized and presents the basic information.
- Conclusions and results summarize the principal findings and answer each of the objectives of the work.
- References are cited in the text and in the references section.

ELEMENT MANAGER

DATE:

COGNIZANT DIRECTOR

DATE:

CNWRA FORM QAP-12-2 (Rev. 5/91)

Figure 2

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

Proc. QAP-002 _____
Revision 1
Page 15 of 15

**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 conclusions.

Element Manager Date

Cognizant Director Date

CNWRA Form QAP-13-1 (Rev. 5/91)

Figure 3

Superseded by Rev. 1, Chg 2

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

Proc. QAP-002
Revision 1, Chg 1
Page 1 of 15

Title
QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS, PAPERS AND PRESENTATION MATERIALS

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on May 31, 1991. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	1	6/14/91
2 - 14	0	5/31/91
14A, 15, 15A	1	6/14/91

SUPERSEDED

Supersedes Procedure No. QAP-002 Rev. 1, Change 0

Approvals

Written By <i>Robert Burt</i>	Date <i>6/11/91</i>	Technical Review <i>Wesley Petrus</i>	Date <i>6/12/91</i>
Quality Assurance <i>Donna Malin</i>	Date <i>6/14/91</i>	Cognizant Director <i>[Signature]</i>	Date <i>6/14/91</i>

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

Proc. QAP-002
Revision 1, Chg 1
Page 15 of 15

**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 conclusions.

Element Manager Date

Cognizant Director Date

CNWRA Form QAP-13-1 (Rev. 5/91)

Figure 4

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 1, Chg 2

Page 1 of 15

Title

QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS, PAPERS AND PRESENTATION MATERIALS

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on May 31, 1991. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	1	6/14/91
2	0	5/31/91
3 - 86 LWS 8/28/91	2	8/14/91
7, 8 - 14 LWS 8/28/91	0	5/31/91
14A, 15, 15A	1	6/14/91

*Superseded by Revision 2, Change 0.
5/1/92*

SUPERSEDED

Supersedes Procedure No. QAP-002 Rev. 1, Change 1

Approvals

Written By <i>Robert Buent</i>	Date <i>8/13/91</i>	Technical Review <i>Walter P. [Signature]</i>	Date <i>8/14/91</i>
Quality Assurance <i>[Signature]</i>	Date <i>8/14/91</i>	Cognizant Director <i>[Signature]</i>	Date <i>8/14/91</i>

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 1, Chg 2

Page 3 of 15

- 3.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of 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, and industry practice.

- 3.5 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4. PROCEDURE

Center Technical Documents, Papers and Presentation Materials, Guidance Documents, QA Program Documents, and Administrative/Fiscal Documents shall receive, as applicable, Format, Technical/Peer, Concurrence, Programmatic, and QA Reviews in accordance with this procedure. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall likewise be reviewed in accordance this procedure.

4.1 INITIATION OF REVIEWS

- (a) Authors/Analysts shall submit completed items requiring review to the cognizant Element Manager, along with any supporting documentation needed to perform the review (Scientific Notebooks, calculation verifications, etc.).

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 1, Chg 2

Page 4 of 15

- (b) The author shall also provide information for initiating the "Document Review and Transmittal Control", Form AP-6, (Figure 1). The Document type shall be one of the review item categories identified in Table 1, Review Requirements Matrix.
- (c) From the Review Requirements Matrix, the Element Manager shall check the required review types on the AP-6 form. For revisions and changes to previously submitted documents, the AP-6 form shall specify reviews commensurate with the extent of the revision/change, along with a brief justification for any reviews less than specified in the Review Requirements Matrix.
- (d) A Peer Review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is required:
- Critical interpretations or decisions will be made in the face of significant uncertainty or subjective judgement, including the planning for data collection, research, or testing;
 - Interpretations having significant impact on licensing decisions 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;

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

Proc. QAP-002
Revision 1, Chg 2
Page 5 of 15

TABLE 1. REVIEW REQUIREMENTS MATRIX

Review Type	<u>Format</u> 4.2	Technical/ <u>Peer</u> 4.3/4.4	<u>Concurrence</u> 4.5	Center <u>Programmatic</u> 4.6	<u>QA</u> 4.7
<u>Technical Documents:</u>					
Reports on Research and Technical Assistance, NUREGS/CRs	X	X		X	X
Research Quarterly Reports:	X	X		X	X
Letter Reports	X		X	X	
PADB Documents		X	X		X
<u>Papers/Presentations:</u>					
Journal Articles, Proceedings, Conference Presentation Materials		X		X	
<u>Guidance Documents:</u>					
Draft Technical Positions, Rulemakings, and Regulatory Guides	X	X		X	X
<u>QA Program Documents:</u>					
CQAM, QAPs	X		X	X	X
TOPs	X	X		X	X
<u>Administrative/Fiscal Documents:</u>					
Operations Plans	X		X	X	X
Project Plans	X	X		X	X
Administrative Procedures	X		X	X	
Program Manager's Periodic Reports	X		X	X	

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

Proc. QAP-002

Revision 1, Chg 2

Page 6 of 15

- Data or interpretations are ambiguous;
- Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program (see QAP-014 "Qualification of Existing Data").

- (e) A Peer Review shall also be used when 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.
- (f) If Technical, Peer, or Concurrence reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 4.3.2 and 4.4.2, and identify them on the AP-6 form.
- (g) If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 4.3(c) and 4.4(c). Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.
- (h) Review items, the AP-6 form, and supporting documentation shall be routed for reviews in the order of listing on the AP-6 form, however, Technical, Concurrence, and Programmatic reviews may be conducted simultaneously. Instructions to reviewers shall also be provided to Technical and Peer Reviewers, as applicable. Any comments shall be resolved as specified below, and the AP-6 form shall be initialled and dated by the reviewer before proceeding for the next specified review.

4.2 FORMAT REVIEWS

- (a) Format Reviews shall be performed by personnel cognizant of correspondence, report and other document requirements.

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

Proc. QAP-002

Revision 1, Chg 2

Page 3 of 15

- 3.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of 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, and industry practice.

- 3.5 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4. PROCEDURE

Center Technical Documents, Papers and Presentation Materials, Guidance Documents, QA Program Documents, and Administrative/Fiscal Documents shall receive, as applicable, Format, Technical/Peer, Concurrence, Programmatic, and QA Reviews in accordance with this procedure. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall likewise be reviewed in accordance this procedure.

4.1 INITIATION OF REVIEWS

- (a) Authors/Analysts shall submit completed items requiring review to the cognizant Element Manager, along with any supporting documentation needed to perform the review

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 1, Chg 2

Page 4 of 15

(Scientific Notebooks, calculation verifications, etc.).

- (b) The author shall also provide information for initiating the "Document Review and Transmittal Control", Form AP-6, (Figure 1). The Document type shall be one of the review item categories identified in Table 1, Review Requirements Matrix.
- (c) From the Review Requirements Matrix, the Element Manager shall check the required review types on the AP-6 form. For revisions and changes to previously submitted documents, the AP-6 form shall specify reviews commensurate with the extent of the revision/change, along with a brief justification for any reviews less than specified in the Review Requirements Matrix.
- (d) A Peer Review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is required:
- Critical interpretations or decisions will be made in the face of significant uncertainty or subjective judgement, including the planning for data collection, research, or testing;
 - Interpretations having significant impact on licensing decisions 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;

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

Proc. QAP-002

Revision 2

Page 1 of 17

Title

Review of CNWRA Documents, Reports and Papers

EFFECTIVITY AND APPROVAL

Revision 2 of this procedure became effective on May 1, 1992. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
A11	0	05/01/92

SUPERSEDED by Revision 3, Change 0
12/15/92

Supersedes Procedure No. QAP-002, Rev. 1

Approvals

Written By <i>Bob Brient</i> Bob Brient	Date <i>5/1/92</i> 5/1/92	Technical Review <i>Bruce E. Mabrito</i> Bruce E. Mabrito	Date <i>5/1/92</i> 5/1/92
Quality Assurance <i>Bruce E. Mabrito</i> Bruce E. Mabrito	Date <i>5/1/92</i> 5/1/92	Cognizant Director <i>Wesley C. ...</i> Wesley C. ...	Date <i>5/1/92</i> 5/1/92

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

Proc. QAP-002

Revision 2

Page 2 of 17

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 the various types of reviews required for Center documents, reports, and papers. This procedure is developed in conformance with the "Generic Technical Position On Peer Review For High-Level Nuclear Waste Repositories", NUREG-1297 and implements CQAM Section 3.

2. RESPONSIBILITIES

- 2.1 Element Managers are responsible for implementation of 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 reviewers' comments.

3. DEFINITIONS

- 3.1 Concurrence Reviews - Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide a basis for consistency among like products of the Center. Concurrence reviews are performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed.
- 3.2 Peer - A peer is a person having 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.
- 3.3 Peer Review Group - A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 3 of 17

- 3.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of 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, and industry practice.

- 3.5 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4. PROCEDURE

Center Technical Documents, Papers and Presentation Materials, Guidance Documents, QA Program Documents, and Administrative/Fiscal Documents shall receive, as applicable, Format, Technical/Peer, Concurrence, Programmatic, and QA Reviews in accordance with this procedure. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall likewise be reviewed in accordance with this procedure.

4.1 INITIATION OF REVIEWS

- (a) The Author/Analyst shall submit completed items requiring review to the cognizant Element Manager, along with any supporting documentation needed to perform the review (Scientific Notebooks, calculation verifications, etc.).

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 4 of 17

- (b) The author shall also provide information for initiating the "Document Review and Transmittal Control", Form AP-6, (Figure 1). The document type shall be one of the review item categories identified in Table 1, Review Requirements Matrix.
- (c) From the Review Requirements Matrix, the Element Manager shall check the required review types on the AP-6 form. For revisions and changes to previously submitted documents, the AP-6 form shall specify reviews commensurate with the extent of the revision/change, along with a brief justification for any reviews less than specified in the Review Requirements Matrix.
- (d) A Peer Review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is required:
- Critical interpretations or decisions will be made in the face of significant uncertainty or subjective judgement, including the planning for data collection, research, or testing;
 - Interpretations having significant impact on licensing decisions 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;

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 5 of 17

TABLE 1. REVIEW REQUIREMENTS MATRIX

Review Type	<u>Format</u> 4.2	<u>Technical/ Peer</u> 4.3/4.4	<u>Concurrence</u> 4.5	<u>Center Programmatic</u> 4.6	<u>QA</u> 4.7
<u>Reference</u>					
<u>Technical Documents:</u>					
Reports on Research and Technical Assistance, NUREGS/CRs	X	X		X	X
Research Semi-Annual Reports:	X	X		X	X
PADB Documents		X	X		X
<u>Papers/Presentations:</u>					
Journal Articles, Proceedings, Conference Papers		X		X	
<u>Guidance Documents:</u>					
Draft Technical Positions, Rulemakings, and Regulatory Guides	X	X		X	X
<u>QA Program Documents:</u>					
CQAM, QAPs	X		X	X	X
TOPs	X	X		X	X
<u>Administrative/Fiscal Documents:</u>					
Operations Plans, Work Plans	X		X	X	X
Project Plans, Test Plans	X	X		X	X
Administrative Procedures	X		X	X	
Program Manager's Periodic Reports	X		X	X	

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 6 of 17

- Data or interpretations are ambiguous;
 - Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program (see QAP-014 "Qualification of Existing Data").
- (e) A Peer Review shall also be used when 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.
- (f) If Technical, Peer, or Concurrence reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 4.3(b) and 4.4(b), and identify them on the AP-6 form.
- (g) If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 4.3(c) and 4.4(c). Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.
- (h) Review items, the AP-6 form, and supporting documentation shall be routed for reviews in the order of listing on the AP-6 form, however, Technical, Concurrence, and Programmatic reviews may be conducted simultaneously. Instructions to reviewers shall also be provided to Technical and Peer Reviewers, as applicable. Any comments shall be resolved as specified below, and the AP-6 form shall be initialled and dated by the reviewer before proceeding for the next specified review.

4.2 FORMAT REVIEWS

- (a) Format Reviews shall be performed by personnel cognizant of correspondence, report and other document requirements.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 7 of 17

(b) Format Reviews shall verify the following:

- Spelling, grammar, and general clarity and readability;
- Conformance to applicable document format requirements;
- Internal and NRC document distribution requirements are met, as applicable.

4.3 TECHNICAL REVIEWS

- (a) Formally planned and fully documented Technical Reviews shall be performed to verify the technical correctness of the work against established practices.
- (b) Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with CQAM Section 2.
- (c) The Element Manager shall identify those Technical Review items applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12, Instructions to Technical Reviewers (Figure 2). Instructions to Technical Reviewers shall be approved by the cognizant Director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practices.
- (d) Technical Review comments requiring resolution and the status of each of the review items identified in the Instructions to Technical Reviewers shall be identified on CNWRA Form TOP-3, CNWRA Report Review/Comment Resolution Record, (Figure 3). Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 8 of 17

- (e) 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 attached to it.
- (f) The author shall respond to the reviewer's comments, and the reviewer shall indicate concurrence with the responses by signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the Center Technical Director or President shall serve as final arbiter.

4.4 PEER REVIEWS

- (a) A Peer Review shall be conducted by individuals technically capable of performing the original work. A Peer Review shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.
- (b) In addition to having qualifications equivalent to Technical Reviewers (paragraph 4.3(b)), Peer Reviewers cannot have been involved as participants, supervisors, Technical Reviewers, or advisors in the work being reviewed. A Peer Review shall be conducted by an individual or by a Peer Review Group of sufficient size and composition to span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought, as appropriate. Technical areas more central to the work to be reviewed should receive proportionally more representation on the Peer Review Group.
- (c) The Element Manager shall identify those Peer Review issues applicable to the work being reviewed by checking the appropriate blocks of CNWRA Form QAP-13, Instructions to Peer Reviewers (Figure 4). Instructions to Peer Reviewers shall be approved by the cognizant Director. The basis of the evaluation shall be the reviewer's expert judgement.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 9 of 17

- (d) Individual reviewer's comments, minutes of Peer Review Group meetings and telephone conference records, as applicable, shall be compiled into a Peer Review Report and presented to the author of the work being reviewed. The report shall include a clear description of the work or issue that was peer reviewed, conclusions reached by the Peer Review process for each of the issues identified in the Instructions to Peer Reviewers, and individual statements by Peer Review Group members reflecting dissenting views or additional comments, as appropriate.
- (e) The author shall respond in writing to each comment requiring resolution. The Peer Review Group shall document concurrence with the resolutions by written memoranda, letters, or teleconference records. If concurrence between the Peer Review Group and author cannot be reached, the Center Technical Director or President shall serve as final arbiter.
- (f) The Peer Review Group Chairman shall verify that resolved comments have been incorporated into the final document.

4.5 CONCURRENCE REVIEWS

- (a) A Concurrence Review shall be performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed. This type of review provides general concurrence with the author for the overall approach and presentation of the work being reviewed, and provides a basis for consistency among like products of the Center.
- (b) A Concurrence Review shall verify 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;

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 10 of 17

- 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.
- (c) Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, CNWRA Report Review/Comment Resolution Record. Editorial comments of a minor nature may be made as marginalia on the reviewer's copy of the report.
- (d) The author shall respond to the reviewer's comments, and the reviewer shall indicate concurrence with the responses by signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the Center Technical Director or President shall serve as final arbiter.

4.6 CENTER PROGRAMMATIC REVIEWS

- (a) A Center Programmatic Review, performed by Center management, verifies that Center contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the report.
- (b) A Center Programmatic Review shall be conducted by the cognizant Director, Technical Director, or President.
- (c) A Center Programmatic Review shall verify the following:
- General compliance to contractual requirements;
 - Review item satisfies the objectives of all applicable Center plans;
 - The general approach, presentation and clarity of the review item are satisfactory;
 - The approach, methods and/or conclusions are consistent with Center policy.

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

Proc. QAP-002

Revision 2

Page 11 of 17

- (d) The reviewer shall present any comments requiring resolution to the author, and shall verify that the review item is revised based on the resolution.

4.7 QA PROGRAMMATIC REVIEWS

- (a) Performed by the Center QA staff, a QA Review verifies that the requirements of this procedure, the CQAM and other applicable procedures are met.
- (b) A QA Review shall be conducted by Center QA staff cognizant of the applicable QA program and procedural requirements.
- (c) A QA Review shall verify the following:
- Required reviews are conducted in accordance with applicable CQAM, TOP, and QAP requirements;
 - The review item and supporting documentation provide objective evidence that the work was performed in accordance with applicable CQAM, Operations Plan, Project Plan, TOPs, and QAP requirements;
 - The review item satisfies applicable content and format requirements.
- (d) QA Review comments requiring resolution shall be documented on CNWRA Form QAP-6, QA Document Review (Figure 5), and forwarded to the author. The author shall provide responses to the comments, and the reviewer shall indicate concurrence with the responses by signature in the lower left hand block of the form. The reviewer shall verify revision of the review item based on resolution of comments, if necessary. In cases when satisfactory resolution is not obtained, the Center President shall be final arbiter.

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

Proc. QAP-002

Revision 2

Page 12 of 17

5. RECORDS

All items identified as review documentation within this procedure shall be maintained as QA Records in accordance with CQAM Section 17 and retained for six years, including:

- Document Review Package;
- QA Document Review Forms;
- Document Review Request and Transmittal Control Forms;
- Instructions to Technical Reviewers;
- Instructions to Peer Reviewers;
- Report Review/Comment Resolution Record Forms;
- Peer Review Reports, minutes and teleconference records.

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

Proc. QAP-002

Revision 2

Page 13 of 17



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

ELEMENT MANAGER: *COMPLETE AS REQUIRED*

AUTHOR: _____

DOCUMENT TITLE: _____

DOCUMENT TYPE: _____

CONTROLLED UNCONTROLLED

PROJECT: _____ MILESTONE NUMBER: _____ SUBJECT CODE: _____

TODAY'S DATE: _____ SCHEDULED TRANSMITTAL DATE: _____

REVIEW TYPES: *Check only those that are applicable.* Review Complete
Affix reviewer name(s) as required. Req'd Date Initials Date

<input type="checkbox"/> FORMAT	_____	_____	_____	_____
<input type="checkbox"/> TECHNICAL(Attach CNWRA QAP Form 12-1)	_____	_____	_____	_____
<input type="checkbox"/> PEER(Attach CNWRA QAP Form 13)	_____	_____	_____	_____
	_____	_____	_____	_____
<input type="checkbox"/> CONCURRENCE	_____	_____	_____	_____
	_____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC	_____	_____	_____	_____
	_____	_____	_____	_____
<input type="checkbox"/> QA	_____	_____	_____	_____
	_____	_____	_____	_____

TRANSMITTAL
TO: _____ FROM: _____

COPIES TO:(Please add/delete names as required.)

<input type="checkbox"/> Standard Distribution (listed below).	_____	_____
Sharon Mearse	_____	_____
Malcolm Knapp	_____	_____
Shirley Fortuna	_____	_____
Barbara Stiltenspoel	_____	_____
Sharon Rowe	_____	_____
John Latz	_____	_____
CNWRA Directors	_____	_____
CNWRA Element Managers	_____	_____
Margaret Federline	_____	_____

CNWRA FORM AP-6.1 (05/92)

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 2

Page 14 of 17

 <p>CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES INSTRUCTIONS TO TECHNICAL REVIEWERS Technical Review Items to Verify</p>			
TO: _____			
SUBJECT: Review of _____			
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.			
Required review completion date: _____			
TECHNICAL CORRECTNESS			
<input type="checkbox"/> Assumptions are reasonable and clearly stated.			
<input type="checkbox"/> Appropriate techniques are used.*			
<input type="checkbox"/> Computations are correct, calculations are documented and verified in accordance with QAP-014.			
<input type="checkbox"/> Existing data are qualified (or exempted) in accordance with QAP-015.			
<input type="checkbox"/> Conclusions are properly supported by correctly interpreted data.*			
* Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.			
READABILITY			
<input type="checkbox"/> Document is written for the intended audience, with correct grammar and syntax.			
<input type="checkbox"/> Illustrations and tables clearly present basic information and emphasize relationships.			
CONTENT AND FORMAT			
<input type="checkbox"/> Title reflects the objectives of the document.			
<input type="checkbox"/> Abstract states purpose, describes study, and summarizes the pertinent results and conclusions.			
<input type="checkbox"/> Introduction states the objectives and scope of the work and presents background information.			
<input type="checkbox"/> Body of the manuscript is logically organized and presents the basic information.			
<input type="checkbox"/> Conclusions and results summarize the principal findings and answer each of the objectives of the work.			
<input type="checkbox"/> References are cited in the text and in the references section.			
ELEMENT MANAGER	DATE:	COGNIZANT DIRECTOR	DATE:

CNWRA FORM QAP-12-3 (Rev. 4/92)

Figure 2

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

Proc. QAP-002
Revision 2
Page 16 of 17

**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 conclusions.

Element Manager Date

Cognizant Director Date

CNWRA Form QAP-13-1 (Rev. 5/91)

Figure 4

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 3

QUALITY ASSURANCE PROCEDURE

Page 1 of 17

Title

QAP-002 – Review of CNWRA Documents, Reports, and Papers

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 12/15/92. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
all	0	12/15/92

SUPERSEDED by Revision 4, Chg 0
12/31/92

Supercedes Procedure No. QAP-002, Rev. 2

Approvals

Written By 	Date 12/14/92	Concurrence Review 	Date 12/15/92
Quality Assurance 	Date 12/15/92	Cognizant Director 	Date 12/15/92

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

Proc. QAP-002

Revision 3

Page 2 of 17

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 the various types of reviews required for CNWRA documents, reports, and papers. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall be reviewed in accordance with this procedure. This procedure is developed in conformance with the "Generic Technical Position On Peer Review For High-Level Nuclear Waste Repositories", NUREG-1297 and implements CQAM Section 3.

2. RESPONSIBILITIES

- 2.1 Element Managers are responsible for implementation of 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 reviewers' comments.

3. DEFINITIONS

- 3.1 Concurrence Reviews - Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide 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 being described or being prescribed.
- 3.2 Peer - A peer is a person having 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.
- 3.3 Peer Review Group - A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 3

QUALITY ASSURANCE PROCEDURE

Page 3 of 17

vary in size based on the subject matter and the importance of the subject matter to licensing.

- 3.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer (a) was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and (b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of 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, and industry practice.

- 3.5 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4. DOCUMENT PREPARATION AND REVIEW PROCESS

4.1 Document Submittal for Review

- 4.1.1 The Author/Analyst shall submit completed items requiring review to the cognizant Element Manager sufficiently in advance of the due date to allow for word processing, review, and distribution. The document shall be submitted along with any supporting documentation needed to perform the reviews (Scientific Notebooks, calculation verifications, etc.).

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 3

QUALITY ASSURANCE PROCEDURE

Page 4 of 17

4.1.2 The Element Manager shall review the document and determine i) if editing is necessary and ii) to determine the technical areas covered by the document in order to identify reviewers.

4.1.3 If editing is necessary, it shall be accomplished as a cooperative effort between the author and editor, and shall be accomplished before additional word processing is performed. The objectives of editing are to enhance and improve style and grammar, and to assure that the intent of the writing is effectively communicated.

4.2 Review Planning

4.2.1 The "Document Review Request and Transmittal Control", Form AP-6, (Figure 1) shall be initiated by the Element 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 Element Manager shall check the required review types on the AP-6 form. For revisions and changes to previously submitted documents, reviews are necessary commensurate with the extent of the revision/change. The AP-6 shall include a brief justification for any reviews less than specified in the Review Requirements Matrix.

4.2.2 In addition to a Technical Review, a Peer Review shall be required when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is required:

- Critical interpretations or decisions will be made in the face of significant uncertainty or subjective judgement, including the planning for data collection, research, or testing;

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

Proc. QAP-002

Revision 3

Page 5 of 17

TABLE 1. REVIEW REQUIREMENTS MATRIX

Review Type	<u>Format</u> 4.2	<u>Technical/Peer</u> 4.3/4.4	<u>Concurrence</u> 4.5	<u>Center Programmatic</u> 4.6	<u>QA</u> 4.7
Reference					
<u>Technical Documents:</u>					
Reports on Research and Technical Assistance, NUREGS/CRs	X	X		X	X
Research Semi-Annual Reports:	X	X		X	X
PADB Documents		X	X		X
<u>Papers/Presentations:</u>					
Journal Articles, Proceedings, Conference Papers		X		X	
<u>Guidance Documents:</u>					
Draft Technical Positions, Rulemakings, and Regulatory Guides	X	X		X	X
<u>QA Program Documents:</u>					
CQAM, QAPs	X		X	X	X
TOPs	X	X		X	X
<u>Administrative/Fiscal Documents:</u>					
Operations Plans, Work Plans	X		X	X	X
Project Plans, Test Plans	X	X		X	X
Administrative Procedures	X		X	X	
Program Manager's Periodic Reports	X		X	X	

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

Proc. QAP-002

Revision 3

Page 6 of 17

- 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--such as, data may not have been collected in conformance with an established QA program (see QAP-014 "Qualification of Existing Data").

4.2.3 A Peer Review shall also be used when 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 If Technical, Peer, or Concurrence reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 5.2.2 and 5.3.2, and identify them on the AP-6 form.

4.2.5 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.2.3 and 5.3.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.

4.3 Reviews and Comment Resolution

4.3.1 Review items, the AP-6 form, and supporting documentation shall be routed to reviewers in the order of listing on the AP-6 form, however, Technical, Concurrence, and Programmatic reviews may be conducted

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 3

Page 7 of 17

of listing on the AP-6 form, however, Technical, Concurrence, and Programmatic reviews may be conducted simultaneously. Instructions to reviewers shall also be provided to Technical and Peer Reviewers, as applicable.

4.3.2 Review comments and their resolution shall be documented as specified in Section 5 of this procedure. Comments should be consolidated and changes shall be made to the document to incorporate the comment resolutions.

4.3.3 Reviewers shall verify that the comment resolutions have been incorporated, then initial and date the AP-6 form. After all reviews have been completed, changes made and the AP-6 completely signed off, the document may be released for issuance.

5. SPECIFIC REVIEW METHODS

5.1 FORMAT REVIEWS

5.1.1 Format Reviews shall be performed by personnel who did not format the document under review and are cognizant of correspondence, report and other document style, format, and distribution requirements.

5.1.2 Format Reviews shall verify the following:

- Conformance to applicable document format requirements;
- Internal and NRC document distribution requirements are met, as applicable;
- Spelling, grammar, and general clarity and readability are acceptable.

5.2 TECHNICAL REVIEWS

5.2.1 Formally planned and fully documented Technical Reviews shall be performed to verify the technical correctness of the work against established practices.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 3

Page 8 of 17

Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with CQAM Section 2.

- 5.2.3 The Element Manager shall identify those Technical Review items applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12, "Instructions to Technical Reviewers" (Figure 2). Instructions to Technical Reviewers shall be approved by the cognizant Director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practices.
- 5.2.4 Technical Review comments requiring resolution shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record," (Figure 3). In addition to comments requiring resolution, the reviewer shall also indicate on the Comment Resolution Record that all review criteria identified on the Instructions to Technical Reviewers have been addressed. Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document. The Technical Reviewer shall sign and date each Comment Resolution Record used to document comments.
- 5.2.5 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.
- 5.2.6 The author shall respond to the reviewer's comments and sign and date the form. The reviewer's concurrence with the responses shall be indicated by signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbiter.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 3

Page 9 of 17

5.3 PEER REVIEWS

5.3.1 Peer Reviews shall be conducted by individuals technically capable of performing the original work. Peer Reviews shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.

5.3.2 In addition to having qualifications equivalent to Technical Reviewers (paragraph 5.2.2), Peer Reviewers cannot have been involved as participants, supervisors, Technical Reviewers, or advisors in the work being reviewed. Peer Reviews shall be conducted by individuals or by Peer Review Groups of sufficient sizes and compositions to span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought, as appropriate. Technical areas more central to the work to be reviewed should receive proportionally more representation on the Peer Review Groups.

5.3.3 The Element Manager shall identify those Peer Review issues applicable to the work being reviewed by checking the appropriate blocks of CNWRA Form QAP-13, Instructions to Peer Reviewers (Figure 4). Instructions to Peer Reviewers shall be approved by the cognizant Director. The basis of the evaluation shall be the reviewer's expert judgement.

5.3.4 Individual reviewer's comments, minutes of Peer Review Group meetings and telephone conference records, as applicable, shall be compiled into a Peer Review Report and presented to the author of the work being reviewed for resolution. The report shall include a clear description of the work or issue that was peer reviewed, conclusions reached by the Peer Review process for each of the issues identified in the Instructions to Peer Reviewers, and individual statements by Peer Review Group members reflecting dissenting views or additional comments, as appropriate.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 3

Page 10 of 17

5.3.5 The author shall respond in writing to each comment requiring resolution. Concurrence with the resolutions shall be indicated by written memoranda, letters, or teleconference records. If concurrence between the Peer Review Group and author cannot be reached, the CNWRA Technical Director or President shall serve as final arbiter.

5.3.6 The Peer Review Group Chairman shall verify that resolved comments have been incorporated into the final document.

5.4 CONCURRENCE REVIEWS

5.4.1 Concurrence Reviews shall be performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed. This type of review provides general concurrence with the author for the overall approach and presentation of the work being reviewed, and provides a basis for consistency among like products of the CNWRA.

5.4.2 A Concurrence Review shall verify 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.

5.4.3 Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, CNWRA Report Review/Comment Resolution Record. Editorial comments of a minor nature may be made as marginalia on the reviewer's copy of the report. Upon completion of the review, the reviewer shall sign and date the form.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 3

Page 11 of 17

5.4.4 The author shall respond to the reviewer's comments, and concurrence with the responses shall be indicated by the reviewer's signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbiter.

5.5 CNWRA PROGRAMMATIC REVIEWS

5.5.1 CNWRA Programmatic Reviews, performed by CNWRA management, verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review.

5.5.2 CNWRA Programmatic Reviews shall be conducted by the cognizant Director, CNWRA Technical Director, or President.

5.5.3 CNWRA Programmatic Reviews shall verify the following:

- General compliance to contractual requirements;
- Review item satisfies the objectives of all applicable CNWRA plans;
- The general approach, presentation and clarity of the review item are satisfactory;
- The approach, methods and/or conclusions are consistent with CNWRA policy.

5.5.4 The reviewer shall present any comments requiring resolution to the author, and shall verify that the review item is revised based on the resolution.

5.6 QA PROGRAMMATIC REVIEWS

5.6.1 Performed by the CNWRA QA staff, QA Reviews verify that the requirements of this procedure, the CQAM and other applicable procedures are met.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 3

QUALITY ASSURANCE PROCEDURE

Page 12 of 17

5.6.2 QA Reviews shall be conducted by CNWRA QA staff cognizant of the applicable QA program and procedural requirements.

5.6.3 QA Reviews shall verify the following:

- Required reviews are conducted in accordance with applicable CQAM, TOP, and QAP requirements;
- The review item and supporting documentation provide objective evidence that the work was performed in accordance with applicable CQAM, Operations Plan, Project Plan, TOPs, and QAP requirements;
- The review item satisfies applicable content and format requirements.

5.6.4 QA Review comments requiring resolution shall be documented on CNWRA Form QAP-6, QA Document Review (Figure 5), and forwarded to the author. The author shall provide responses to the comments, and the reviewer's concurrence with the resolution shall be indicated by signature in the lower left hand block of the form. The reviewer shall verify incorporation of the comment resolutions. In cases when satisfactory resolution is not obtained, the CNWRA President shall be final arbiter.

6. RECORDS

All items identified as review documentation within this procedure shall be maintained as QA Records in accordance with CQAM Section 17 and retained for six years, including:

Document Review Packages;
QA Document Review Forms;
Document Review Request and Transmittal Control Forms;
Instructions to Technical Reviewers;
Instructions to Peer Reviewers;
Report Review/Comment Resolution Record Forms;
Peer Review Reports, minutes and teleconference records.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 3

Page 16 of 17

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 conclusions.

Element Manager Date

Cognizant Director Date

CNWRA Form QAP-13-1 (Rev. 5/91)

Figure 4

Figure 3

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.)		
[Dotted lines for comments]			[Dotted lines for response]		
REVIEWER SIGNATURE	DATE	RESPONDER SIGNATURE	DATE:		
Response accepted by: _____ Signature Date		If resolution cannot be achieved, the matter shall be elevated to the next level of authority. Distribution: This completed form shall be maintained in a record file.			

CNWRA Form TOP-3 (Rev. 6/90)

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

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 3

Page 14 of 17



**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
INSTRUCTIONS TO TECHNICAL REVIEWERS
Technical Review Items to Verify**

TO: _____

SUBJECT: Review of _____

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.

Required review completion date: _____

TECHNICAL CORRECTNESS

- Assumptions are reasonable and clearly stated.
- Appropriate techniques are used.*
- Computations are correct, calculations are documented and verified in accordance with QAP-014
- Existing data are qualified (or exempted) in accordance with QAP-015.
- Conclusions are properly supported by correctly interpreted data.*

** Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.*

READABILITY

- Document is written for the intended audience, with correct grammar and syntax.
- Illustrations and tables clearly present basic information and emphasize relationships.

CONTENT AND FORMAT

- Title reflects the objectives of the document.
- Abstract states purpose, describes study, and summarizes the pertinent results and conclusions.
- Introduction states the objectives and scope of the work and presents background information.
- Body of the manuscript is logically organized and presents the basic information.
- Conclusions and results summarize the principal findings and answer each of the objectives of the work.
- References are cited in the text and in the references section.

ELEMENT MANAGER

DATE

COGNIZANT DIRECTOR

DATE

CNWRA FORM QAP-12-3 (Rev. 4/92)

Figure 2

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 3

Page 13 of 17



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

I. DOCUMENT INFORMATION

a. TITLE: _____

b. DOCUMENT TYPE:

Technical Report AP PADB Paper/Presentation Project/Test Plan
 Guidance Document TOP CQAM/QAP OPs/Work Plan PMPR

c. PROJECT INFORMATION

PROJECT NO. _____ MILESTONE NO. _____ SUBJECT CODE _____

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

II. RESPONSIBILITIES

Author _____ Element Manager _____ Assigned Secretary _____

EDITING REQUIRED? Yes No

III. REVIEW (see QAP-002 Table 1 for Applicable review types)

Review Types & Reviewers Determined by Element Manager _____ Date _____

	Req'd Date	Initials	Review Complete Date
<input type="checkbox"/> FORMAT			
<input type="checkbox"/> TECHNICAL (Attach CNWRA QAP12-1 Form) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> PEER (Attach CNWRA QAP13 Form) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> CONCURRENCE Reviewer: _____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC QA	_____	_____	_____

IV. TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Please add/delete names as required.)

Standard Distribution (listed below).
 Barbara Meehan _____
 Malcolm Knapp _____
 Willard B. Brown _____
 Barbara Stiltenspole _____
 Sharon Rowe _____
 John Latz _____
 Wes Patrick _____
 CNWRA Directors _____
 CNWRA Element Managers _____

CNWRA FORM AP-6.2 (12/92)

Figure 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 4

QUALITY ASSURANCE PROCEDURE

Page 1 of 16

Title

QAP-002 – Review of CNWRA Documents, Reports, and Papers

EFFECTIVITY AND APPROVAL

Revision 4 of this procedure became effective on 12/31/92. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
all	0	12/31/92

SUPERSEDED

*By Revision 4, Change 1
1/27/93*

Supersedes Procedure No. QAP-002, Rev. 3

Approvals

Written By <i>Robert D. [Signature]</i>	Date 12/29/92	Concurrence Review <i>[Signature]</i>	Date 12/30/92
Quality Assurance <i>J.C. [Signature]</i>	Date 12/31/92	Cognizant Director <i>[Signature]</i>	Date 12/31/92

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 5 of 16



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 Report	<input type="checkbox"/> AP	<input type="checkbox"/> PADB	<input type="checkbox"/> Paper/Presentation	<input type="checkbox"/> Project/Test Plan
<input type="checkbox"/> Guidance Document	<input type="checkbox"/> TOP	<input type="checkbox"/> CQAM/QAP	<input type="checkbox"/> OPs/Work Plan	<input type="checkbox"/> PMPR

c. PROJECT INFORMATION

PROJECT NO. _____ MILESTONE NO. _____ SUBJECT CODE _____

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

II. RESPONSIBILITIES

Author _____ Element Manager _____ Assigned Secretary _____

EDIT LEVEL Low (CNWRA) High (SwRI)

III. REVIEW (see QAP-002 Table 1 for Applicable review types)

Review Types & Reviewers Determined by Element Manager _____ Date _____

	Req'd Date	Initials	Review Complete Date
<input type="checkbox"/> TECHNICAL (Attach CNWRA Form QAP12) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> PEER (Attach CNWRA Form QAP13) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> CONCURRENCE Reviewer: _____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC FORMAT QA	_____ _____ _____	_____ _____ _____	_____ _____ _____

IV. TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Please add/delete names as required.)

<input type="checkbox"/> Standard Distribution (listed below). Barbara Meehan Malcolm Knapp Willard B. Brown Barbara Stikempole Sharon Rowe John Latz Wes Patrick CNWRA Directors CNWRA Element Managers	_____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____
---	--	--

CNWRA FORM AP-6

SAMPLE

Figure 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 6 of 16

TABLE 1. REVIEW REQUIREMENTS MATRIX

Review Type Reference	Technical/		CNWRA Programmatic 5.4	QA 5.5	Format 5.6
	Peer 5.1/5.2	Concurrence 5.3			
<u>Technical Documents:</u>					
Reports on Research and Technical Assistance, NUREGS/CRs	X		X	X	X
Research Quarterly Reports	X		X	X	X
PADB Documents	X	X		X	
<u>Papers/Presentations:</u>					
Journal Articles, Proceedings, Conference Papers	X		X		
<u>Guidance Documents:</u>					
Draft Technical Positions, Rulemakings, and Regulatory Guides	X		X	X	X
<u>QA Program Documents:</u>					
CQAM, QAPs		X	X	X	X
TOPs	X		X	X	X
<u>Administrative/Fiscal Documents:</u>					
Operations Plans, Work Plans		X	X		X
Project Plans, Test Plans	X		X		X
Administrative Procedures		X	X		X
Program Manager's Periodic Reports		X	X		X

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 7 of 16

- Results of tests are not reproducible or repeatable;
- Data or interpretations are ambiguous;
- Data adequacy is questionable, such as, data may not have been collected in conformance with an established Quality Assurance (QA) program (see QAP-014 "Qualification of Existing Data").

4.2.3 A Peer Review shall also be used when 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 If Technical, Peer, or Concurrence reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 5.1.2 and 5.2.2, and identify them on the AP-6 form.

4.2.5 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.1.3 and 5.2.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.

4.3 Reviews and Comment Resolution

4.3.1 Review items and supporting documentation shall be routed to reviewers in the following order: Technical/Peer or Concurrence, Programmatic, QA, and Format. Technical/Peer, Concurrence, and Programmatic reviews may be conducted simultaneously. Instructions to reviewers shall also be provided to Technical and Peer Reviewers, as applicable.

4.3.2 Review comments and their resolution shall be documented as specified in Section 5 of this procedure. Comments should be consolidated and changes shall be made to the document to incorporate the comment resolutions.

4.3.3 After comments have been incorporated, the revised document, comment resolution records, and the AP-6 form shall be routed to the reviewers. The reviewers shall verify that the comment resolutions have been incorporated, then initial and date the AP-6 form. Although the QA review is performed prior to the Format review, QA shall sign-off the AP-6 form last, to verify that all other reviewers have verified that their comments have been incorporated.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 13 of 16

5.3.2 A Concurrence Review shall verify 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.

5.3.3 Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, CNWRA Report Review/Comment Resolution Record. Editorial comments of a minor nature may be made as marginalia on the reviewer's copy of the report. Upon completion of the review, the reviewer shall sign and date the form.

5.3.4 The author shall respond to the reviewer's comments, and concurrence with the responses shall be indicated by the reviewer's signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbiter.

5.4 CNWRA Programmatic Reviews

5.4.1 CNWRA Programmatic Reviews verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review.

5.4.2 CNWRA Programmatic Reviews shall be conducted by the cognizant Director, CNWRA Technical Director, or President.

5.4.3 CNWRA Programmatic Reviews shall verify the following:

- General compliance to contractual requirements;
- Review item satisfies the objectives of all applicable CNWRA plans;
- The general approach, presentation and clarity of the review item are satisfactory;

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 14 of 16

- The approach, methods and/or conclusions are consistent with CNWRA policy.

5.4.4 The reviewer shall present any comments requiring resolution to the author, and shall verify that the review item is revised based on the resolution.

5.5 QA Reviews

5.5.1 QA Reviews verify that the requirements of this procedure, the CQAM and other applicable procedures are met. QA reviews consist of an initial review of the document for compliance and reviews to verify that the review process has been properly performed and documented. QA reviews are essentially two-part, initially after Technical/Peer, Concurrence, and Programmatic reviews have been conducted, and finally after all other reviews are complete, comments incorporated, and all other reviewers have signed-off the AP-6 form as described in section 4.3.3.

5.5.2 QA Reviews shall be conducted by QA staff cognizant of the applicable QA program and procedural requirements.

5.5.3 QA Reviews shall verify the following:

- Required reviews and comment resolution are conducted in accordance with applicable CQAM, TOP, and QAP requirements;
- The review item and supporting documentation provide objective evidence that the work was performed in accordance with applicable CQAM, Operations Plan, Project Plan, TOPs, and QAP requirements;
- The review item satisfies applicable content and format requirements.

5.5.4 QA Review comments requiring resolution shall be documented on CNWRA Form QAP-6, QA Document Review (Figure 5), and forwarded to the author. The author shall provide responses to the comments, and the reviewer's concurrence with the resolution shall be indicated by signature in the lower left hand block of the form. The reviewer shall verify incorporation of the comment resolutions. In cases when satisfactory resolution is not obtained, the CNWRA President shall be final arbiter.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 4, Chg. 1

QUALITY ASSURANCE PROCEDURE

Page 1 of 16

Title

QAP-002 — Review of CNWRA Documents, Reports, and Papers

EFFECTIVITY AND APPROVAL

Revision 4 of this procedure became effective on 12/31/92. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	1	1/27/93
2-4	0	12/31/92
5-7	1	1/27/93
8-12	0	12/31/92
13-14	1	1/27/93
15-16	0	12/31/92

*Superseded by Revision 5, Change 0.
6/23/94*

Supersedes Procedure No. QAP-002, Rev. 4, Chg. 0

Approvals

Written By <i>[Signature]</i>	Date 1/26/93	Concurrence Review <i>[Signature]</i>	Date 1/27/93
Quality Assurance <i>[Signature]</i>	Date 1/26/93	Cognizant Director <i>[Signature]</i>	Date 1/27/93

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 2 of 16

**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 the various types of reviews required for the Center for Nuclear Waste Regulatory Analyses (CNWRA) documents, reports, and papers. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall be reviewed in accordance with this procedure. This procedure is developed reflecting the guidance of the "Generic Technical Position On Peer Review For High-Level Nuclear Waste Repositories", NUREG-1297 and implements CQAM Section 3.

2 RESPONSIBILITIES

- 2.1 Element Managers are responsible for implementation of 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 reviewers' comments.

3 DEFINITIONS

- 3.1 Concurrence Reviews - Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide 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 being described or being prescribed.
- 3.2 Peer - A peer is a person having 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.
- 3.3 Peer Review Group - A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 3 of 16

3.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer was not involved as a participant, supervisor, technical reviewer or advisor for the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of 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, and industry practice.

3.5 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4 DOCUMENT PREPARATION AND REVIEW PROCESS

4.1 Document Submittal for Review and Editing

4.1.1 The Author/Analyst shall submit final drafts of items requiring review to the cognizant Element Manager sufficiently in advance of the due date to allow for word processing, review, reproduction, and distribution. The document shall be submitted along with any supporting documentation needed to perform the reviews (Scientific Notebooks, calculation verifications, etc.).

4.1.2 Intermediate and Major Milestone deliverable items shall be edited to enhance and improve writing style, grammar, and punctuation, and to assure that the intent of the writing is effectively communicated. Other documents shall be edited as determined necessary by the Element Manager.

4.1.3 The Element Manager shall review each document and determine (i) the level of editing necessary and (ii) the technical areas covered by the document in order to identify reviewers. The Element Manager should also verify that relevant programmatic objectives are satisfied by the document.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 4 of 16

4.1.4 The level of editing shall be based on the complexity of the document and the writing skills of the author. Generally speaking, for documents with relatively few graphics, references and simple format, low-level editing may be performed by appropriate CNWRA staff. More complex documents require high-level editing, which shall be performed by Southwest Research Institute (SwRI) Publications staff editors.

4.1.5 Editing shall consist of (i) review by the editor (whether CNWRA or SwRI Publications staff), (ii) discussion of the review results between the editor and author and, (iii) as necessary, modification of the document in a collaborative effort. Editing shall be completed before additional word processing or reviews are performed.

4.2 Review Planning

4.2.1 The "Document Review Request and Transmittal Control", Form AP-6, (Figure 1) shall be initiated by the Element 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 Element Manager shall check the required review types on the AP-6 form. For revisions and changes to previously submitted documents, reviews are necessary commensurate with the extent of the revision/change. The AP-6 shall include a brief justification for any reviews less than that specified in the Review Requirements Matrix.

4.2.2 In addition to a Technical Review, a Peer Review shall be required when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is required:

- Critical interpretations or decisions will be made in the face of significant uncertainty or subjective judgement, including the planning for data collection, research, or testing;
- Interpretations having significant impact on licensing decisions 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;

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4, Chg. 1

Page 5 of 16



**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 Report	<input type="checkbox"/> AP	<input type="checkbox"/> PADB	<input type="checkbox"/> Paper/Presentation	<input type="checkbox"/> Project/Test Plan
<input type="checkbox"/> Guidance Document	<input type="checkbox"/> TOP	<input type="checkbox"/> CQAM/QAP	<input type="checkbox"/> OPs/Work Plan	<input type="checkbox"/> PMPR

c. PROJECT INFORMATION

PROJECT NO. 20- MILESTONE NO. 20- SUBJECT CODE _____

CNWSA DOCUMENT NO. Yes _____ No _____ Assigned No. CNWSA 93 -

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

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

Author _____ Element Manager _____ Assigned Secretary _____

EDIT LEVEL Low (CNWSA) _____ High (SwRI) _____

III. REVIEW (see QAP-002 Table 1 for applicable review types)

Review Types & Reviewers Determined by Element Manager

	(EM Signature)		(Date)
	Req'd Date	Initials	Review Complete Date
<input type="checkbox"/> TECHNICAL (Attach CNWSA Form QAP12) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> PEER (Attach CNWSA Form QAP13) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> CONCURRENCE Reviewer: _____	_____	_____	_____
<input type="checkbox"/> QA Reviewer: _____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC Reviewer: _____	_____	_____	_____
<input type="checkbox"/> FORMAT Reviewer: _____	_____	_____	_____
Verification of Compliance with QAP-002	_____	_____	_____

IV. TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Please add/delete names as required.)

<input type="checkbox"/> Standard Distribution (listed below)	_____	_____
Barbara Meehan	_____	_____
Malcolm Knapp	_____	_____
Willard Brown	_____	_____
Barbara Stiltenspole	_____	_____
Sharon Rowe	_____	_____
John Latz	_____	_____
Wes Patrick	_____	_____
CNWSA Directors	_____	_____
CNWSA Element Managers	_____	_____

CNWSA FORM AP-6-2 (1/93)

Figure 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4, Chg. 1

Page 6 of 16

REVIEW REQUIREMENTS MATRIX

DOCUMENT TYPE	REVIEW TYPE	Technical/ Peer	Concurrence	QA	CNWRA Programmatic	Format
Technical Documents						
Reports on Research and Technical Assistance, NUREGs/CRs		X			X	X
Semi-Annual Research Reports		X			X	X
PADB Documents						
		X	X			
Papers/Presentations						
Journal Articles, Proceedings, Conference Papers		X			X	
Guidance Documents						
Draft Technical Positions, Rulemakings, and Regulatory Guides		X			X	X
QA Program Documents						
CQAM, QAPs			X	X	X	X
TOPs		X		X	X	X
Administrative/Fiscal Documents						
Operations Plans, Work Plans			X	X	X	X
Project Plans, Test Plans		X		X	X	X
Administrative Procedures			X	X	X	X
Program Manager's Periodic Reports			X		X	X

Table 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4, Chg. 1

Page 7 of 16

- Results of tests are not reproducible or repeatable;
- Data or interpretations are ambiguous;
- Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program (see QAP-014 "Qualification of Existing Data").

4.2.3 A Peer Review shall also be used when 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 If Technical, Peer, or Concurrence reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 5.1.2, 5.2.2, and 5.3.1, and identify them on the AP-6 form.

4.2.5 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.1.3 and 5.2.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.

4.3 Reviews and Comment Resolution

4.3.1 Review items and supporting documentation shall be routed to reviewers in the following order: Technical/Peer or Concurrence, QA, Programmatic, and Format. Technical/Peer, Concurrence, QA, and Programmatic reviews may be conducted simultaneously. Instructions to reviewers shall also be provided to Technical and Peer Reviewers, as applicable.

4.3.2 Review comments and their resolution shall be documented as specified in Section 5 of this procedure. Comments should be consolidated and changes shall be made to the document to incorporate the comment resolutions.

4.3.3 After comments have been incorporated, the revised document, comment resolution records, and the AP-6 form shall be routed to the reviewers. The reviewers shall verify that the comment resolutions have been incorporated, then initial and date the AP-6 form. After the AP-6 form has been signed-off by all reviewers, compliance with the provisions of this procedure shall be verified by QA staff. The verification will determine if required reviews and comment resolution are conducted in accordance with applicable CQAM, TOP, and QAP requirements.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 8 of 16

5 SPECIFIC REVIEW METHODS

5.1 Technical Reviews

5.1.1 Formally planned and fully documented Technical Reviews shall be performed to verify the technical correctness of the work against established practices.

5.1.2 Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with Center Quality Assurance Manual (CQAM) Section 2.

5.1.3 The Element Manager shall identify those Technical Review items applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12, "Instructions to Technical Reviewers" (Figure 2). Instructions to Technical Reviewers shall be approved by the cognizant Director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practices.

5.1.4 Technical Review comments requiring resolution shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record," (Figure 3). In addition to comments requiring resolution, the reviewer shall also indicate on the Comment Resolution Record that all review criteria identified on the Instructions to Technical Reviewers have been addressed. Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document. The Technical Reviewer shall sign and date each Comment Resolution Record used to document comments.

5.1.5 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 Technical Operating Procedure (TOP)-3 form or shall be attached to it.

5.1.6 The author shall respond to the reviewer's comments and sign and date the form. The reviewer's concurrence with the responses shall be indicated by signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbiter.

5.2 Peer Reviews

5.2.1 Peer Reviews shall be conducted by individuals technically capable of performing the

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 9 of 16



**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
INSTRUCTIONS TO TECHNICAL REVIEWERS
Technical Review Items to Verify**

TO: _____

SUBJECT: Review of _____

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.

Required review completion date: _____

TECHNICAL CORRECTNESS

- Assumptions are reasonable and clearly stated.
- Appropriate techniques are used.*
- Computations are correct, calculations are documented and verified in accordance with QAP-014.
- Existing data are qualified (or exempted) in accordance with QAP-015.
- Conclusions are properly supported by correctly interpreted data.*

** Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.*

READABILITY

- Document is written for the intended audience, with correct grammar and syntax.
- Illustrations and tables clearly present basic information and emphasize relationships.

CONTENT AND FORMAT

- Title reflects the objectives of the document.
- Abstract states purpose, describes study, and summarizes the pertinent results and conclusions.
- Introduction states the objectives and scope of the work and presents background information.
- Body of the manuscript is logically organized and presents the basic information.
- Conclusions and results summarize the principal findings and answer each of the objectives of the work.
- References are cited in the text and in the references section.

ELEMENT MANAGER

DATE:

COGNIZANT DIRECTOR

DATE:

CNWRA FORM QAP-12

SAMPLE

Figure 2

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. 0AP-002
 Revision 4
 Page 10 of 16

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:	DATE	RESPONDER SIGNATURE:	DATE:	
Response accepted by _____ Signature Date		If resolution cannot be achieved, the matter shall be elevated to the next level of authority. Distribution: This completed form shall be maintained in a record file.		

CNWRA Form TOP:3

SAMPLE

Figure 3

CNWRA Form QAP-2

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 11 of 16

original work. Peer Reviews shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.

5.2.2 In addition to having qualifications equivalent to Technical Reviewers (section 5.1.2), Peer Reviewers cannot have been involved as participants, supervisors, Technical Reviewers, or advisors in the work being reviewed. Peer Reviews shall be conducted by individuals or by Peer Review Groups of sufficient sizes and compositions to span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought, as appropriate. Technical areas more central to the work to be reviewed should receive proportionally more representation on the Peer Review Groups.

5.2.3 The Element Manager shall identify those Peer Review issues applicable to the work being reviewed by checking the appropriate blocks of CNWRA Form QAP-13, Instructions to Peer Reviewers (Figure 4). Instructions to Peer Reviewers shall be approved by the cognizant Director. The basis of the evaluation shall be the reviewer's expert judgement.

5.2.4 Individual reviewer's comments, minutes of Peer Review Group meetings and telephone conference records, as applicable, shall be compiled into a Peer Review Report and presented to the author of the work being reviewed for resolution. The report shall include a clear description of the work or issue that was peer reviewed, conclusions reached by the Peer Review process for each of the issues identified in the Instructions to Peer Reviewers, and individual statements by Peer Review Group members reflecting dissenting views or additional comments, as appropriate.

5.2.5 The author shall respond in writing to each comment requiring resolution. Concurrence with the resolutions shall be indicated by written memoranda, letters, or teleconference records. If concurrence between the Peer Review Group and author cannot be reached, the CNWRA Technical Director or President shall serve as final arbiter.

5.2.6 The Peer Review Group Chairman shall verify that resolved comments have been incorporated into the final document.

5.3 Concurrence Reviews

5.3.1 Concurrence Reviews shall be performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed. This type of review provides general concurrence with the author for the overall approach and presentation of the work being reviewed, and provides a basis for consistency among like products of the CNWRA.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 12 of 16

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 conclusions.

Element Manager Date

Cognizant Director Date

CNWRA Form QAP-13

SAMPLE

Figure 4

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4, Chg. 1

Page 13 of 16

5.3.2 A Concurrence Review shall verify 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.

5.3.3 Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, CNWRA Report Review/Comment Resolution Record. Editorial comments of a minor nature may be made as marginalia on the reviewer's copy of the report. Upon completion of the review, the reviewer shall sign and date the form.

5.3.4 The author shall respond to the reviewer's comments, and concurrence with the responses shall be indicated by the reviewer's signature in the appropriate block in the lower left hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbiter.

5.4 QA Reviews

5.4.1 QA Reviews verify that the requirements of the CQAM and other applicable procedures are met in Operating Procedures and quality-affecting planning documents which implement the CNWRA QA program.

5.4.2 QA Reviews shall be conducted by QA staff cognizant of the applicable QA program and procedural requirements.

5.4.3 QA Review comments requiring resolution shall be documented on CNWRA Form QAP-6, QA Document Review (Figure 5), and forwarded to the author. The author shall provide responses to the comments, and the reviewer's concurrence with the resolution shall be indicated by signature in the lower left hand block of the form. The reviewer shall verify incorporation of the comment resolutions. In cases when satisfactory resolution is not obtained, the CNWRA President shall be final arbiter.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4, Chg. 1

Page 14 of 16

5.5 CNWRA Programmatic Reviews

5.5.1 CNWRA Programmatic Reviews verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review.

5.5.2 CNWRA Programmatic Reviews shall be conducted by the cognizant Director, CNWRA Technical Director, or President.

5.5.3 CNWRA Programmatic Reviews shall verify the following:

- General compliance to contractual requirements;
- Review item satisfies the objectives of all applicable CNWRA plans;
- The general approach, presentation and clarity of the review item are satisfactory;
- The approach, methods and/or conclusions are consistent with CNWRA policy.

5.5.4 The reviewer shall present any comments requiring resolution to the author, and shall verify that the review item is revised based on the resolution.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 4

Page 16 of 16

5.6 Format Reviews

5.6.1 Format Reviews shall be performed by personnel who did not format the document under review and are cognizant of correspondence, report and other document style, format, and distribution requirements.

5.6.2 Format Reviews shall verify the following:

- Conformance to applicable document format requirements;
- Internal and NRC document distribution requirements are met, as applicable;
- Spelling is correct (a spelling check program shall be run).

6 RECORDS

All items identified as review documentation within this procedure shall be maintained as QA Records in accordance with CQAM Section 17 and retained for six years, including:

Document Review Packages;
QA Document Review Forms;
Document Review Request and Transmittal Control Forms;
Instructions to Technical Reviewers;
Instructions to Peer Reviewers;
Report Review/Comment Resolution Record Forms;
Peer Review Reports, minutes and teleconference records.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5

Page 1 of 15

Title

QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS AND PAPERS

EFFECTIVITY AND APPROVAL

Revision 5 of this procedure became effective on 6/23/94. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	6/23/94

Superseded by Rev 5 Chg 1 10/27/95

Supersedes Procedure No. QAP-002, Rev. 4, Chg. 1

Approvals

Written By <i>Robert Brient</i> ROBERT BRIENT	Date 6/23/94	Concurrence Review <i>Wesley C. Patrick</i> WESLEY C. PATRICK	Date 6/23/94
Quality Assurance <i>Bruce Mabrito</i> BRUCE MABRITO	Date 6/23/94	Cognizant Director <i>Henry Garcia</i> HENRY GARCIA	Date 6/23/94

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Proc. QAP-002

Revision 5

QUALITY ASSURANCE PROCEDURE

Page 5 of 15



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 Report	<input type="checkbox"/> AP	<input type="checkbox"/> PADB	<input type="checkbox"/> Paper/Presentation	<input type="checkbox"/> Project/Test Plan
<input type="checkbox"/> Guidance Document	<input type="checkbox"/> TOP	<input type="checkbox"/> CQAM/QAP	<input type="checkbox"/> OPs/Work Plan	<input type="checkbox"/> PMPR

c. PROJECT INFORMATION

PROJECT NO. 20-XXXX-XXX MILESTONE NO. 20-XXXX-XXX-XXX-XXX SUBJECT CODE XXX.X

CNwRA DOCUMENT NO. Yes _____ No _____ Assigned No. CNwRA 93 - XXX

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

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

Author _____ Element Manager _____ Assigned Secretary _____

EDIT LEVEL Low (CNwRA) _____ High (SwRI) _____

III. REVIEW (see QAP-002 Table 1 for applicable review types)

Review Types & Reviewers Determined by Element Manager

	(EM Signature)	(Date)	
	Req'd Date	Initials	Review Complete Date
<input type="checkbox"/> TECHNICAL (Attach CNwRA Form QAP12) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> PEER (Attach CNwRA Form QAP13) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> CONCURRENCE Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC Reviewer: _____	_____	_____	_____
<input type="checkbox"/> QA Reviewer: _____	_____	_____	_____
<input type="checkbox"/> FORMAT Reviewer: _____	_____	_____	_____

IV. TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Please add/delete names as required.)

<input type="checkbox"/> Standard Distribution (listed below) Barbara Meehan Malcolm Knapp Willard Brown Barbara Stiltenspole Sharon Rowe John Latz Wes Patrick CNwRA Directors CNwRA Element Managers	_____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____
---	--	--

CNwRA FORM AP-6-2 (1/93) Sample

Figure 1 - Document Review Request and Transmittal Control (Form AP-6)

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 5

Page 8 of 15

QUALITY ASSURANCE PROCEDURE

if required reviews and comment resolutions are conducted in accordance with applicable CQAM, TOP, and QAP requirements.

5 SPECIFIC REVIEW METHODS

- 5.1 Formally planned and fully documented Technical Reviews shall be performed, when required, to verify the technical correctness of the work against established practices.
- 5.1.2 Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with CQAM Section 2.
- 5.1.3 The Element Manager shall identify those Technical Review criteria applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12, "Instructions to Technical Reviewers" (Figure 2). Instructions to Technical Reviewers shall be approved by the Technical Director or cognizant director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practices.
- 5.1.4 Technical Review comments requiring resolution, e.g., those associated with the applicable review criteria, shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record," (Figure 3). In addition to comments requiring resolution, the reviewer shall also indicate on the Comment Resolution Record that all review criteria identified on the Instructions to Technical Reviewers have been addressed. Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document. The Technical Reviewer shall sign and date each Comment Resolution Record used to document comments.
- 5.1.5 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.
- 5.1.6 The author shall respond to the reviewer's comments and sign and date the form. The reviewer's concurrence with the responses shall be indicated by signature in the appropriate block in the lower left-hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbitrator.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5

Page 9 of 15

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES INSTRUCTIONS TO TECHNICAL REVIEWERS Technical Review Items to Verify			
			
TO: _____			
SUBJECT: Review of _____			
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.			
Required review completion date: _____			
TECHNICAL CORRECTNESS			
<input type="checkbox"/> Assumptions are reasonable and clearly stated.			
<input type="checkbox"/> Appropriate techniques are used.*			
<input type="checkbox"/> Computations are correct, calculations are documented and verified in accordance with QAP-014.			
<input type="checkbox"/> Existing data are qualified (or exempted) in accordance with QAP-015.			
<input type="checkbox"/> Conclusions are properly supported by correctly interpreted data.*			
<small>* Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.</small>			
READABILITY			
<input type="checkbox"/> Document is written for the intended audience, with correct grammar and syntax.			
<input type="checkbox"/> Illustrations and tables clearly present basic information and emphasize relationships.			
CONTENT AND FORMAT			
<input type="checkbox"/> Title reflects the objectives of the document.			
<input type="checkbox"/> Abstract states purpose, describes study, and summarizes the pertinent results and conclusions.			
<input type="checkbox"/> Introduction states the objectives and scope of the work and presents background information.			
<input type="checkbox"/> Body of the manuscript is logically organized and presents the basic information.			
<input type="checkbox"/> Conclusions and results summarize the principal findings and answer each of the objectives of the work.			
<input type="checkbox"/> References are cited in the text and in the references section.			
ELEMENT MANAGER	DATE:	COGNIZANT DIRECTOR	DATE:

CNWRA FORM QAP-12-3 (Rev. 4/92)

Sample

Figure 2 - Instructions to Technical Reviewers (Form QAP-12)

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5

Page 10 of 15

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	DATE:	RESPONDER SIGNATURE	DATE:		
Response accepted by:		If resolution cannot be achieved, the matter shall be elevated to the next level of authority. Distribution: This completed form shall be maintained in a record file.			
_____ <small>Signature</small>	_____ <small>Date</small>				

CNWRA Form TOP-3 (Rev. 6/90)

Sample

Figure 3 - CNWRA Report Review/Comment Resolution Record (Form TOP-3)

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 5

Page 15 of 15

QUALITY ASSURANCE PROCEDURE

5.5.3 CNWRA Programmatic Reviews shall verify the following:

- General compliance to contractual requirements.
- Review item satisfies the objectives of all applicable CNWRA plans.
- The general approach, presentation, and clarity of the review items are satisfactory.
- The approach, methods, and/or conclusions are consistent with CNWRA policy.

5.5.4 The reviewer shall present any comments requiring resolution of the author and shall verify that the review item is revised based on the resolution.

5.6 Format Review

5.6.1 Format Reviews shall be performed by personnel who did not format the document under review and are cognizant of correspondence, reports and other document style, format, and distribution requirements.

5.6.2 Format Reviews shall verify the following:

- Conformance to applicable document format requirements.
- Internal and NRC document distribution requirements are met, as applicable.
- Spelling is correct (a spelling check program can be run).

6 RECORDS

All items identified as review documentation within this procedure shall be maintained as QA Records in accordance with CQAM Section 17 and retained for 6 years, including:

- Document Review Packages
- QA Document Review Forms
- Document Review Request and Transmittal Control Forms
- Instructions to Technical Reviewers
- Instructions to Peer Reviewers
- Report Review/Comment Resolution Record Forms
- Peer Review Reports, minutes, and teleconference records

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5

Page 4 of 16

4.1.4 The level of editing shall be based on the complexity of the document and the writing skills of the author. Generally speaking, for documents with relatively few graphics, references, and simple format, low-level editing may be performed by the appropriate CNWRA staff. More complex documents require high-level editing, which shall be performed by Southwest Research Institute (SwRI) Publications staff editors.

4.1.5 Editing shall consist of: (i) review by the editor (whether CNWRA or SwRI Publications staff), (ii) discussion of the review results between the editor and author, and (iii) as necessary, modification of the document in a collaborative effort. Editing shall be completed before additional word processing or reviews are performed.

4.2 Review Planning

4.2.1 The "Document Review Request and Transmittal Control," CNWRA Form AP-6, (Figure 1) shall be initiated by the Element 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 Element Manager shall check the required review types on the AP-6 form. For revisions and changes to previously submitted documents, reviews are necessary commensurate with the extent of the revision/change. The AP-6 form shall include a brief justification for any review less than that specified in the Review Requirements Matrix.

4.2.2 When a Technical Review is required, a Peer Review shall additionally be required if the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is 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 licensing decisions 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.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Proc. QAP-002

Revision 5

Page 7 of 16

QUALITY ASSURANCE PROCEDURE

- Results of tests are not reproducible or repeatable.
- Data or interpretations are ambiguous.
- Data adequacy is questionable—such as, data may not have been collected in conformance with an established QA program (see QAP-014 “Qualification of Existing Data”).

4.2.3 Peer Review may be conducted on activities as well as documents. While the complete review process may not apply, Peer Review of this type shall, in any case, be conducted in accordance with Section 5.2 of this procedure. A Peer Review shall also used when 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 If Technical, Peer, or Concurrence Reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 5.1.2, 5.2.2, and 5.3.1, and identify them on the AP-6 form.

4.2.5 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.1.3 and 5.2.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.

4.3 Reviews and Comment Resolution

4.3.1 Review items and supporting documentation shall be routed to reviewers in the following order: Technical or Concurrence, QA, Programmatic, and Format. Technical (or Concurrence), QA, and Programmatic Reviews may be conducted simultaneously. Peer Reviews are generally conducted after the other prescribed reviews are completed, however, that is not a requirement.

4.3.2 Technical Review comments and their resolution shall be documented as specified in Section 5 of this procedure. Comments from several reviewers should be consolidated and changes shall be made to the document to incorporate the comment resolutions.

4.3.3 After comments have been incorporated, the revised document, comment resolution records, and the AP-6 form shall be returned to the reviewers. The reviewers shall verify that the comment resolutions have been incorporated, then initial and date the AP-6 form. The Technical Director shall initial and date the AP-6 form to indicate that the Peer Review comments have been satisfactorily addressed. After the AP-6 form has been signed-off by all reviewers, compliance with the provisions of this procedure shall be verified by QA staff. The verification will determine

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5

Page 2 of 16

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 the various types of reviews required for the Center for the Nuclear Waste Regulatory Analyses (CNWRA) documents, reports, and papers. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall be reviewed in accordance with this procedure. This procedure is developed reflecting the guidance of the "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, and implements Center Quality Assurance Manual (CQAM) Section 3.

2 RESPONSIBILITY

- 2.1 Element managers are responsible for the implementation of 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 reviewers' comments.

3 DEFINITIONS

- 3.1 Concurrence Reviews - Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide 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 being described or performed.
- 3.2 Peer - Peer is a person having 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.
- 3.3 Peer Review Group - A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 5

Page 3 of 16

QUALITY ASSURANCE PROCEDURE

- 3.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor for the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria employed, and of 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, and industry practice.

- 3.5 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4 DOCUMENT PREPARATION AND REVIEW PROCESS

4.1 Document Submittal for Review and Editing

- 4.1.1 The Author/Analyst shall submit final drafts of items requiring review to the cognizant Element Manager sufficiently in advance of the due date to allow for word processing, review, reproduction, and distribution. The document shall be submitted along with any supporting documentation needed to perform the reviews (Scientific Notebooks, calculation verifications, etc.).
- 4.1.2 Intermediate and Major Milestone deliverable items shall be edited to enhance and improve writing style, grammar and punctuation, and to assure that the intent of the writing is effectively communicated. Other documents, as determined necessary, shall be edited by the Element Manager.
- 4.1.3 The Element Manager shall review each document and determine: (i) the level of editing necessary, and (ii) the technical areas covered by the document in order to identify reviewers. The Element Manager should also verify that relevant programmatic objectives are satisfied by the document.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 5

Page 11 of 15

QUALITY ASSURANCE PROCEDURE

5.2 Peer Review

- 5.2.1 Peer Review shall be conducted by individuals technically capable of performing the original work. Peer Reviews shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.
- 5.2.2 In addition to having qualifications equivalent to Technical Reviewers (section 5.1.2), Peer Reviewers cannot have been involved as participants, supervisors, technical reviewers, or advisors in the work being reviewed. Peer reviews shall be conducted by an individual or by groups of sufficient sizes and composition to span the technical issues and appropriate areas. Technical areas more central to the work to be reviewed should receive proportionally more representation on the Peer Review Groups.
- 5.2.3 The Element 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 (Figure 4). Instructions to Peer Reviewers shall be approved by the cognizant director. The basis of the evaluation shall be the reviewer's expert judgment.
- 5.2.4 Individual reviewer's 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. The document under review shall be revised to address to Peer Review comments. Appropriate resolution of Peer Review comments shall be verified by the cognizant director and documented by initialling and dating the AP-6 form or by some other method.

5.3 Concurrence Reviews

- 5.3.1 Concurrence Reviews shall be performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed. This type of review provides general concurrence with the author for the overall approach and presentation of the work being reviewed, and provides a basis for consistency among like products of the CNWRA.
- 5.3.2 A Concurrence Review shall verify 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.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5

Page 12 of 15

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 conclusions.

Element Manager Date

Cognizant Director Date

CNWR Form QAP-13-1 (Rev. 5/91)

Sample

Figure 4 - Instructions to Peer Reviewers (Form QAP-13)

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 5

Page 13 of 16

QUALITY ASSURANCE PROCEDURE

- 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.

5.3.3 Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record." Editorial comments of a minor nature may be made as marginalia on the reviewer's copy of the report. Upon completion of the review, the reviewer shall sign and date the form.

5.3.4 The author shall respond to the reviewer's comments, and concurrence with the responses shall be indicated by the reviewer's signature in the appropriate block in the lower left-hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA cognizant director or President shall serve as the final arbitrator.

5.4 QA Reviews

5.4.1 QA Reviews verify that the requirements of the CQAM and other applicable procedures are met in Operating Procedures and quality-affecting planning documents which implement the CQAM.

5.4.2 QA Reviews shall be conducted by QA staff cognizant of the applicable QA program and procedural requirements.

5.4.3 QA Review comments requiring resolution shall be documented on CNWRA Form QAP-6, "QA Document Review" (Figure 5), and forwarded to the author. The author shall provide responses to the comments, and the reviewer's concurrence with the resolution shall be indicated by signature in the lower left-hand block of the form. The reviewer shall verify incorporation of the comment resolutions. In cases when satisfactory resolution is not obtained, the CNWRA President shall be arbitrator.

5.5 CNWRA Programmatic Reviews

5.5.1 CNWRA Programmatic Reviews verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review.

5.5.2 CNWRA Programmatic Reviews shall be conducted by the cognizant CNWRA director, Technical Director, Deputy Technical Director for Systems Engineering and Integration, or President.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5, Chg 1

Page 1 of 16

Title

QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS AND PAPERS

EFFECTIVITY AND APPROVAL

Revision 5 of this procedure became effective on 6/23/94. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	1	10/27/95
2-4	0	06/23/94
5-6	1	10/27/95
7	0	06/23/94
8-10	1	10/27/95
11-13	0	06/23/94
14-16	1	10/27/95

Superseded by Rev 5 Chg 2 dated 5/30/97

Supersedes Procedure No. QAP-002, Rev. 5, Chg. 0 dated 06/23/94

Approvals

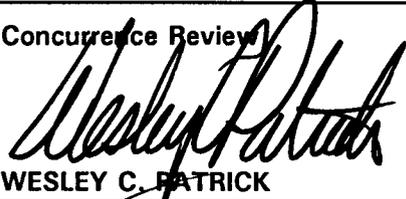
<p>Written By</p>  <p>BRUCE MABRITO</p>	<p>Date</p> <p align="center">10/30/95</p>	<p>Concurrence Review</p>  <p>WESLEY C. PATRICK</p>	<p>Date</p> <p align="center">10/25/95</p>
<p>Quality Assurance</p>  <p>ROBERT BRIANT</p>	<p>Date</p> <p align="center">10/20/95</p>	<p>Cognizant Director</p>  <p>HENRY GARCIA</p>	<p>Date</p> <p align="center">10/26/95</p>

Table 1. Review requirements matrix

Document Type	Review Type	Technical/Peer	Concurrence	QA	CNWRRA Programmatic	Format
Technical Documents						
Reports on Research and Technical Assistance, NUREGs/CRs		X			X	X
Semi-Annual Research Reports		X			X	X
RPD						
RPD Documents		X	X		X	X
Papers/Presentations						
Journal Articles, Proceedings, Conference Papers		X			X	
Guidance Documents						
Draft Technical Positions, Rulemakings, and Regulatory Guides		X			X	X
QA Program Documents						
CQAM, QAPs			X	X	X	X
TOPs		X		X	X	X
Administrative/Fiscal Documents						
Operations Plans, Work Plans		X	X	X	X	X
Project Plans, Test Plans		X		X	X	X
Administrative Procedures			X	X	X	X
Program Manager's Periodic Reports			X		X	X

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

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5, Chg 1

Page 5 of 16



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

Proc. QAP-002
Revision 5, Chg 1
Page 5 of 16

I. DOCUMENT INFORMATION

a. TITLE: _____

b. DOCUMENT TYPE

<input type="checkbox"/> Technical Report	<input type="checkbox"/> AP	<input type="checkbox"/> PADB	<input type="checkbox"/> Paper/Presentation *	<input type="checkbox"/> Project/Test Plan
<input type="checkbox"/> Guidance Document	<input type="checkbox"/> TOP	<input type="checkbox"/> CQAM/QAP	<input type="checkbox"/> OPs/Work Plan	<input type="checkbox"/> PMPR

* Conference Title: _____

Sponsoring Organization(s) _____ Location _____ Date(s) _____

c. PROJECT INFORMATION

Project No. _____ Milestone No. _____ Subject Code _____

CNWRA DOCUMENT NO. Yes _____ No _____ Assigned No. CNWRA 95 _____

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

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

Author(s) _____ Element Manager _____ Assigned Secretary _____

EDIT LEVEL Low (CNWRA) _____ High (SwRI) _____

III. REVIEW (see QAP-002 Table 1 for applicable review types)

Review Types & Reviewers Determined by Element Manager

	(EM Signature)		(Date)
	Req'd Date	Initials	Review Complete Date
<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"/> CONCURRENCE Reviewer: _____	_____	_____	_____
<input type="checkbox"/> QA Reviewer: _____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC Reviewer: _____	_____	_____	_____
<input type="checkbox"/> FORMAT Reviewer: _____	_____	_____	_____
Verification of Compliance with QAP-002	_____	_____	_____

IV. TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Please add/delete names as required.)

Standard Distribution (listed below)

J. Linehan	_____	_____	_____
S. Fortuna	_____	_____	_____
B. Stutenpolic	_____	_____	_____
B. Meehan	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

CNWRA FORM AP-6-2 (1/95)

Figure 1. Sample Form AP-6—Document Review Request and Transmittal Control

Table 1. Review requirements matrix

Document Type	Review Type	Technical/Peer	Concurrence	QA	CNWRA Programmatic	Format
Technical Documents						
Reports on Research and Technical Assistance, NUREGs/CRs		X			X	X
Semi-Annual Research Reports		X			X	X
RPD						
RPD Documents		X	X		X	X
Papers/Presentations						
Journal Articles, Proceedings, Conference Papers		X			X	
Guidance Documents						
Draft Technical Positions, Rulemakings, and Regulatory Guides		X			X	X
QA Program Documents						
CQAM, QAPs			X	X	X	X
TOPs		X		X	X	X
Administrative/Fiscal Documents						
Operations Plans, Work Plans		X	X	X	X	X
Project Plans, Test Plans		X		X	X	X
Administrative Procedures			X	X	X	X
Program Manager's Periodic Reports			X		X	X

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

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

Proc. QAP-002
Revision 5, Chg 1
Page 9 of 16



**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
INSTRUCTIONS TO TECHNICAL REVIEWERS
Technical Review Items to Verify**

TO: _____
SUBJECT: Review of _____

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: _____

ASSIGNED ACCOMPLISHED

TECHNICAL CORRECTNESS

- | | | |
|--------------------------|--|--------------------------|
| <input type="checkbox"/> | Assumptions are reasonable and clearly stated. | <input type="checkbox"/> |
| <input type="checkbox"/> | Appropriate techniques are used.* | <input type="checkbox"/> |
| <input type="checkbox"/> | Computations are correct, calculations are documented and verified in accordance with QAP-014. | <input type="checkbox"/> |
| <input type="checkbox"/> | Existing data are qualified (or exempted) in accordance with QAP-015. | <input type="checkbox"/> |
| <input type="checkbox"/> | Conclusions are properly supported by correctly interpreted data.* | <input type="checkbox"/> |
- * *Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrants application of the Peer Review.*

READABILITY

- | | | |
|--------------------------|---|--------------------------|
| <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

- | | | |
|--------------------------|---|--------------------------|
| <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 answer each of the objectives if the work. | <input type="checkbox"/> |
| <input type="checkbox"/> | References are cited in the text and in the references section. | <input type="checkbox"/> |

ELEMENT MANAGER	DATE	COGNIZANT DIRECTOR	DATE

CNWRA FORM QAP-12-4 (Rev. 7/95)

Figure 2. Sample Form QAP-12—Instructions to Technical Reviewers

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5 Chg 1

Page 16 of 16

- Documentation package is complete and ready to be put in QA Records.

6 RECORDS

All items identified as review documentation within this procedure shall be maintained as QA Records in accordance with CQAM Section 17 and retained for 6 years, including:

- Document Review Packages
- QA Document Review Forms
- Document Review Request and Transmittal Control Forms
- Instructions to Technical Reviewers
- Instructions to Peer Reviewers
- Report Review/Comment Resolution Record Forms
- Peer Review Reports, minutes, and teleconference records

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5 Chg 1

Page 8 of 16

if required reviews and comment resolutions are conducted in accordance with applicable CQAM, TOP, and QAP requirements.

5 SPECIFIC REVIEW METHODS

- 5.1 Formally planned and fully documented Technical Reviews shall be performed, when required, to verify the technical correctness of the work against established practices.
- 5.1.2 Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with CQAM Section 2.
- 5.1.3 The Element Manager shall identify those Technical Review criteria applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12, "Instructions to Technical Reviewers" (Figure 2). Instructions to Technical Reviewers shall be approved by the Technical Director or Cognizant Director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practices.
- 5.1.4 Technical Review comments requiring resolution, e.g., those associated with the applicable review criteria, shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record," (Figure 3). In addition to comments requiring resolution, the reviewer shall also indicate on the Instructions to Technical Reviewers form (Form QAP-12) that all review criteria identified have been addressed by initialling the appropriate empty "box" on the right side of the form under "Accomplished." Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document. The Technical Reviewer shall sign and date each Comment Resolution Record used to document comments.
- 5.1.5 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.
- 5.1.6 The author shall respond to the reviewer's comments and sign and date the form. The reviewer's concurrence with the responses shall be indicated by signature in the appropriate block in the lower left-hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbitrator.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5 Chg 1

Page 15 of 16

5.5.3 CNWRA Programmatic Reviews shall verify the following:

- General compliance to contractual requirements.
- Review item satisfies the objectives of all applicable CNWRA plans.
- The general approach, presentation, and clarity of the review items are satisfactory.
- The approach, methods, and/or conclusions are consistent with CNWRA policy.

5.5.4 The reviewer shall present any comments requiring resolution of the author and shall verify that the review item is revised based on the resolution.

5.6 Format Review

5.6.1 Format Reviews shall be performed by personnel who did not format the document under review and are cognizant of correspondence, reports and other document style, format, and distribution requirements.

5.6.2 Format Reviews shall verify the following:

- Conformance to applicable document format requirements.
- Internal and NRC document distribution requirements are met, as applicable.
- Spelling is correct (a spelling check program can be run).

5.7 Verification of Compliance

5.7.1 Verification of Compliance with QAP-002 shall be performed by CNWRA QA staff or a person acting in their capacity after all other steps in the review process have been completed.

5.7.2 Verification of Compliance with QAP-002 reviews shall determine the following:

- All required review criteria have been addressed.
- Report Review/Comment Resolution Sheets are complete.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 5, Chg 2

QUALITY ASSURANCE PROCEDURE

Page 1 of 16

Title

QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS AND PAPERS

EFFECTIVITY AND APPROVAL

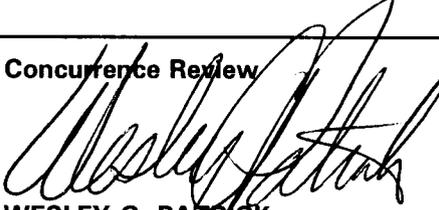
Revision 5 of this procedure became effective on 6/23/94. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	2	05/30/97
2-3	0	06/23/94
4-7	2	05/30/97
8	1	10/27/95
9	2	05/30/97
10	1	10/27/95
11-13	0	06/23/94
14-15	1	10/27/95
16	2	05/30/97

Superseded by Rev 6 Chg 0 dated 8/11/98

Supersedes Procedure No. QAP-002, Rev 5, Chg 1 dated 10/27/95

Approvals

Written By  BRUCE MABRITO	Date <u>5/29/97</u>	Concurrence Review  WESLEY C. PATRICK	Date <u>5/30/97</u>
Quality Assurance  ROBERT BRIENT <i>RDB</i>	Date <u>6/2/97</u>	Cognizant Director  HENRY GARCIA	Date <u>5/31/97</u>

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 5 Change 2

QUALITY ASSURANCE PROCEDURE

Page 4 of 16

4.1.4 The level of editing shall be based on the complexity of the document and the writing skills of the author. Generally speaking, for documents with relatively few graphics, references, and simple format, low-level editing may be performed by the appropriate CNWRA staff. More complex documents require high-level editing, which can be performed by selected CNWRA staff or by Southwest Research Institute (SwRI) Publications staff editors.

4.1.5 Editing shall consist of: (i) review by the editor (whether CNWRA or SwRI Publications staff); (ii) discussion of the review results between the editor and author; and (iii) as necessary, modification of the document in a collaborative effort. Editing shall be completed before additional word processing or reviews are performed.

4.2 Review Planning

4.2.1 The "Document Review Request and Transmittal Control," CNWRA Form AP-6-2, (Figure 1) shall be signed and dated by the Element 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 Element Manager shall check the required review types on the AP-6-2 form. For revisions and changes to previously submitted documents, reviews are necessary commensurate with the extent of the revision/change. The AP-6 form shall include a brief justification for any review less than that specified in the Review Requirements Matrix.

4.2.2 When a Technical Review is required, a Peer Review shall additionally be required if the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is 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 licensing decisions 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.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5, Chg 2

Page 5 of 16

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 Report	<input type="checkbox"/> AP	<input type="checkbox"/> RPD	<input type="checkbox"/> Paper/Presentation *	<input type="checkbox"/> Project/Test Plan
<input type="checkbox"/> Guidance Document	<input type="checkbox"/> TOP	<input type="checkbox"/> CQAM/QAP	<input type="checkbox"/> OPs/Work Plan	<input type="checkbox"/> Proposal

* Conference/Journal Title: _____

Sponsoring Organization(s) _____ Location _____ Date(s) _____

c. PROJECT INFORMATION

Project No. _____ Milestone No. _____ Subject Code _____

CNWSA DOCUMENT NO. Yes _____ No _____ Assigned No. CNWSA 97 _____

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

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

Author(s) _____ Element Manager _____

Assigned Secretary _____ Editor _____

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

Review Types & Reviewers Determined by Element Manager _____ (EM Signature) _____ (Date)

	Req'd Date	Initials	Completed
<input type="checkbox"/> TECHNICAL (Attach CNWSA form QAP-12.) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> PEER (Attach CNWSA form QAP-13.) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> CONCURRENCE Reviewer: _____	_____	_____	_____
<input type="checkbox"/> QA Reviewer: _____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC Reviewer: _____	_____	_____	_____
<input type="checkbox"/> FORMAT Reviewer: _____	_____	_____	_____
Verification of Compliance with QAP-002 _____	_____	_____	_____

IV. TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Add/delete names as required using current information in "Guidelines for Minimum Distribution of CNWSA Correspondence.")

Distribution (listed below)

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

CNWSA FORM AP-6-2 (5/97)

Figure 1. Sample Form AP-6-2—Document Review Request and Transmittal Control

Table 1. Review requirements matrix

Document Type	Review Type	Technical/Peer	Concurrence	QA	CNWRRA Programmatic	Format
Technical Documents						
Reports on Research and Technical Assistance, NUREGs/CRs		X			X	X
Annual Reports		X			X	X
RPD						
Regulatory Program Database (RPD) Documents		X	X		X	X
Papers/Presentations						
Journal Articles, Proceedings, Conference Papers		X			X	
Guidance Documents						
Draft Technical Positions, Rulemakings, and Regulatory Guides		X			X	X
QA Program Documents						
CQAM, QAPs			X	X	X	X
TOPs		X		X	X	X
Administrative/Fiscal Documents						
Operations Plans, Work Plans		X	X	X	X	X
Project Plans, Test Plans		X		X	X	X
Administrative Procedures			X	X	X	X
Proposals		X	X	X	X	X

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

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 5 Change 2

Page 7 of 16

QUALITY ASSURANCE PROCEDURE

- Results of tests are not reproducible or repeatable.
 - Data or interpretations are ambiguous.
 - Data adequacy is questionable—such as, data may not have been collected in conformance with an established QA program (see QAP-015 “Qualification of Existing Data”).
- 4.2.3 Peer Review may be conducted on activities as well as documents. While the complete review process may not apply, Peer Review of this type shall, in any case, be conducted in accordance with Section 5.2 of this procedure. A Peer Review shall also be used when 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 If Technical, Peer, or Concurrence Reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 5.1.2, 5.2.2, and 5.3.1, and identify them on the AP-6 form.
- 4.2.5 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.1.3 and 5.2.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.
- 4.3 Reviews and Comment Resolution**
- 4.3.1 Review items and supporting documentation shall be routed to reviewers in the following order: Technical or Concurrence, QA, Programmatic, and Format. Technical (or Concurrence), QA, and Programmatic Reviews may be conducted simultaneously. Peer Reviews are generally conducted after the other prescribed reviews are completed, however, that is not a requirement.
- 4.3.2 Technical Review comments and their resolution shall be documented as specified in Section 5 of this procedure. Comments from several reviewers should be consolidated and changes shall be made to the document to incorporate the comment resolutions.
- 4.3.3 After comments have been incorporated, the revised document, comment resolution records, and the AP-6 form shall be returned to the reviewers. The reviewers shall verify that the comment resolutions have been incorporated, then initial and date the AP-6 form. The Technical Director shall initial and date the AP-6 form to indicate that the Peer Review comments have been satisfactorily addressed. After the AP-6 form has been signed-off by all reviewers, compliance with the provisions of this procedure shall be verified by QA staff. The verification will determine

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5, Chg 2

Page 9 of 16



**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
INSTRUCTIONS TO TECHNICAL REVIEWERS**

Technical Review Items to Verify

TO: _____

SUBJECT: Review of _____

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: _____

ASSIGNED

ACCOMPLISHED

TECHNICAL CORRECTNESS

- | | | |
|--------------------------|--|--------------------------|
| <input type="checkbox"/> | Assumptions are reasonable and clearly stated. | <input type="checkbox"/> |
| <input type="checkbox"/> | Appropriate techniques are used.* | <input type="checkbox"/> |
| <input type="checkbox"/> | Computations are correct, calculations are documented and verified in accordance with QAP-014 (document this review by a statement on the TOP-3 form). | <input type="checkbox"/> |
| <input type="checkbox"/> | Existing data are qualified (or exempted) in accordance with QAP-015. | <input type="checkbox"/> |
| <input type="checkbox"/> | Conclusions are properly supported by correctly interpreted data.* | <input type="checkbox"/> |

* *Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.*

READABILITY

- | | | |
|--------------------------|---|--------------------------|
| <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

- | | | |
|--------------------------|---|--------------------------|
| <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 answer 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"/> |

ELEMENT MANAGER	DATE	COGNIZANT DIRECTOR	DATE

CNWRA FORM QAP-12-4 (Rev. 5/97)

Figure 2. Sample Form QAP-12-4—Instructions to Technical Reviewers

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 5 Chg 2

Page 16 of 16

- Documentation package is complete and ready to be put in QA Records.

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:

- Document Review Packages
- QA Document Review Forms
- Document Review Request and Transmittal Control Forms
- Instructions to Technical Reviewers
- Instructions to Peer Reviewers
- Report Review/Comment Resolution Record Forms
- Peer Review Reports, minutes, and teleconference records

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6

Page 1 of 17

Title QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS AND PAPERS

EFFECTIVITY

Revision 6 of this procedure became effective on 8/11/98. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
All	0	08/11/98

Supersedes Procedure No. QAP-002, Rev 5, Chg 2 dated 5/30/97

Approvals			
Written by <i>Bruce Mabrigo</i> BRUCE MABRITO	Date 8/11/98	Technical Review <i>Wesley C. Patrick</i> WESLEY C. PATRICK	Date 8/11/98
Quality Assurance <i>Mark R. Ehnstrom</i> MARK R. EHNSTROM	Date 8/11/98	Cognizant Director <i>Henry Garcia</i> HENRY GARCIA	Date 8/11/98

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 2 of 17

**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 the various types of reviews required for the Center for the Nuclear Waste Regulatory Analyses (CNWRA) documents, reports, and papers. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall be reviewed in accordance with this procedure. This procedure is developed reflecting the guidance of the "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, and implements Center Quality Assurance Manual (CQAM) Section 3.

2. RESPONSIBILITY

- 2.1 Element Managers (EMs) are responsible for the implementation of 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 reviewers' comments.

3. DEFINITIONS

- 3.1 Concurrence Reviews - Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide 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 being described or performed.
- 3.2 Peer - Peer is a person having 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.
- 3.3 Peer Review Group - A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 3 of 17

- 3.4 Peer Review - A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor for the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria employed, and of 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, and industry practice.

- 3.5 Technical Review - A documented, traceable review performed by qualified personnel who are 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.

4. DOCUMENT PREPARATION AND REVIEW PROCESS

4.1 Document Submittal for Review and Editing

- 4.1.1 The Author shall submit final drafts of items requiring review to the cognizant EM sufficiently in advance of the due date to allow for word processing, review, reproduction, and distribution. The document shall be submitted along with any supporting documentation needed to perform the reviews (Scientific Notebooks, calculation verifications, etc.).
- 4.1.2 Intermediate and Major Milestone deliverable items shall be edited to enhance and improve writing style, grammar and punctuation, and to assure that the writing is effective, unless otherwise directed by the EM. Other documents, as determined necessary, shall be edited by the EM.
- 4.1.3 The EM shall review each document and determine: (i) the extent of editing necessary, and (ii) the technical areas covered by the document in order to identify reviewers. The EM should also verify that relevant programmatic objectives are satisfied by the document. The EM will work with the author until an "author final" version of the document is ready to be formatted and enter the review cycle.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 4 of 17

4.1.4 Editing shall be conducted as shown in Table 1. As indicated, certain types of documents may be edited at the discretion of the EM. Documents that require editing will be submitted to the CNWRA or Southwest Research Institute (SwRI) Publications staff member responsible for editorial coordination.

4.1.5 Editing shall consist of (i) review by the editor; (ii) discussion of the review results between the editor and author; and (iii) as necessary, modification of the document in a collaborative effort. Editing shall be completed before additional word processing or reviews are performed.

4.2 Review Planning

4.2.1 The "Document Review Request and Transmittal Control," CNWRA Form AP-6-2, (Figure 1) shall be signed and dated by the EM. The document type shall be one of the review item categories identified in Table 1, Review Requirements Matrix. From the Review Requirements Matrix, the EM shall check the required review types on the AP-6-2 form. For revisions and changes to previously submitted documents, reviews are necessary commensurate with the extent of the revision/change. The AP-6 form shall include a brief justification for any review less than that specified in the Review Requirements Matrix.

4.2.2 When a Technical Review is required, a Peer Review shall additionally be required if the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods important to licensing 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 is 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.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 5 of 17



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 Report	<input type="checkbox"/> AP	<input type="checkbox"/> RPD	<input type="checkbox"/> Paper/Presentation *	<input type="checkbox"/> Project/Test Plan
<input type="checkbox"/> Guidance Document	<input type="checkbox"/> TOP	<input type="checkbox"/> CQAM/QAP	<input type="checkbox"/> OPs/Work Plan	<input type="checkbox"/> Proposal

* Conference/Journal Title: _____

Special Markings (such as "Predecisional" or "Proprietary") Yes _____ No _____

c. PROJECT INFORMATION

Project No. _____ Milestone No. _____ Subject Code _____

CNwRA DOCUMENT NO. Yes _____ No _____ Assigned No. CNwRA 97

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

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

Author(s) _____ Element Manager _____

Assigned Secretary _____ Editor _____

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

Review Types & Reviewers Determined by Element Manager

	(EM Signature)	(Date)		
	Req'd Date	Initials	Completed	
<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"/> CONCURRENCE Reviewer:	_____	_____	_____	_____
<input type="checkbox"/> QA Reviewer:	_____	_____	_____	_____
<input type="checkbox"/> PROGRAMMATIC Reviewer:	_____	_____	_____	_____
<input type="checkbox"/> FORMAT Reviewer:	_____	_____	_____	_____

Verification of Compliance with QAP-002 _____

IV. TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Add/delete names as required using current information in "Guidelines for Minimum Distribution of CNwRA Correspondence.")

Distribution (listed below)

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

CNwRA FORM AP-6-2 (10/97)

Figure 1. Sample Form AP-6-2—Document Review Request and Transmittal Control

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 6 of 17

Table 1. Review requirements matrix

DOCUMENT TYPE	REQUIRED REVIEW(S)					
	EDITORIAL	TECHNICAL/PEER	CONCURRENCE	QA	PROGRAMMATIC	FORMAT
Technical Documents						
Reports on Research/Technical Assistance, NUREGs/CRs	X	X			X	X
Annual Reports	X	X			X	X
Papers/Presentations						
Journal Articles, Proceedings, Abstracts, Conference Papers	X*	X			X	
Guidance Documents						
Technical Positions, Rulemakings, & Regulatory Guides	X*	X			X	X
QA Program Documents						
CQAM, QAPs			X	X	X	X
TOPs		X		X	X	X
Administrative/Fiscal Documents						
Operations Plans, Work Plans	X*	X	X	X	X	X
Project Plans, Test Plans	X*	X		X	X	X
Administrative Procedures (APs)			X	X	X	X
Proposals	X*	X	X	X	X	X
RPD						
Regulatory Program Database (RPD) Documents		X	X		X	X

*Optional (per Element Manager)

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 7 of 17

- Interpretations having significant impact on licensing decisions 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—such as, data may not have been collected in conformance with an established Quality Assurance (QA) program (see QAP-015 "Qualification of Existing Data").

4.2.3 Peer Review may be conducted on activities as well as documents. While the complete review process may not apply, Peer Review of this type shall, in any case, be conducted in accordance with Section 5.2 of this procedure. A Peer Review shall also be used when 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 If Technical, Peer, or Concurrence Reviews are required, the EM shall select reviewers based on the criteria described in paragraphs 5.1.2, 5.2.2, and 5.3.1, and identify them on the AP-6 form.

4.2.5 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.1.3 and 5.2.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 8 of 17

4.3 Reviews and Comment Resolution

4.3.1 Review items and supporting documentation shall be routed to reviewers in the following order: Technical or Concurrence, QA, Programmatic, and Format. Technical (or Concurrence), QA, and Programmatic Reviews may be conducted simultaneously. Peer Reviews are generally conducted after the other prescribed reviews are completed, however, that is not a requirement.

4.3.2 Technical Review comments and their resolution shall be documented as specified in Section 5 of this procedure. Comments from several reviewers should be consolidated and changes shall be made to the document to incorporate the comment resolutions.

4.3.3 After comments have been incorporated, the revised document, comment resolution records, and the AP-6 form shall be returned to the reviewers. The reviewers shall verify that the comment resolutions have been incorporated, then initial and date the AP-6 form. The Technical Director shall initial and date the AP-6 form to indicate that the Peer Review comments have been satisfactorily addressed. After the AP-6 form has been signed-off by all reviewers, compliance with the provisions of this procedure shall be verified by QA staff. The verification will determine if required reviews and comment resolutions are conducted in accordance with applicable CQAM, Technical Operating Procedure (TOP), and Quality Assurance Procedure (QAP) requirements.

5. SPECIFIC REVIEW METHODS

5.1 Formally planned and fully documented Technical Reviews shall be performed, when required, to verify the technical correctness of the work against established practices.

5.1.2 Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with CQAM Section 2.

5.1.3 The EM shall identify those Technical Review criteria applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12-4, "Instructions to Technical Reviewers" (Figure 2). Instructions to Technical Reviewers shall be approved by the Technical Director or Cognizant Director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practices.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 9 of 17



CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES INSTRUCTIONS TO TECHNICAL REVIEWERS Technical Review Items to Verify

TO: _____
SUBJECT: Review of _____

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: _____

ASSIGNED

ACCOMPLISHED

TECHNICAL CORRECTNESS

<input type="checkbox"/>	Assumptions are reasonable and clearly stated.	<input type="checkbox"/>
<input type="checkbox"/>	Appropriate techniques are used.*	<input type="checkbox"/>
<input type="checkbox"/>	Computations are correct, calculations are documented and verified in accordance with QAP-014 (document this review by a statement on the TOP-3 form).	<input type="checkbox"/>
<input type="checkbox"/>	Existing data are qualified (or exempted) in accordance with QAP-015.	<input type="checkbox"/>
<input type="checkbox"/>	Conclusions are properly supported by correctly interpreted data.* <small>* Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.</small>	<input type="checkbox"/>

READABILITY

<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

<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 answer 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"/>

ELEMENT MANAGER	DATE	COGNIZANT DIRECTOR	DATE
-----------------	------	--------------------	------

CNWRA FORM QAP-12-4 (Rev. 5/97)

Figure 2. Sample Form QAP-12-4—Instructions to Technical Reviewers

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 10 of 17

5.1.4 Technical Review comments requiring resolution, e.g., those associated with the applicable review criteria, shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record," (Figure 3). In addition to comments requiring resolution, the reviewer shall also indicate on the Instructions to Technical Reviewers form (Form QAP-12) that all review criteria identified have been addressed by initialling the appropriate empty "box" on the right side of the form under "Accomplished." Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document. The Technical Reviewer shall sign and date each Comment Resolution Record used to document comments.

5.1.5 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.

5.1.6 The author shall respond to the reviewer's comments and sign and date the form. The reviewer's concurrence with the responses shall be indicated by signature in the appropriate block in the lower left-hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbitrator.

5.2 Peer Review

5.2.1 Peer Review shall be conducted by individuals technically capable of performing the original work. Peer Reviews shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.

5.2.2 In addition to having qualifications equivalent to Technical Reviewers (section 5.1.2), Peer Reviewers cannot have been involved as participants, supervisors, technical reviewers, or advisors in the work being reviewed. Peer reviews shall be conducted by an individual or by groups of sufficient sizes and composition to span the technical issues and appropriate areas. Technical areas more central to the work to be reviewed should receive proportionally more representation on the Peer Review Groups.

5.2.3 The Element 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 (Figure 4). 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 6 Change 0

Page 12 of 17

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 conclusions.

Element Manager Date

Cognizant Director Date

CNWRRA Form QAP-13-1 (Rev. 5/91)

Figure 4. Sample Form QAP-13 - Instructions to Peer Reviewers

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 13 of 17

5.2.4 Individual reviewer's 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. The document under review shall be revised to address to Peer Review comments. Appropriate resolution of Peer Review comments shall be verified by the cognizant director and documented by initialling and dating the AP-6 form or by some other method.

5.3 Concurrence Reviews

5.3.1 Concurrence Reviews shall be performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed. This type of review provides general concurrence with the author for the overall approach and presentation of the work being reviewed, and provides a basis for consistency among like products of the CNWRA.

5.3.2 A Concurrence Review shall verify 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.

5.3.3 Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record." Editorial comments of a minor nature may be made as marginalia on the reviewer's copy of the report. Upon completion of the review, the reviewer shall sign and date the form.

5.3.4 The author shall respond to the reviewer's comments, and concurrence with the responses shall be indicated by the reviewer's signature in the appropriate block in the lower left-hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA cognizant director or President shall serve as the final arbitrator.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 14 of 17

5.4 QA Reviews

- 5.4.1 QA Reviews verify that the requirements of the CQAM and other applicable procedures are met in Operating Procedures and quality-affecting planning documents which implement the CQAM.
- 5.4.2 QA Reviews shall be conducted by QA staff cognizant of the applicable QA program and procedural requirements.
- 5.4.3 QA Review comments requiring resolution shall be documented on CNWRA Form QAP-6, "QA Document Review" (Figure 5), and forwarded to the author. The author shall provide responses to the comments, and the reviewer's concurrence with the resolution shall be indicated by signature in the lower left-hand block of the form. The reviewer shall verify incorporation of the comment resolutions. In cases when satisfactory resolution is not obtained, the CNWRA President shall be arbitrator.

5.5 CNWRA Programmatic Reviews

- 5.5.1 CNWRA Programmatic Reviews verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review.
- 5.5.2 CNWRA Programmatic Reviews shall be conducted by the cognizant CNWRA director, Technical Director, Deputy Technical Director for Systems Engineering and Integration, or President
- 5.5.3 CNWRA Programmatic Reviews shall verify the following:
- General compliance to contractual requirements.
 - Review item satisfies the objectives of all applicable CNWRA plans.
 - The general approach, presentation, and clarity of the review items are satisfactory.
 - The approach, methods, and/or conclusions are consistent with CNWRA policy.
- 5.5.4 The reviewer shall present any comments requiring resolution of the author and shall verify that the review item is revised based on the resolution.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 16 of 17

5.6 Format Review

5.6.1 Format Reviews shall be performed by personnel who did not format the document under review and are cognizant of correspondence, reports and other document style, format, and distribution requirements.

5.6.2 Format Reviews shall verify the following:

- Conformance to applicable document format requirements.
- Internal and NRC document distribution requirements are met, as applicable.
- Spelling is correct (a spell check program can be run).

5.7 Verification of Compliance

5.7.1 Verification of Compliance with QAP-002 shall be performed by CNWRA QA staff or a person acting in their capacity after all other steps in the review process have been completed.

5.7.2 Verification of Compliance with QAP-002 reviews shall determine the following:

- All required review criteria have been addressed.
- Report Review/Comment Resolution Sheets are complete.
- Documentation package is complete and ready to be put in QA Records.

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:

- Document Review Packages
- QA Document Review Forms
- Document Review Request and Transmittal Control Forms

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 0

Page 17 of 17

- Instructions to Technical Reviewers
- Instructions to Peer Reviewers
- Report Review/Comment Resolution Record Forms
- Peer Review Reports

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6

Page 1 of 17

Title QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS AND PAPERS

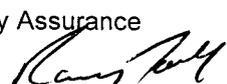
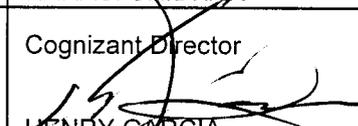
EFFECTIVITY

Revision 6 of this procedure became effective on 8/11/98. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
1-2	1	12/31/99
3-6	0	08/11/98
7	1	12/31/99
8-13	0	08/11/98
14	1	12/31/99
15	0	08/11/98

SUPERSEDED

Supersedes Procedure No. QAP-002, Rev 6, Chg 0 dated 8/11/98

Approvals			
Written by  BRUCE MABRITO	Date 12/30/99	Technical Review  NARASI SRIVIDHAR	Date 12/20/99
Quality Assurance  RANDY FOLCK	Date 12/30/99	Cognizant Director  HENRY GARCIA	Date 12/30/99

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 1

Page 2 of 17

**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 the various types of reviews required for the Center for the Nuclear Waste Regulatory Analyses (CNWRA) documents, reports, papers, plans, and proposals. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall be reviewed in accordance with this procedure. This procedure is developed reflecting the guidance of the "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, and implements Center Quality Assurance Manual (CQAM) Section 3.

2. RESPONSIBILITY

- 2.1 Element Managers (EMs) are responsible for the implementation of 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 reviewers' comments.

3. DEFINITIONS

- 3.1 Concurrence Reviews—Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide 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 being described or performed.
- 3.2 Peer—Peer is a person having 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.
- 3.3 Peer Review Group—A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 1

Page 7 of 17

- Interpretations having significant impact on licensing decisions 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—such as, data may not have been collected in conformance with an established Quality Assurance (QA) program (see QAP-015 “Qualification of Existing Data”).

4.2.3 Peer Review may be conducted on activities as well as documents. While the complete review process may not apply, Peer Review of this type shall, in any case, be conducted in accordance with Section 5.2 of this procedure. A Peer Review shall also used when 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 If Technical, Peer, or Concurrence Reviews are required, the EM shall select reviewers based on the criteria described in paragraphs 5.1.2, 5.2.2, and 5.3.1, and identify them on the AP-6 form.

4.2.5 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.1.3 and 5.2.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.

4.2.6 If the review involves an operations or project plan, or a proposal, the review package shall include a Quality Requirements Application Matrix (QRAM) prepared in accordance with QAP-013, Quality Planning.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 6 Change 1

Page 14 of 17

5.4 QA Reviews

5.4.1 QA Reviews verify that the requirements of the CQAM and other applicable procedures are met in Operating Procedures and quality-affecting planning documents which implement the CQAM.

5.4.2 QA Reviews shall be conducted by QA staff cognizant of the applicable QA program and procedural requirements.

5.4.3 QA Review comments requiring resolution shall be documented on CNWRA Form QAP-6, "QA Document Review" (Figure 5), and forwarded to the author. The author shall provide responses to the comments, and the reviewer's concurrence with the resolution shall be indicated by signature in the lower left-hand block of the form. The reviewer shall verify incorporation of the comment resolutions. In cases when satisfactory resolution is not obtained, the CNWRA President shall be arbitrator.

5.5 CNWRA Programmatic Reviews

5.5.1 CNWRA Programmatic Reviews verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review.

5.5.2 CNWRA Programmatic Reviews shall be conducted by the cognizant CNWRA director, Technical Director, Deputy Technical Director for Systems Engineering and Integration, or President.

5.5.3 CNWRA Programmatic Reviews shall verify the following:

- General compliance to contractual requirements.
- Review item satisfies the objectives of all applicable CNWRA plans.
- The general approach, presentation, and clarity of the review items are satisfactory.
- The approach, methods, and/or conclusions are consistent with CNWRA policy.
- The QRAM satisfies the requirements of the contract or request for proposal, and describes the defined scope of work.

5.5.4 The reviewer shall present any comments requiring resolution of the author and shall verify that the review item is revised based on the resolution.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 7 Change 0

QUALITY ASSURANCE PROCEDURE

Page 1 of 16

Title QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS AND PAPERS

EFFECTIVITY

Revision 7 of this procedure became effective on 4/04/2002. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
ALL	0	4/04/2002

SUPERSEDED

Supersedes Procedure No. QAP-002, Rev 6, Chg 0 dated 8/11/98

Approvals			
Written by <i>Mark R. Ehrstrom</i> Mark Ehrstrom	Date 3/29/02	Technical Review <i>E. C. H.</i> English Percy	Date 3/27/2002
Quality Assurance <i>Bruce Mabrito</i> Bruce Mabrito	Date 4/1/2002	Cognizant Director <i>Henry Garcia</i> Henry Garcia	Date 4/1/2002

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 7 Change 0

Page 2 of 16

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 the various types of reviews required for the Center for the Nuclear Waste Regulatory Analyses (CNWRA) documents, reports, papers, plans, and proposals. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall be reviewed in accordance with this procedure. This procedure is developed reflecting the guidance of the "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, and implements CNWRA Quality Assurance Manual (CQAM) Section 3.

Documents, reports and papers shall be reviewed in accordance with this procedure unless a specific review process is described in another controlling procedure (e.g., for QRAMs, SDPs, and scientific notebooks).

2. RESPONSIBILITY

- 2.1 Element Managers are responsible for the implementation of 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 reviewers' comments.

3. DEFINITIONS

- 3.1 **Concurrence Reviews**—Reviews which provide for general concurrence with the author for the overall approach and presentation of the work being reviewed, and provide 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 being described or performed.
- 3.2 **Peer**—Peer is a person having 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.
- 3.3 **Peer Review Group**—A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 7 Change 0

Page 3 of 16

3.4 Peer Review—A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor for the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A Peer Review is an in-depth critique of matters such as assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria employed, and of 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, and industry practice.

3.5 Technical Review—A documented, traceable review performed by qualified personnel who are 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.

4. DOCUMENT PREPARATION AND REVIEW PROCESS

4.1 Document Submittal for Review and Editing

4.1.1 The Author shall submit final drafts of items requiring review to the cognizant Element Manager sufficiently in advance of the due date to allow for word processing, review, reproduction, and distribution. The document shall be submitted along with any supporting documentation needed to perform the reviews (Scientific Notebooks, calculation verifications, etc.).

4.1.2 Intermediate and Major Milestone deliverable items shall be edited to enhance and improve writing style, grammar and punctuation, and to assure that the writing is effective, unless otherwise directed by the Element Manager. Other documents, as determined necessary, shall be edited by the Element Manager.

4.1.3 The Element Manager shall review each document and determine: (i) the extent of editing necessary, and (ii) the technical areas covered by the document in order to identify reviewers. The Element Manager should also verify that relevant programmatic objectives are satisfied by the document. The Element Manager will work with the author until an "author final" version of the document is ready to be formatted and enter the review cycle.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 7 Change 0

Page 4 of 16

QUALITY ASSURANCE PROCEDURE

4.1.4 Editing shall be conducted as shown in Table 1. As indicated, certain types of documents may be edited at the discretion of the Element Manager. Documents that require editing will be submitted to the CNWRA or Southwest Research Institute (SwRI) Publications staff member responsible for editorial coordination.

4.1.5 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. Editing should be completed before additional word processing or reviews are performed.

4.2 Review Planning

4.2.1 The "Document Review Request and Transmittal Control," CNWRA Form AP-6, (Figure 1) shall be completed, signed, and dated by the Element Manager. The document type shall be one of the review item categories identified in Table 1, Review Requirements Matrix. The Element Manager shall identify whether special markings (e.g., predecisional) are required for the document. From the Review Requirements Matrix, the Element Manager shall check the required review types on the AP-6 form. The review process may be tailored taking into consideration the complexity of the document, report-writing skill level of the authors(s), client needs, and contractual commitments.

4.2.2 For revisions and changes to previously submitted documents, review may not be required for a revision/change that does not materially affect the intent or content of the document (e.g., editorial and clarification). The AP-6 form shall include a brief justification by the Element Manager for any review less than that in the Review Requirements Matrix Table.

4.2.3 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 important to licensing 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 licensing decisions will be made.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 7 Change 0

Page 5 of 16

QUALITY ASSURANCE PROCEDURE

- 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—such as, data may not have been collected in conformance with an established Quality Assurance program (see QAP-015 “Qualification of Existing Data”).

4.2.4 Peer Review may be conducted on activities as well as documents. While the complete review process may not apply, Peer Review of this type shall, in any case, be conducted in accordance with Section 5.2 of this procedure. A Peer Review shall also be used when 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.

4.2.5 If Technical, Peer, or Concurrence Reviews are required, the Element Manager shall select reviewers based on the criteria described in paragraphs 5.1.1, 5.2.1, and 5.3.1, and identify them on the AP-6 form.

4.2.6 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.1.2 and 5.2.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria.

4.2.7 If the review involves an operations plan, project plan, or other contractual commitment to work, a Quality Requirements Application Matrix (GRAM) shall be prepared in accordance with QAP-013, Quality Planning. The GRAM shall be completed and approved prior to initiation of work activities.

4.3 Reviews and Comment Resolution

4.3.1 Review items and supporting documentation shall be routed to reviewers in the following order: Technical or Concurrence, Quality Assurance, Programmatic, and Format. Technical (or Concurrence), Quality Assurance, and Programmatic Reviews may be conducted simultaneously. Peer Reviews are generally conducted after the other prescribed reviews are completed, however, that is not a requirement.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 7 Change 0

Page 6 of 16

4.3.2 Technical Review comments and their resolution shall be documented as specified in Section 5 of this procedure. Comments from several reviewers should be consolidated and changes shall be made to the document to incorporate the comment resolutions.

4.3.3 After comments have been incorporated, the revised document, comment resolution records, and the AP-6 form shall be returned to the reviewers. The reviewers shall verify that the comment resolutions have been incorporated, then initial and date the AP-6 form. The Technical Director shall initial and date the AP-6 form to indicate that the Peer Review comments have been satisfactorily addressed. 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. The verification will determine if required reviews and comment resolutions are conducted in accordance with this procedure.

5. SPECIFIC REVIEW METHODS

5.1 Formally planned and fully documented Technical Reviews shall be performed, when required, to verify the technical correctness of the work against established practices.

5.1.1 Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with CNWRA Quality Assurance Manual Section 2.

5.1.2 The Element Manager shall identify those Technical Review criteria applicable to the work being reviewed by checking the appropriate blocks on CNWRA Form QAP-12, "Instructions to Technical Reviewers" (Figure 2). Instructions to Technical Reviewers shall be approved by the Technical Director or Cognizant Director. The basis for verification shall be predetermined requirements, industry standards, or common scientific, engineering, and industry practices.

5.1.3 Technical Review comments requiring resolution (e.g., those associated with the applicable review criteria) shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record," (Figure 3). In addition to comments requiring resolution, the reviewer shall also indicate on the Instructions to Technical Reviewers form (Form QAP-12) that all review criteria identified have been addressed by initialing the appropriate empty "box" on the right side of the form under "Accomplished." Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document. The Technical Reviewer shall sign and date each Comment Resolution Record used to document comments.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 7 Change 0

Page 7 of 16

QUALITY ASSURANCE PROCEDURE

5.1.4 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.

5.1.5 The author shall respond to the review comments and sign and date the form. Concurrence with the responses shall be indicated by signature in the appropriate block in the lower left-hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbitrator.

5.2 Peer Review

5.2.1 Peer Review shall be conducted by individuals technically capable of performing the original work. Peer Reviews shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.

5.2.2 In addition to having qualifications equivalent to Technical Reviewers (section 5.1.2), Peer Reviewers cannot have been involved as participants, supervisors, technical reviewers, or advisors in the work being reviewed. Peer reviews shall be conducted by an individual or by groups of sufficient sizes and composition to span the technical issues and appropriate areas. Technical areas more central to the work to be reviewed should receive proportionally more representation on the Peer Review Groups.

5.2.3 The Element 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 (Figure 4). Instructions to Peer Reviewers shall be approved by the cognizant director. The basis of the evaluation shall be the reviewer's expert judgment.

5.2.4 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. The document under review shall be revised to address to Peer Review comments. Appropriate resolution of Peer Review comments shall be verified by the cognizant director and documented by initialing and dating the AP-6 form or by some other method.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 7 Change 0

QUALITY ASSURANCE PROCEDURE

Page 8 of 16

5.3 Concurrence Reviews

5.3.1 Concurrence Reviews shall be performed by individuals cognizant of the applicable technical and procedural requirements, and of the objectives of the work being described or being prescribed. This type of review provides general concurrence with the author for the overall approach and presentation of the work being reviewed, and provides a basis for consistency among like products of the CNWRA.

5.3.2 A Concurrence Review shall verify 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.

5.3.3 Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record." Editorial comments of a minor nature may be made as marginalia on the review copy of the report. Upon completion of the review, the reviewer shall sign and date the form.

5.3.4 The reviewer shall present any comments requiring resolution of the author and shall verify that the review item is revised based on the resolution.

5.4 Quality Assurance Reviews

5.4.1 Quality Assurance Reviews verify that the requirements of the CNWRA Quality Assurance Manual and other applicable procedures are met in Operating Procedures and quality-affecting planning documents that implement the CNWRA Quality Assurance Manual.

5.4.2 Quality Assurance Reviews shall be conducted by Quality Assurance staff cognizant of the applicable Quality Assurance program and procedural requirements.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 7 Change 0

Page 9 of 16

QUALITY ASSURANCE PROCEDURE

5.4.3 Quality Assurance Review comments requiring resolution shall be documented on CNWRA Form QAP-6, "Quality Assurance Document Review" (Figure 5) or on a TOP-3 form that has been marked as a QA Review, and forwarded to the author. Completion of the form shall be in the same manner as described in paragraph 5.1.5.

5.5 CNWRA Programmatic Reviews

5.5.1 CNWRA Programmatic Reviews verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review.

5.5.2 CNWRA Programmatic Reviews shall be conducted by the cognizant CNWRA director, Technical Director, Deputy Technical Director for Systems Engineering and Integration, or President.

5.5.3 CNWRA Programmatic Reviews shall verify the following:

- General compliance to contractual requirements.
- Review item satisfies the objectives of all applicable CNWRA plans.
- The general approach, presentation, and clarity of the review items are satisfactory.
- The approach, methods, and/or conclusions are consistent with CNWRA policy.

5.5.4 The reviewer shall present any comments requiring resolution of the author and shall verify that the review item is revised based on the resolution.

5.6 Format Review

5.6.1 Format Reviews shall be performed by personnel who did not format the document under review and are cognizant of correspondence, reports and other document style, format, and distribution requirements.

5.6.2 Format Reviews shall verify the following:

- Conformance to applicable document format requirements.
- Internal and NRC document distribution requirements are met, as applicable.
- Spelling is correct (a spell check program can be run).

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-002

Revision 7 Change 0

QUALITY ASSURANCE PROCEDURE

Page 10 of 16

5.7 Verification of Compliance

5.7.1 Verification of Compliance with QAP-002 shall be performed by CNWRA Quality Assurance staff or a person acting in their capacity after all other steps in the review process have been completed.

5.7.2 Verification of Compliance with QAP-002 reviews shall determine the following:

- All required review criteria have been addressed.
- Report Review/Comment Resolution Sheets are complete.
- Documentation package is complete and ready to be put in Quality Assurance Records.

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:

- Document Review Packages
- Quality Assurance Document Review Forms
- Document Review Request and Transmittal Control Forms
- Instructions to Technical Reviewers
- Instructions to Peer Reviewers
- Report Review/Comment Resolution Record Forms
- Peer Review Reports

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Proc. QAP-002

Revision 7 Change 0

QUALITY ASSURANCE PROCEDURE

Page 11 of 16



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"/> Abstract	<input type="checkbox"/> Presentation/Poster	<input type="checkbox"/> Project/Test Plan	<input type="checkbox"/> AP	<input type="checkbox"/> TOP	<input type="checkbox"/> Technical Report (Publication)
<input type="checkbox"/> Peer-Reviewed	<input type="checkbox"/> OPs Plans	<input type="checkbox"/> CQAM	<input type="checkbox"/> QAP	<input type="checkbox"/> Proposal	<input type="checkbox"/> NRC Guidance

* Conference/Journal Title: _____

Special Markings (e.g., "Predecisional" or "Proprietary") _____ Licensing Support Network Yes _____ No _____

Copyright Permission Yes _____ No _____

c. PROJECT INFORMATION

Project No. _____ Milestone No. _____ Subject Code _____

CNWA DOCUMENT NO. Yes _____ No _____ Assigned No. CNWA 200 _____

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

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

Author(s) _____ Element Manager _____ Assigned Secretary _____

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

Review Types & Reviewers Determined by Element Manager

	(Element Manager Signature)		(Date)
	Req'd Date	Initials	
<input type="checkbox"/> TECHNICAL (Attach CNWA form QAP-12.) Reviewer(s): _____	_____	_____	_____
<input type="checkbox"/> PEER (Attach CNWA 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 Reviewer: _____	_____	_____	_____
<input type="checkbox"/> FORMAT Reviewer/Style: _____	_____	_____	_____

Verification of Compliance with QAP-002 _____

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

IV TRANSMITTAL

TO: _____ FROM: _____

COPIES TO: (Add/delete names as required using current information in "Guidelines for Minimum Distribution of CNWA Correspondence.")

Distribution (listed below) _____

CNWA FORM AP-6 (3/2001)

Figure 1. Sample Form AP-6, Document Review Request and Transmittal Control

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 7 Change 0

Page 12 of 16

Table 1. Review requirements matrix

DOCUMENT TYPE	REQUIRED REVIEW(S)					
	EDITORIAL	TECHNICAL/PEER	CONCURRENCE	QA	PROGRAMMATIC	FORMAT
Technical Documents						
Reports on Research/Technical Assistance, SRD, NUREGs/CRs, Validation Reports	X	X			X	X*
Annual Reports	X	X			X	X*
Papers/Presentations						
Journal Articles, Proceedings, Abstracts, Conference Papers	X*	X			X	
Guidance Documents						
Technical Positions, Rulemakings, & Regulatory Guides	X*	X			X	X*
Quality Assurance Program Documents						
CQAM, QAPs, APs			X	X	X	X*
TOPs		X		X	X	X*
Administrative/Fiscal Documents						
Operations Plans, Work Plans	X*	X	X	X	X	X*
Project Plans, Test Plans, Validation Plans	X*	X		X	X	X*
Proposals	X*	X	X	X	X	X*

*Optional (per Element Manager)

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 7 Change 0

Page 13 of 16



CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES INSTRUCTIONS TO TECHNICAL REVIEWERS Technical Review Items to Verify

TO: _____

SUBJECT: Review of _____

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: _____

ASSIGNED TECHNICAL CORRECTNESS

ACCOMPLISHED

<input type="checkbox"/>	Assumptions are reasonable and clearly stated.	<input type="checkbox"/>
<input type="checkbox"/>	Appropriate techniques are used.*	<input type="checkbox"/>
<input type="checkbox"/>	Existing data are qualified (or exempted) in accordance with QAP-015.	<input type="checkbox"/>
<input type="checkbox"/>	Conclusions are properly supported by correctly interpreted data.*	<input type="checkbox"/>
* Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of the Peer Review.		
	Are there calculations? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, are "over checks" required? YES <input type="checkbox"/> NO <input type="checkbox"/>	
<input type="checkbox"/>	If no "over checks" are required, explain why: _____	<input type="checkbox"/>
<input type="checkbox"/>	Calculations are correct, documented and verified in accordance with QAP-014 (document this review by a statement on the TOP-3 form).	<input type="checkbox"/>

READABILITY

<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

<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 answer 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"/>

ELEMENT MANAGER	DATE	COGNIZANT DIRECTOR	DATE

CNWRA FORM QAP-12 (Rev.2/2001)

Figure 2. Sample Form QAP-12, Instructions to Technical Reviewer

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 7 Change 0

Page 15 of 16

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.

Element Manager

Date

Cognizant Director

Date

CNWRA FORM QAP-13 (02/02)

Figure 4. Sample Form QAP-013, Instructions to Peer Reviewers

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 7 Change 0

Page 16 of 16

QUALITY ASSURANCE DOCUMENT REVIEW		PAGE	OF	PAGES	
PROJECT NUMBER	DOCUMENT DATE	DOCUMENT NUMBER			
TITLE:					
The comments shown below address questions conditions that may have quality implications and may require corrective action and response.		RESPONSE:			
					REVIEWER SIGNATURE:
QA verification of changes and/or acceptance of response:					
by _____ Signature Date					

Figure 5. Sample Form QAP-6, Quality Assurance Document Review

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

Proc. QAP-002

Revision 8 Change 0

QUALITY ASSURANCE PROCEDURE

Page 1 of 11

Title: REVIEW OF CNWRA DOCUMENTS, REPORTS AND PAPERS

EFFECTIVITY

Revision 8 of this procedure became effective on 8/29/2003. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
ALL	0	8/29/2003

Supersedes Procedure No. QAP-002, Rev 7, Chg 0 dated 4/04/2002

Approvals			
Written by <i>Robert Brient</i> Robert Brient	Date 8/29/03	Concurrence Review <i>Budhi Sagar</i> Budhi Sagar	Date 08/29/2003
Quality Assurance <i>Mark R. Ehnstrom</i> Mark Ehnstrom	Date 8/29/03	Cognizant Director <i>Pat Mackin</i> Pat Mackin	Date 8/29/2003

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 8 Change 0

Page 2 of 11

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 the various types of reviews required for the Center for the Nuclear Waste Regulatory Analyses (CNWRA) documents, reports, papers, plans, and proposals. Draft documents to be submitted, as well as revisions and changes to previously submitted documents, shall be reviewed in accordance with this procedure. For peer reviews, 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.

Documents, reports and papers shall be reviewed in accordance with this procedure unless a specific review process is described in another controlling procedure (e.g., for Quality Requirements Application Matrix, Software Development Plans, and scientific notebooks).

2. RESPONSIBILITY

2.1 Managers (i.e., CNWRA President, Directors, and Managers) having responsibility for CNWRA documents and deliverables are responsible for the 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 reviewers' comments.

3. DEFINITIONS

3.1 Concurrence Reviews—Reviews which provide general concurrence with the overall approach and presentation of the work being reviewed and provide 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 being described or performed.

3.2 Peer—Peer is a person having 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.

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 8 Change 0

Page 3 of 11

3.3 Peer Review Group—A Peer Review Group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and the importance of the subject matter to licensing.

3.4 Peer Review—A Peer Review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor for the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

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, and industry practice.

3.5 Technical Review—A documented, traceable review performed by qualified personnel who are 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.

4. DOCUMENT PREPARATION AND REVIEW PROCESS

4.1 Document Submittal for Review and Editing

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. The document shall be submitted along with any supporting documentation needed to perform the reviews (Scientific Notebooks, calculation verifications, etc.).

4.1.2 As required by contract, Intermediate and Major Milestone deliverable items shall be edited to enhance and improve writing style, grammar, and punctuation, and to assure that the writing is effective, following the CNWRA Editorial Style Guide. Other documents, as determined necessary by the Manager, may be edited.

4.1.3 The Manager shall review each document and determine: (i) the extent of editing necessary, and (ii) the technical areas covered by the document to identify reviewers. The Manager should also verify that relevant programmatic objectives are satisfied by the document. The Manager will work with the author until an "author final" version of the document is ready to be formatted and enter review.

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 8 Change 0

Page 4 of 11

4.2 Review Planning

4.2.1 The "Document Review Request and Transmittal Control," CNWRA Form AP-6, (Figure 1) 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. The Manager shall identify whether special markings (e.g., predecisional) are required for the document. From the Review Requirements Matrix, the Manager shall check the required review types on the AP-6 form. The review process may be tailored taking into consideration the complexity of the document, report-writing skill level of the author(s), client needs, and contractual commitments.

4.2.2 All reviews may not be required for revisions and changes to previously submitted documents, that do not materially affect the intent or content of the document (e.g., editorial and clarification). 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 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 important to licensing 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 licensing decisions 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 8 Change 0

Page 5 of 11

- 4.2.4 Peer Review may be conducted on activities as well as documents. While the complete review process may not apply, Peer Review of this type shall be conducted in accordance with Section 5.2 of this procedure. A Peer Review shall also be used when 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.
- 4.2.5 If Technical, Peer, or Concurrence Reviews are required, the Manager shall select reviewers based on the criteria described in paragraphs 5.1.1, 5.2.1, and 5.3.2, and identify them on the AP-6 form.
- 4.2.6 If Technical or Peer Reviews are required, instructions to reviewers shall be prepared as specified in paragraphs 5.1.2 and 5.2.3. Separate review instructions shall be prepared for different reviewers, as necessary, when the review assignments are to different criteria or for different subject matter.
- 4.2.7 If the review involves an operations plan, project plan, or other contractual commitment to work, a Quality Requirements Application Matrix (GRAM) shall be prepared in accordance with QAP-013, Quality Planning. The GRAM shall be completed and approved prior to initiation of work activities.
- 4.3 Reviews and Comment Resolution
- 4.3.1 Review items and supporting documentation should usually be routed to reviewers in the following order: Technical or Concurrence, Editorial, Quality Assurance, Programmatic, and Format. Supporting documentation shall include, as appropriate, scientific notebooks and other supporting documents. If NRC staff contributes to the report, their scientific notebooks should be obtained and provided to reviewers when appropriate. Peer Reviews are generally conducted after the other prescribed reviews are completed, however, that is not a requirement.
- 4.3.2 Technical Review comments and their resolution shall be documented as specified in Section 5 of this procedure. Comments from several reviewers should be consolidated, and changes shall be made to the document to incorporate the comment resolutions.
- 4.3.3 After comments have been incorporated, the revised document, comment resolution records, and the AP-6 form shall be returned to the reviewers. The reviewers shall verify that the comment resolutions have been incorporated, then initial and date the AP-6 form. 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. The verification will determine if required reviews and comment resolutions are conducted in accordance with this procedure.

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 8 Change 0

Page 6 of 11

5. SPECIFIC REVIEW METHODS

5.1 Formally planned and fully documented Technical Reviews shall be performed, when required, to verify the technical correctness of the work against established practices.

5.1.1 Individuals performing Technical Reviews shall have technical qualifications at least equivalent to those required to perform the original work under review. Reviewers shall be independent of the work being reviewed. Reviewers shall be qualified in accordance with CNWRA Quality Assurance Manual Section 2.

5.1.2 The Manager shall identify those 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 Technical Director or Cognizant Director.

5.1.3 Technical Review comments requiring resolution (e.g., those associated with the applicable review criteria) shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record." In addition to comments requiring resolution, the reviewer shall also indicate on the Instructions to Technical Reviewers form (Form QAP-12) that all review criteria identified have been addressed by initialing the appropriate empty "box" on the right side of the form under "Accomplished." Editorial comments of a minor nature (not requiring resolution) may be made as marginalia on the reviewer's copy of the document. The Technical Reviewer shall sign and date each Comment Resolution Record used to document comments.

5.1.4 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.

5.1.5 The author shall respond to the review comments and sign and date the form. Concurrence with the responses shall be indicated by signature in the appropriate block in the lower left-hand portion of the form. If resolution between the author and reviewer cannot be reached, the CNWRA Technical Director or President shall serve as final arbitrator.

5.2 Peer Review

5.2.1 Peer Review shall be conducted by individuals technically capable of performing the original work. Peer Reviews shall be planned and fully documented, evaluating the technical adequacy of work based on expert judgement when significant uncertainties in methods or data exist, or when no accepted practices have been established.

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 8 Change 0

Page 7 of 11

- 5.2.2 In addition to having qualifications equivalent to Technical Reviewers (section 5.1.2), Peer Reviewers cannot have been involved as participants, supervisors, technical reviewers, or advisors in the work being reviewed. Peer reviews shall be conducted by an individual or by groups of sufficient sizes and composition to span the technical issues and areas. Generally, technical areas more central to the work to be reviewed should receive more representation on the Peer Review Groups.
- 5.2.3 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 (Figure 4). Instructions to Peer Reviewers shall be approved by the cognizant director. The basis of the evaluation shall be the reviewer's expert judgment.
- 5.2.4 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. The document under review shall be revised as necessary to address to Peer Review comments. Appropriate resolution of Peer Review comments shall be verified by the cognizant director and documented by initialing and dating the AP-6 form.
- 5.3 Editorial Reviews
- 5.3.1 Editing shall be conducted as shown in Table 1. As indicated, editorial reviews of some document types are optional.
- 5.3.2 Editing shall be 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.
- 5.4 Concurrence Reviews
- 5.4.1 Concurrence Reviews shall be performed by individuals cognizant of the applicable technical and procedural requirements and of the objectives of the work being described or being prescribed. This type of review 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.

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

Proc. QAP-002

Revision 8 Change 0

QUALITY ASSURANCE PROCEDURE

Page 8 of 11

5.4.2 A Concurrence Review shall verify 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.

5.4.3 Concurrence Review comments requiring resolution shall be identified on CNWRA Form TOP-3, "CNWRA Report Review/Comment Resolution Record." Editorial comments of a minor nature may be made as marginalia on the review copy of the report. Upon completion of the review, the reviewer shall sign and date the form.

5.4.4 The reviewer shall present any comments requiring resolution to the author and shall verify that the review item is revised based on the resolution.

5.5 Quality Assurance Reviews

5.5.1 Quality Assurance Reviews verify that the requirements of the CNWRA Quality Assurance Manual and other applicable procedures are met for quality-affecting documents that implement the CNWRA Quality Assurance Manual.

5.5.2 Quality Assurance Reviews shall be conducted by Quality Assurance staff cognizant of the applicable Quality Assurance program and procedural requirements.

5.5.3 Quality Assurance Review comments requiring resolution shall be documented on a TOP-3 form that has been marked as a QA Review, and forwarded to the author. Completion of the form shall be in the same manner as described in paragraph 5.1.5.

5.6 CNWRA Programmatic Reviews

5.6.1 CNWRA Programmatic Reviews verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed by the documents under review.

5.6.2 CNWRA Programmatic Reviews shall be conducted by the cognizant CNWRA director, Technical Director, Deputy Technical Director for Systems Engineering and Integration, or President.

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 8 Change 0

Page 9 of 11

5.6.3 CNWRA Programmatic Reviews shall verify the following:

- Contractual requirements are complied with.
- The objectives of applicable CNWRA plans are satisfied.
- The general approach, presentation, and clarity are satisfactory.
- The approach, methods, and/or conclusions are consistent with CNWRA policy.

Programmatic reviewers may require an additional editorial review if a significant number of editorial errors are identified.

5.6.4 The reviewer shall present any comments requiring resolution to the author on form TOP-013 and shall verify that the review item is revised based on the resolution.

5.7 Format Review

5.7.1 Format Reviews shall be performed by personnel who did not format the document under review and are cognizant of document style, format, and distribution requirements.

5.7.2 Format Reviews shall verify the following:

- Document format requirements are complied with.
- Internal and NRC document distribution requirements are met.
- Spelling is correct.

5.8 Verification of Compliance

5.8.1 Verification of Compliance with QAP-002 shall be performed by CNWRA QA staff or a person acting in their capacity after all other steps in the review process have been completed. Verification reviews of QA deliverables shall be performed by qualified individuals independent of the development of the deliverable.

5.8.2 Verification of Compliance with QAP-002 reviews shall determine the following:

- All required review types have been selected and review criteria have been addressed.
- Report Review/Comment Resolution Sheets are complete.
- Documentation package is complete and ready to be filed in QA records.

CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 8 Change 0

Page 10 of 11

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:

- Document Review Packages
- Quality Assurance Document Review Forms
- Document Review Request and Transmittal Control Forms
- Instructions to Technical Reviewers
- Instructions to Peer Reviewers
- Report Review/Comment Resolution Record Forms
- Peer Review Reports

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-002

Revision 8 Change 0

Page 11 of 11

Table 1. Review Requirements Matrix

DOCUMENT TYPE	REQUIRED REVIEW(S)					
	TECHNICAL/PEER	EDITORIAL	CONCURRENCE	QA	PROGRAMMATIC	FORMAT
Technical Documents						
Reports on Research/Technical Assistance, SRD, NUREGs/CRs, Validation Reports, Annual Reports	X	X			X	X
Papers/Presentations						
Journal Articles, Proceedings, Abstracts, Conference Papers, Posters	X	X*			X	
Guidance Documents						
Technical Positions, Rulemakings, & Regulatory Guides	X	X*			X	X
Quality Assurance Manual and Procedures						
CQAM, QAPs, APs		X*	X	X	X	X
TOPs	X	X*		X	X	X
Administrative/Fiscal Documents						
Operations Plans, Work Plans, Proposals	X	X*	X	X	X	X
Project Plans, Test Plans, Validation Plans	X	X*		X	X	X

*Mandatory if the document is an intermediate or major milestone, otherwise optional (per Manager)



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 Report	<input type="checkbox"/> Papers/Poster	<input type="checkbox"/> Guidance Documents	<input type="checkbox"/> CQAM, QAPs, APs	<input type="checkbox"/> TOPs
<input type="checkbox"/> Project Plans, Plans, Validation Plans	<input type="checkbox"/> Operations Plans, Work Plans, Proposals			

* Conference/Journal Title: _____

Special Markings (e.g., "Predecisional" or "Proprietary") _____ Licensing Support Network **Yes** _____ **No** _____

Copyright Permission **Yes** _____ **No** _____

c. PROJECT INFORMATION

Project No. _____ Milestone No. _____ Subject Code _____

CNWRA DOCUMENT NO. **Yes** _____ **No** _____ Assigned No. _____ CNWRA 200_ _____

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

	<u>Req'd Date</u>	(Manager Signature) <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 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: (Add/delete names as required using current information in "Guidelines for Minimum Distribution of CNWRA Correspondence.")

Distribution (listed below)

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



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"/>	Appropriate techniques are used.	<input type="checkbox"/>
<input type="checkbox"/>	Existing data are qualified (or exempted) in accordance with QAP-015.	<input type="checkbox"/>
<input type="checkbox"/>	Conclusions are properly supported by correctly interpreted data. (Novel or beyond state-of-the-art techniques or significant uncertainties in data and interpretations warrant application of a Peer Review.)	<input type="checkbox"/>

Are there calculations? YES NO If yes, are "over checks" required? YES NO

If no "over checks" are required, explain why: _____

If "over checks" are required, specify type(s) of calculation (per Section 3.2 and 3.2.3 of QAP-014) and describe extent of verification.

<input type="checkbox"/>	Controlled Software	
<input type="checkbox"/>	Uncontrolled Software	
<input type="checkbox"/>	Commercial Off-the-Shelf Software	
<input type="checkbox"/>	Other Calculation(s)	

Calculations are correct, documented and verified in accordance with QAP-014, Section 3.2.3. Document this review by a statement on TOP-3 form explaining which calculations were checked, and how they were checked. Attach verification calculation, in accordance with Section 3.2.4 of QAP-014.



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"/>			
ELEMENT MANAGER		DATE	COGNIZANT DIRECTOR		DATE

