NYE COUNTY NUCLEAR WASTE REPOSITORY PROJECT OFFICE

QUALITY ADMINISTRATIVE PROCEDURE

TITLE: **Independent Technical Review**	REVISION: **2** DATE: **9-17-08** PAGE: **1 of 10**
PROCEDURE NUMBER: **QAP-3.1**	SUPERSEDES: **Revision 1, 3-31-04**
APPROVAL Director — Date: 9/18/08	CONCURRENCE Geoscience Manager — Date: 9/17/08 Quality Assurance Officer — Date: 9/17/08

1.0 PURPOSE

This quality administrative procedure (QAP) describes Nye County Nuclear Waste Repository Project Office (NWRPO) requirements and responsibilities for conducting independent technical reviews, both internal technical reviews and external peer reviews.

2.0 APPLICABILITY

This QAP applies to independent reviews conducted on work products (i.e., documents) developed for NWRPO technical programs.

Documents for which internal technical reviews are mandatory include technical reports and quality assurance (QA) plans and procedures. In addition, at the discretion of the Geoscience Manager (GSM), other types of work products (e.g., scientific notebooks, progress reports, or field and laboratory data sets) may require internal technical review.

External peer reviews shall be conducted at the discretion of the GSM for technical issues that cannot be resolved by internal technical review.

3.0 DEFINITIONS

3.1 ***External peer review***—a documented independent technical review conducted by a technical expert or experts, usually external to the NWRPO, when issues cannot be resolved by internal technical review.

3.2 ***Independent technical review***—a formal critique of technical documents conducted to ensure that planned and completed work complies with predetermined requirements, industry standards, or common scientific, engineering, or industry practices. Independent technical reviewers shall in most cases have technical expertise at least comparable to the originators of the work and shall not have been directly involved in generating the document under review.

3.3 ***Internal technical review***—a documented independent technical review conducted by a technical expert or experts, usually NWRPO personnel, to provide independent, timely, and technically defensible feedback to the Principal Investigator (PI) for improving documents, as appropriate.

3.4 ***Quality administrative procedure***—a procedure developed to implement the QA requirements described in the QA Program Plan (QAPP).

3.5 ***Quality Assurance Program Plan***—the controlled plan that outlines the NWRPO QA requirements, which are based principally on the applicable portions of the requirements set forth by the U.S. Nuclear Regulatory Commission and the American National Standards Institute for nuclear power plants, as adapted for a nuclear waste repository.

4.0 RESPONSIBILITIES

4.1 Director

The Director or designee is responsible for approving this QAP.

4.2 Quality Assurance Officer

The QA Officer (QAO) is responsible for ensuring that the review and documentation requirements specified in this QAP are met, working with the GSM and PI to determine the scope of the review, and submitting review records to the QA records center (QARC) upon completion of the review.

4.3 Geoscience Manager

The GSM is responsible for identifying NWRPO documents that require independent technical review (i.e., other than technical reports or QA plans and procedures, for which review is mandatory), working with the PI and QAO to select the technical reviewer(s), and serving as the final arbitrator of unresolved issues between the PI and the reviewer(s).

4.4 Principal Investigator

The PI, with the support of the GSM, is responsible for producing a quality document; ensuring that document has received technical editing prior to the required formal technical review, transmitting the product and supporting material to the reviewer(s), briefing the reviewer(s) on these items as necessary, responding to reviewer comments and edits, resolving outstanding issues with the reviewer(s) to the extent possible, and revising the document as appropriate.

4.5 Reviewer

The reviewer(s) is responsible for conducting the technical review according to the review scope, providing comments and edits to improve the document, and working with the PI to resolve technical disputes to the extent possible.

5.0 PROCESS

5.1 Internal Technical Review

5.1.1 Technical Reviewer Selection Criteria

Technical reviewers shall meet the following criteria:

- Have no direct participation in developing the document, unless such participation is approved by the QAO
- Possess the technical/scientific qualifications required to successfully conduct the work or analysis under review

5.1.2 Review Scope

Unless otherwise specified, the entire document shall be reviewed. The reviewer shall evaluate, to the extent reasonably possible, the consistency, applicability, and defensibility of the following:

- Technical approach
- Methods
- Calculations
- Technical concepts
- Assumptions
- Analyses
- Significant conclusions
- Recommendations
- References
- Any other relevant items

5.1.3 Technical Review Process

It is assumed that the PI will be the lead author of the document. Documents shall receive technical editing and be formatted appropriately prior to formal review. The reviewer shall suggest, to the extent possible, resolutions to all comments.

Steps in the technical review process include the following:

1. The GSM, with the help of the PI, selects reviewer(s) and forwards reviewer name(s) and qualifications to the QAO for concurrence.

2. Upon QAO concurrence, the PI transmits the document and proposed review schedule to the reviewer(s).

3. The reviewer(s) conducts the review, preferably using word processing review features (i.e., "track changes") to incorporate edits and comments directly into the document. After proofreading the edits and comments, the reviewer(s) transmits the reviewed document to the PI.

4. The PI reads and responds to all edits and comments, preferably using electronic tracking, as briefly as possible. The PI consults with the reviewer(s) as needed, incorporates the comment resolutions into the document, and returns the document to the reviewer(s).

5. The reviewer(s) reads the comment responses. If all issues are resolved, the PI and reviewer(s) sign the Technical Review Form 1 (Attachment 1) and the PI submits the form and reviewed document to the GSM for concurrence. After review by the GSM, the final review package is submitted to the QAO.

6. If unresolved issues remain, the PI attaches a list of these issues to the Technical Review Form 2 (Attachment 2) and submits them to the GSM for resolution. The GSM resolves the issues, records the resolution in an attachment, and returns the form with the attachment to the PI. The PI incorporates the final comment resolutions into the document and submits the revised document to the GSM and the reviewer(s). If the GSM finds the revisions acceptable, the PI and the reviewer(s) sign Technical Review Form 2, and submit the document and form to the QAO.

7. If the GSM finds the final revisions unacceptable, the PI continues to revise the document until the GSM accepts the revisions.

8. The QAO reviews the final document and technical review form to ensure that all review steps have been followed. If the requirements of this QAP have been met, the QAO signs the form and submits the records package to the QARC. The review package includes the review draft; a list of edits, comments, and responses, preferably in electronic format; the final document; and the completed technical review form. If changes were tracked electronically, the redlined file version of the document satisfies all requirements except the technical review form.

9. If QA requirements have not been met, the QAO returns the document to the PI with clear instructions for revision. The PI revises the document until QA requirements have been met.

5.2 External Peer Review

External peer reviews shall be conducted at the discretion of the GSM, in consultation with the Director, QAO, and PI. Peer reviews shall be conducted in situations where uncertainties inherent in data, methods, interpretations, or conclusions cannot be resolved by internal technical review. The following are examples of situations in which external peer review may be necessary:

- Crucial interpretations or decisions that must be made in the face of significant uncertainty
- New, untried, or unconventional tests, plans, procedures, or analyses
- Detailed technical criteria or standard industry procedures that do not exist or are in development
- Results of tests that are not reproducible or repeatable

5.2.1 Peer Reviewer Selection Criteria

Peer reviewers shall meet the following criteria:

- Are independent from the work being reviewed
- Possess recognized and verifiable technical/scientific credentials in all or part of the subject matter under review at least equal to those needed to perform the work or analysis under review
- Are employed outside the NWRPO; all exceptions must be documented in order to clearly establish reviewer independence

5.2.2 Peer Review Scope

The scope of the peer review shall be defined by the GSM, with the assistance of the PI. As stated previously, reasons for the necessity of an external peer review shall be clearly specified. When requested in the peer review scope, the reviewer shall evaluate, to the extent reasonably possible, the consistency, applicability, and defensibility of the following:

- Technical approach
- Methods
- Calculations
- Technical concepts
- Assumptions
- Analyses

- Significant conclusions
- Recommendations
- References
- Any other relevant items

5.2.3 Peer Review Process

Steps in the peer review process include the following:

1. The GSM, with the assistance of the PI, defines the peer review scope, documents the qualifications of the peer reviewer(s), and forwards both scope and qualifications to the QAO.

2. The QAO reviews and accepts, if appropriate, reviewer qualifications, trains the reviewer(s) in this QAP, and instructs the PI to begin the formal review process.

3. The PI provides the reviewer(s) with the review scope and relevant documents (e.g., the document to be reviewed, pertinent QA plans and procedures, technical reports, data sets, and other material deemed necessary).

4. The reviewer(s) conducts the review as described in the scope. Reviewer activities may include, but are not limited to, the following:

    a. Reviewing and evaluating materials supplied by the NWRPO.

    b. Obtaining, reviewing, and evaluating other relevant reference documents, as needed.

    c. Consulting with the PI, GSM, and other appropriate NWRPO technical personnel, as needed.

    d. Conducting numerical or conceptual analyses to support peer review evaluations.

    e. Visiting field study locations, laboratories, or other sites of concern.

5. The reviewer(s) prepares and submits a draft report to the QAO, who distributes it to the GSM, PI, and other appropriate NWRPO personnel for review and identification of any issues requiring clarification or resolution.

6. The reviewer(s) meets with the personnel who reviewed the report to discuss, clarify, and resolve, to the extent possible, issues identified in the draft report.

7. The reviewer(s) revises the report as appropriate and submits a final peer review report to the QAO, who distributes copies to the GSM, PI, and other appropriate personnel.

8. The QAO prepares a records package and submits it to the QARC. The package includes the review scope, reviewer qualifications, materials supplied to the

reviewer(s), draft peer review report, comments by NWRPO personnel on the draft report, and final peer review report.

5.2.4 Peer Review Report

The final peer review report shall include:

- The review scope and material reviewed
- A description of the approach and summary of the specific work performed in the course of the review
- Conclusions and recommendations. Dissenting reviewers shall clearly state reasons for dissension in the appropriate sections of the report
- Sufficient supporting documentation on which conclusions and recommendations are based
- A list of reviewer qualifications or a statement that these qualifications meet the requirements of this QAP
- A cover sheet signed by all peer reviewers

5.2.5 Peer Review Implementation

The GSM, with the assistance of the PI, shall develop a plan for the implementation of peer review recommendations and transmit it to the QAO for submittal to the QARC.

5.3 Documentation

The peer review records package described in the preceding sections shall be maintained in the QARC.

6.0 RECORDS

Documents generated by this QAP are QA records and shall be submitted to the QARC by the QAO. Prior to submittal, the sender shall ensure that each document is complete, legible, and adequately identifiable, as specified in QAP-17.1, *Records Management*.

The QA records generated by this QAP include the following:

- Completed technical review forms
- Reviewed document with comments, edits and resolutions documented and resulting final technical document
- External peer review scope, reviewer qualifications, materials supplied to reviewer, peer review report, report comments, and final report

7.0 REFERENCES

QAP-17.1, *Records Management*. Quality Administrative Procedure. Nye County Nuclear Waste Repository Project Office (NWRPO). Pahrump, Nevada.

QAPP, *Nye County Nuclear Waste Repository Project Office Quality Assurance Program Plan.* Quality Assurance Program Plan. NWRPO. Pahrump, Nevada.

8.0 ATTACHMENTS

Attachment 1 Technical Review Form 1

Attachment 2 Technical Review Form 2

Attachment 1
Technical Review Form 1

Technical Review Form 1 **ALL ISSUES RESOLVED BY PRINCIPAL INVESTIGATOR**			Form QAP-3.1-1 Rev. 1 9/17/08
Document title:			
Draft document is edited and in the appropriate format and reviewers approved: (circle one)	Yes	No	Quality Assurance Officer Date
Designated reviewer(s): (please print)	1. 2. 3. 4.		
Document transmitted to reviewer(s): (circle one)	Yes	No	Principal Investigator Date
Reviewed document received from reviewer(s): (circle one)	Yes	No	Principal Investigator Date
Revised document transmitted to reviewer(s): (circle one)	Yes	No	Principal Investigator Date
All review comments have been addressed and necessary revisions made: (circle one)	Yes	No	1. Reviewer Date
	Yes	No	2. Reviewer Date
	Yes	No	3. Reviewer Date
	Yes	No	4. Reviewer Date
All issues have been resolved and review is complete: (circle one)	Yes	No	Principal Investigator Date
Final review transmitted to Quality Assurance Officer and meets applicable QA requirements: (circle one)	Yes	No	Quality Assurance Officer Date

Attachment 2
Technical Review Form 2

Technical Review Form 2 **UNRESOLVED ISSUES RESOLVED BY GEOSCIENCE MANAGER**			Form QAP-3.1-2 Rev. 1 9/17/08
Document title:			
Draft document is edited and in the appropriate format and reviewers approved: (circle one)	Yes	No	Quality Assurance Officer Date
Designated reviewer(s): (please print)	1.		
	2.		
	3.		
	4.		
Document transmitted to reviewer(s): (circle one)	Yes	No	Principal Investigator Date
Reviewed document received from reviewer(s): (circle one)	Yes	No	Principal Investigator Date
Revised document transmitted to reviewer(s): (circle one)	Yes	No	Principal Investigator Date
Unresolved issues remain and further revision must be made: (circle one)	Yes	No	1. Reviewer Date
	Yes	No	2. Reviewer Date
	Yes	No	3. Reviewer Date
	Yes	No	4. Reviewer Date
Document with unresolved issues transmitted to the Geoscience Manager (GSM): (circle one)	Yes	No	Principal Investigator Date
Unresolved issues have been addressed as recommended by the GSM and the document revised: (circle one)	Yes	No	1. Reviewer Date
	Yes	No	2. Reviewer Date
	Yes	No	3. Reviewer Date
	Yes	No	4. Reviewer Date
All issues have been resolved and review is complete: (circle one)	Yes	No	Principal Investigator Date
Final review transmitted to QAO and meets applicable QA requirements: (circle one)	Yes	No	Quality Assurance Officer Date