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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title:

PEER REVIEW

Procedure No.:

QAAP 3.3

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1

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1 of 10

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Dr DH

Approval

Date:

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1.0 PURPOSE

This procedure prescribes responsibilities and methods for planning, conducting, and documenting peer reviews.

2.0 SCOPE

This procedure shall be implemented by the Office of Civilian Radioactive Waste Management (OCRWM) when judgment by a group of technical experts is needed to assess and confirm the adequacy of work important to safety and waste isolation because the suitability of procedures and methods or adequacy of information cannot otherwise be verified using established standards and practices.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 *Quality Assurance Requirements Document (QARD), DOE/RW-0214*

3.1.2 *Quality Assurance Program Description Document, (QAPD), DOE/RW-0215.*

3.2 DEFINITIONS

3.2.1 Responsible Director - The OCRWM Associate or Office Director responsible for a specific peer review.

3.2.2 Definitions of other quality assurance related terms may be found in the Glossary contained in reference 3.1.1.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE AND OFFICE DIRECTORS, OCRWM

Associate and Office Directors, OCRWM are responsible for determining if and when a peer review should be performed and acting as the Responsible Director for peer reviews covering activities in their areas of responsibility.



4.2 RESPONSIBLE DIRECTOR

The Responsible Director is responsible for:

- 4.2.1 Defining the scope of the peer review;
- 4.2.2 Designating the Peer Review Chairperson;
- 4.2.3 Approving the peer review plan; and
- 4.2.4 Evaluating and issuing the peer review report.

4.3 ASSOCIATE DIRECTOR, OFFICE OF SYSTEMS AND COMPLIANCE (OSC)

In addition to responsibilities identified in Subsection 4.1, the Associate Director, OSC is responsible for preparing and maintaining this procedure.

4.4 PEER REVIEW CHAIRPERSON

The Peer Review Chairperson is responsible for:

- 4.4.1 Determining the technical disciplines needed to complete the peer review;
- 4.4.2 Selecting the peer reviewers, establishing minimum qualifications, and ensuring that the qualifications have been verified;
- 4.4.3 Ensuring that the composite technical expertise of the peer reviewers encompasses that required to complete the peer review;
- 4.4.4 Obtaining information for the review from the organization responsible for the work being reviewed and others, as appropriate;
- 4.4.5 Planning, preparing, and coordinating peer review activities;
- 4.4.6 Issuing a peer review report to the Responsible Director; and
- 4.4.7 Compiling and entering QA records into the OCRWM records management system.

4.5 PEER REVIEWERS

Peer reviewers are responsible for:

- 4.5.1 Performing the peer review in accordance with this procedure and the approved peer review plan;



4.5.2 Documenting their activities during the review and providing comments, concerns and conclusions regarding the work reviewed in their technical areas; and

4.5.3 Reviewing and signing the peer review report.

4.6 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

In addition to responsibilities identified in Subsection 4.1, the Director, OQA is responsible for providing resources and assistance in the peer review, as requested by the Responsible Director.

5.0 GENERAL

5.1 APPLICATION OF PEER REVIEWS

5.1.1 A peer review shall be performed when the adequacy of a critical body of information cannot be established by design review, alternate calculations, replication, or testing, or there is no agreement within the cognizant technical community regarding applicability or appropriateness of those verification methods. Peer reviews should be used in a confirmatory sense and not as a substitute for readily collectable data.

5.1.2 In general, a peer review should be considered for designs, plans, test procedures, reports, material choices, site explorations or other activities to provide confidence in the work where one or more of the following conditions exist:

- a) Critical decisions or interpretations have been or will be made that rely on potential scientific uncertainty;
- b) Decisions or interpretations have significant impact on radiological safety or waste isolation performance assessment conclusions;
- c) Novel or unprecedented testing, plans and procedures, or analyses that depart from established standards and practices have been or will be used;
- d) Industry-accepted detailed technical criteria do not exist;
- e) Tests cannot be repeated or reproduced; or
- f) Data or interpretations are ambiguous or questionable.



5.2 STRUCTURE AND QUALIFICATIONS OF THE PEER REVIEW GROUP

5.2.1 The collective technical expertise and qualifications of peer reviewers shall span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought. Technical areas more central to the work to be reviewed shall receive proportionally more representation in a peer review group. Technical and organizational partiality shall be minimized.

5.2.2 The number of peers comprising a peer review group shall vary depending on the scope and purpose of the review. The size of the group is less important than the reviewers' qualifications and their ability to span the technical issues involved. At least three reviewers should be considered to provide for a consensus opinion, and the size of the group should enable constructive interaction among its members. Factors to consider in determining the size of a group are:

- a) Complexity of the work to be reviewed;
- b) Importance of assuring that safety or waste isolation performance goals are met;
- c) Number of technical disciplines involved;
- d) Degree to which uncertainties in the data or technical approach exist; and
- e) Extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

5.2.3 Recognized and verifiable technical credentials and qualifications of the peer reviewers shall be at least equivalent to that needed for the original work under review and shall be the primary consideration in the selection of peer reviewers.

5.2.4 Peer reviewers shall be independent of the work reviewed. Independence means that the peer reviewer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to ensure that the work is impartially reviewed. In cases where total independence cannot be met, a documented rationale as to why someone of equivalent technical qualifications and greater independence was not selected shall be included in the peer review report.



5.2.5 The Peer Review Chairperson shall ensure that each peer reviewer's education and experience have been verified as meeting the minimum qualifications requirements established and that the independence criteria are met. Documentation completed in accordance with QAAP 2.2, *Verification of Personnel Qualifications*, shall be reviewed for peer reviewers subject to QAAP requirements. For peer reviewers not subject to QAAP requirements, objective evidence shall be obtained that certifies that a peer reviewer's qualifications have been verified in accordance with applicable program requirements. A statement shall be prepared and signed by the Chairperson that documents that the selected peer reviewers' qualifications and independence are acceptable for the purpose of the review.

5.3 PEER REVIEW PLAN

The following criteria for evaluation during the peer review shall be incorporated in the peer review plan, as appropriate:

- a) Validity of basic assumptions and acceptance criteria;
- b) Alternate interpretations;
- c) Uncertainty of results and consequences if incorrect;
- d) Appropriateness and limitations of methods and procedures;
- e) Adequacy of application;
- f) Accuracy of calculations or extrapolations;
- g) Verification and validation of computer software;
- h) Validity of conclusions; and
- i) Adequacy of requirements and criteria.

5.4 PEER REVIEW REPORT

A report that documents the proceedings and results of the peer review shall be prepared and issued to include the following:

- a) A clear description of the work reviewed;
- b) Conclusions reached by the peer review process, including alternative interpretations;
- c) The methodology, criteria, reasoning, and judgment used in reaching the conclusions;



- d) Individual statements by the peer reviewers, as applicable, reflecting dissenting opinions or additional comments;
- e) Specific issues to be addressed by the responsible organization;
- f) The names of the peer reviewers, their individual technical qualifications, a statement of minimum qualifications for reviewers, a summary of the selection process, a statement of acceptability of relevant qualifications, and evidence of independence, including potential technical or organizational partiality;
- g) Signatures of the Peer Review Chairperson and the peer reviewers.

6.0 PROCEDURE

6.1 INITIATING A PEER REVIEW

- 6.1.1 **ASSOCIATE AND OFFICE DIRECTORS, OCRWM** shall identify work in their areas of responsibility that will be subject to peer review considering the criteria in Subsection 5.1 and act as the Responsible Director for the needed peer reviews.
- 6.1.2 The **RESPONSIBLE DIRECTOR** shall issue a notification letter to the organization responsible for the work being reviewed that identifies the work to be reviewed, the scope and schedule of the review, and the Peer Review Chairperson. A copy of the notification letter shall be forwarded to the Director, OQA.
- 6.1.3 The **PEER REVIEW CHAIRPERSON** shall determine the technical disciplines to be used and establish minimum qualifications needed by the peer reviewers to accomplish the scope and purpose of the review in accordance with Subsection 5.2.
- 6.1.4 The **PEER REVIEW CHAIRPERSON** shall select the peer reviewers and verify the qualifications of each individual in accordance with Paragraph 5.2.5.

6.2 PLANNING

- 6.2.1 The **PEER REVIEW CHAIRPERSON** shall prepare a peer review plan that describes the work to be reviewed, the size and technical composition of the peer review group, criteria for the review as selected in accordance with Subsection 5.3, the process to be used, and a schedule for conducting and reporting results of the peer review.
- 6.2.2 The **RESPONSIBLE DIRECTOR** shall approve the peer review plan.



- 6.2.3 The **PEER REVIEW CHAIRPERSON** shall obtain reference material, data, and other information necessary to perform the peer review from the appropriate organizations.
- 6.2.4 The **PEER REVIEW CHAIRPERSON** shall distribute copies of the approved plan and applicable documents that provide the information necessary to achieve the peer review objectives to the peer review group.
- 6.2.5 The **PEER REVIEW CHAIRPERSON** shall ensure that the selected reviewers have been trained to this procedure and are familiarized with the scope, plan, and schedule of the review.

6.3 **PEER REVIEW**

- 6.3.1 **PEER REVIEWERS** shall perform the peer review in accordance with the approved peer review plan.
- 6.3.2 **PEER REVIEWERS** shall direct any questions or requests for clarifications regarding the work undergoing peer review to the Peer Review Chairperson who shall request the information from the organization responsible for the work being reviewed. Responses provided shall be distributed by the Chairperson to each peer reviewer to ensure consistent evaluation during the peer review.
- 6.3.3 **PEER REVIEWERS** shall prepare written minutes of meetings, deliberations, and peer review activities throughout the review process for use in preparing the peer review report.
- 6.3.4 **PEER REVIEWERS** shall document and forward their comments, concerns, and conclusions to the Peer Review Chairperson following the completion of the review.

6.4 **PEER REVIEW REPORT**

- 6.4.1 The **PEER REVIEW CHAIRPERSON** shall review the input and compile consensus opinions, dissenting opinions, conclusions, and recommendations in a written report prepared in accordance with Subsection 5.4.
- 6.4.2 **PEER REVIEWERS** shall review and sign the report indicating that the report adequately and accurately reflects the results of the peer review.
- 6.4.3 The **PEER REVIEW CHAIRPERSON** shall transmit the peer review report to the Responsible Director.



6.5 ISSUANCE OF THE PEER REVIEW REPORT

6.5.1 The **RESPONSIBLE DIRECTOR** shall evaluate the peer review report and determine how the results of the peer review will be used. The determination shall be documented and issued with the peer review report by the Responsible Director. Copies shall be forwarded to the Peer Review Chairman and the Director, OQA.

6.5.2 The **PEER REVIEW CHAIRMAN** shall compile and forward QA Records to the appropriate records center in accordance with Section 7.0.

7.0 RECORDS

The peer review plan, the peer review report, and the Responsible Director's evaluation are QA records and shall be collected and maintained in accordance with QAAP 17.1, *QA Records Management*, or QMP-17-01, *Records Management: Record Source Implementation*.

8.0 ATTACHMENTS

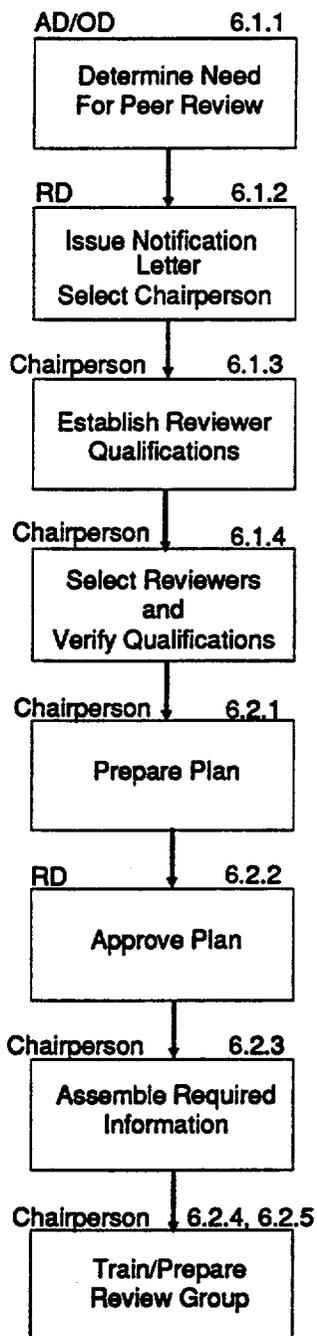
Attachment I - QAAP 3.3 Flowchart



ATTACHMENT I

QAAP 3.3 FLOWCHART

RD = Responsible Director





ATTACHMENT I (continued)

QAAP 3.3 FLOWCHART

