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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: DESIGN REVIEW

Procedure No.: QAAP 3.27	Revision: 0	Date: 3/27/89	Page: 1 of 11
Director, OCRWM <i>[Signature]</i>	Date: 3/10/89	Director, OQA <i>[Signature]</i>	Date: 2/27/89

1.0 PURPOSE

This procedure establishes responsibilities and prescribes methods for conducting design reviews by the Office of Civilian Radioactive Waste Management (OCRWM) for designs that have been developed by OCRWM PROGRAM participants. Design reviews are conducted to verify technical adequacy of completed designs and to gauge the effectiveness of PROGRAM participant design-control measures. The procedure also provides for in-process design reviews and OCRWM participation in design reviews sponsored by PROGRAM participants.

2.0 SCOPE

This procedure applies to OCRWM management, staff, and support personnel involved in planning, performing, documenting, and reporting results of design reviews. Acceptance by the design-review team does not constitute OCRWM approval of a design.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR)-DOE/RW-0214, 1988.
- 3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program", (QAPD)-DOE/RW-0215, 1988.

3.2 DEFINITIONS

- 3.2.1 The definitions of standard terms may be found in the Glossary contained in reference 3.1.1.
- 3.2.2 Critical Design Review - An in-depth technical review of a completed design phase to ensure that all technical requirements are met. A critical design review satisfies the requirements of reference 3.1.1 for design verification.



OCRWM QA
ADMINISTRATIVE
PROCEDURE

Procedure No.:

QAAP 3.2

Revision:

0

Page:

2 of 11

- 3.2.3 Design Review - Refers to either a Critical Design Review or a Milestone Design Review, as defined herein. OCRWM design reviews are referred as "Second-level Design Reviews" in reference 3.1.2.
- 3.2.4 Design Verification - The act of determining and documenting that the design is correct and conforms to all specified requirements. The Critical Design Review is an accepted means of accomplishing design verification.
- 3.2.5 Milestone Design Review - Review conducted periodically during the design process to ascertain the status of technical progress, cost, schedule, and attainment of project objectives. A Milestone Design Review does not meet reference 3.1.1 requirements for design verification unless the requirements for a Critical Design Review are met.
- 3.2.6 Participant Design Review - Review sponsored by a PROGRAM participant in which OCRWM representatives participate.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE DIRECTORS, OCRWM

The Associate Directors, OCRWM, or designee(s) are responsible for:

- 4.1.1 Determining what designs are subject to the design review process;
- 4.1.2 Scheduling and monitoring design reviews for designs developed within their areas of responsibility;
- 4.1.3 Assigning design-review leaders; and
- 4.1.4 Providing resources for implementing OCRWM design reviews.

4.2 ASSOCIATE DIRECTOR, OFFICE OF FACILITIES SITING AND DEVELOPMENT (OFSD)

In addition to responsibilities outlined in 4.1 above, the Associate Director, OFSD, or designee is also responsible for:

- 4.2.1 Preparing and maintaining this QAAP; and
- 4.2.2 Ensuring effective implementation of the OCRWM design-review program.



4.3 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for:

- 4.3.1 Providing resources and assistance in the design-review process, as requested.

5.0 GENERAL

OCRWM conducts design reviews to assess the status and progress of design activities (Milestone Design Reviews), to provide an additional level of independent design verification to particular designs (Critical Design Review), or both.

5.1 CRITICAL DESIGN REVIEW

5.1.1 Critical design reviews are performed by the OCRWM to provide additional assurance that designs meet all technical requirements, and that the responsible design organization's design-control program is performing satisfactorily. These detailed technical reviews cover all aspects of the design, including interfaces with other structures, systems, and components, and meet reference 3.1.1 requirements for design verification.

5.1.2 Designs subject to OCRWM critical design reviews will have been previously design verified in accordance with reference 3.1.1, by the assigned design organization. Primary responsibility for design verification remains with the assigned design organization.

5.2 MILESTONE DESIGN REVIEW

5.2.1 Milestone design reviews are performed by the OCRWM at milestones in the design process primarily to assess the status of the design effort relative to technical progress, cost, and schedule, and to provide assurance that specified requirements are being fulfilled. Milestone design reviews are typically conducted at established percent-completions and at the end of each design phase.

5.2.2 Unless conducted in accordance with the requirements for a critical design review for a 100-percent complete-design phase, the milestone design review does not fulfill the needs of reference 3.1.1 for design verification.

5.3 PARTICIPANT DESIGN REVIEWS

5.3.1 The OCRWM may elect to participate in a design review sponsored by a PROGRAM participant. In such cases, the OCRWM representative(s) will perform in accordance with the applicable participant's procedures.



5.4 DESIGN REVIEW TEAM MEMBERS

The following requirements apply to Critical Design Reviews:

5.4.1 The team members for Critical Design Reviews shall have demonstrated competence in their respective disciplines at least equivalent to that required to perform the design. Documentation of competence should reference degrees, professional certifications and affiliations, and summarize relevant experience. A statement or record of resume verification should be included.

5.4.2 The team members for Critical Design Reviews shall not have performed the design, specified a singular design approach, nor ruled out certain design considerations.

5.5 ALTERNATE CALCULATIONS

5.5.1 Alternate calculations, wherein analyses are conducted by alternate methods to verify correctness of the original analyses, may be used to support the design review.

5.6 QUALIFICATION TESTS

5.6.1 Where the original design verification was based partially upon qualification tests in accordance with reference 3.1.1, review of qualification test documentation may be used in support of the OCRWM design review.

5.7 EXTENT OF DESIGN REVIEW

5.7.1 The rigor and detail required of the design review is a function of the importance to radiological safety or waste isolation, the complexity, degree of standardization, the state-of-the-art, the degree of departure from accepted and proven engineering practices, and the similarity with previously proven designs of the engineered system, structure, or component.

6.0 PROCEDURE

6.1 SCHEDULING

6.1.1 Each OCRWM Associate Director with responsibilities for design shall review program schedules at least semi-annually and determine what designs will be reviewed by the OCRWM in their area of responsibility.



6.1.2 For each design review scheduled, the cognizant OCRWM Associate Director shall determine what type of design review will be conducted, i.e., Milestone Design Review, OCRWM participation in PROGRAM participant-sponsored design review, or Critical Design Review. Considerations for this determination should include those concepts identified in 5.7.1, above.

6.1.3 The cognizant OCRWM Associate Director shall assign a design-review leader for each design review and provide other resources, as needed.

Note: The following instructions for planning, preparation, implementation and reporting are mandatory for Critical Design Reviews, but may be selectively applied for other design reviews.

6.2 PLANNING

6.2.1 The design review leader shall develop a design review plan. The plan shall document the following aspects of the design review:

- a) The exact scope of the design review. Record the specific system(s), structure(s), or component(s) that will be the subject of the review;
- b) Identify all functionally and physically interfacing systems, structures, and components;
- c) Identify all design output documents subject to review;
- d) Determine all disciplines that might affect or be affected by the system(s), structure(s), or component(s) subject to review. Consider operations, maintenance, and construction experts; as well as the design, radiological-safety, and materials-engineering disciplines;
- (e) Establish reviewer qualification requirements, considering the complexity and state-of-the-art of the design; (see section 5.4) and,
- (f) Identify all information, data, and analytical tools that provided input to or support to the design. Consider design requirements documents, safety analyses documents, calculations, computer code and hardware documentation, background information supporting advanced or state-of-the-art engineering techniques, codes, standards, and interface control documents.



- 6.2.2 The design review leader shall contact the responsible design organization and establish a schedule and location for the design review. This information shall be included in the design review plan.
- 6.2.3 The cognizant Associate Director shall approve the design review plan.
- 6.2.4 The design review leader shall assemble the review team from OCRWM, participant, and/or external resources. Documentation of all team members' qualifications shall be obtained, and verified as necessary, in accordance with QAAP 2.2, "Personnel Qualification". The reviewers' independence, per Section 5.4, shall be documented.

6.3 PREPARATION

- 6.3.1 The design review leader shall assemble the review team to prepare for the review. Preparation shall include the following:
- a) Familiarization with the scope, schedule and plan for the design review, and the technical requirements of the particular design. Copies of applicable requirements documents shall be provided to the design-review team members;
 - b) Assurance that the reviewers have been trained to this QAAP;
 - c) Familiarization with the subject system(s), structure(s) or component(s) designs. Design output, such as drawings and specifications, should be provided if available; and
 - d) Assignment of responsibility to team members for areas of the design and preparation of checklists or instructions to be used in the review, as appropriate. The checklists or instructions should address specific design inputs contained in the requirements documents. Attachment I provides subjects to be considered in the review.
- 6.3.2 The design review leader shall review and approve checklists and/or instructions developed by team members.
- 6.3.3 The design review leader should arrange for the responsible design organization to present an overview of the design and design processes, and to make available the cognizant engineers and all information supporting the design.



6.3.4 The accomplishment of the preparation phase shall be documented prior to execution of the design review.

6.4 EXECUTION

6.4.1 The design review team should receive an overview of the design and design processes from the cognizant design organization.

6.4.2 The design review team shall conduct an in-depth review in the assigned areas according to the design review plan and the checklists or instructions that have been developed. Subject items 1 through 6 of Attachment I must be addressed.

6.4.3 If any part of the design uses unproven or beyond state-of-the-art approaches, the design-review leader shall recommend to the cognizant Associate Director that a peer review be performed for that aspect, in accordance with QAAP 3.3, "Peer Review". The recommendation and resulting actions shall be documented in the design review report.

6.4.4 The design review team members shall document review comments and comment resolutions in accordance with QAAP 3.1, "Technical Document Review" and resolve all comments with the responsible design organization. The review team member and responsible design engineer shall sign the comment sheets upon resolution of the comments.

6.4.5 Where a significant difference of opinion prevents consensus within the design review team or resolution between the design review team and responsible design organization, the design review leader shall ensure that the difference is elevated for decision to the appropriate management level until resolution is reached.

6.4.6 If a significant deficiency in a previously verified design is discovered, the adequacy of the design-control/design-verification program is in doubt. In such cases, the design review leader shall initiate corrective action in accordance with QAAP 16.1, "Corrective Action".

6.4.7 Any issues that remain open subsequent to completion of the design review shall be monitored and tracked by the design review leader to ensure resolution. The design review leader shall report the status of open issues to the cognizant Associate Director monthly. The cognizant Associate Director shall monitor the status of all design reviews through closure.



6.5 REPORTING

6.5.1 The design review leader, with input from team members, shall prepare a report of the design review results. The report shall describe the following:

- (a) Scope of the design review, including specific systems, structures, and components;
- (b) Identify the review team members and design organization personnel contacted during the review;
- (c) Summarize results of the review;
- (d) Any significant problems encountered or deficiencies identified and the resolutions, including corrective actions initiated;
- (e) Identify any open issues and actions to be taken; and,
- (f) Present any review team recommendation, such as the need for a peer review on some unique aspect of a design.

6.5.2 The report shall be signed by the design review team leader and forwarded to the cognizant Associate Director, Division Director, and the responsible Branch Chief.

6.5.3 The cognizant Associate Director shall forward a copy of the report to the design organization.

6.5.4 A package consisting of the design review plan, checklists or procedures, comment and resolution records, reviewer qualification and verification records, alternate calculations or other records of design verification, and the design review report shall be submitted to the OCRWM records management system by the review team leader. Documentation regarding open issues and closure thereof shall be added to the package as it is developed.

7.0 RECORDS

Documentation generated as a result of this procedure is collected and maintained in accordance with the requirements specified in QAAP 17.1 "Records Management".

8.0 ATTACHMENTS

8.1 Attachment I - Design Review Subjects

8.2 Attachment II - QAAP Flowchart



**ATTACHMENT I (Example)
DESIGN REVIEW SUBJECTS**

This is a list of subject areas that should be considered in the design review. This is not intended to be a comprehensive list applicable to all designs. Critical Design Reviews must address items 1 through 6.

- 1) Were the design inputs correctly selected?
- 2) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
- 3) Was an appropriate design method used?
- 4) Were the design inputs correctly incorporated into the design?
- 5) Is the design output reasonable compared to design inputs?
- 6) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- 7) Have all computer codes used in the design analysis been validated, and verified on the computer systems used in design?
- 8) Were design, design verification, and peer review (as applicable) procedures correctly implemented?
- 9) Have qualified and certified materials and parts been specified where appropriate?
- 10) Is the design specified producible by conventional means?
- 11) Does the design adequately consider maintainability, operability, reliability and radiological safety?
- 12) Are the appropriate quality and quality assurance requirements specified?
- 13) Are the applicable codes, standards, and regulatory requirements including issue and addenda properly identified and are their requirements for design met?
- 14) Have applicable construction and operating experience been considered?
- 15) Have the design interface requirements been satisfied?



ATTACHMENT I cont'd

- 16) Are the specified parts, equipment, and processes suitable for the required application?
- 17) Are the specified materials compatible with each other and the design environmental conditions to which the material will be exposed?
- 18) Have adequate maintenance features and requirements been specified?
- 19) Are accessibility and other design provisions adequate for performance of needed maintenance, in-service inspection, and repair?
- 20) Has the design properly considered radiation exposure to the public and plant personnel?
- 21) Are the acceptance criteria incorporated in the design documents sufficiently detailed and specific to allow verification that design requirements have been satisfactorily accomplished?
- 22) Have adequate pre-operational and subsequent periodic test requirements been appropriately specified?
- 23) Are adequate handling, storage, cleaning and shipping requirements specified?
- 24) Are adequate identification requirements for control of items and materials specified?
- 25) Is the design cost effective (considering DOE and regulatory restraints)?
- 26) Are requirements for record preparation, submitted review, and approval, retention, adequately specified?



ATTACHMENT II

DESIGN REVIEW

