



QUALITY ASSURANCE MANUAL
NUCLEAR WASTE REPOSITORY IN SALT

SECT.

3.0

TITLE

DESIGN CONTROL

REV. NO.

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3.1 PURPOSE

This section describes the requirements for control of design activities including Morrison-Knudsen design or interfaces with a design subcontractor, review, and control of the design specification or customer specification, preparation of design drawings and/or specifications. Specific implementing procedures will be developed as necessary to describe the means of control for individual activities.

3.2 REQUIREMENTS

3.2.1 The Mine Design Engineering (MDE) Manager is responsible for control of design work performed by Morrison-Knudsen. Morrison-Knudsen may subcontract the design work, but retains the overall responsibility for the design.

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3.2.2 When Morrison-Knudsen is responsible for the design, the MDE Manager is responsible for assuring that applicable design inputs, such as design criteria, performance requirements, regulatory requirements, codes and standards are identified, documented, and their selection reviewed and approved. Changes from approved design inputs including the reason for the changes, shall be identified, approved, documented, and controlled.

3.2.3 The requirements for the control of the design process are described below. Engineering studies developed during a conceptual design effort are subject to the same controls listed below.

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- a. MDE Manager shall prescribe and accomplish design activities in accordance with procedures to assure that applicable design inputs are correctly translated into specifications, drawings, procedures, or instructions.
- b. MDE Manager shall identify and document the appropriate quality standards to be included in the design. The standards shall be reviewed and approved by Quality Assurance.
- c. Changes from approved quality standards, including the reasons for the changes, shall be identified, documented, controlled, and approved at the same level as the original approval.
- d. The selection of design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be reviewed for suitability of application.

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- e. Design activities shall be controlled to permit reviewing and verifying the results of the activity by personnel who are experienced in the subject activity.
- f. The completed design (approved design output documents and approved changes) shall:
 - (1) Be relatable to the design input by documentation in sufficient detail to permit design verification; and
 - (2) Identify assemblies and/or components that are part of the item being designed. When such as assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.
- g. Design analyses shall be performed in a planned, controlled, and documented manner. Design analyses documents shall be detailed as to purpose, method, assumptions, design input, and references such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable.
- h. Computer programs may be utilized for design analysis without individual verification of the program for each application provided:
 - (1) The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and
 - (2) The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.
- i. Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. When changes



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to previously verified computer programs are made, verification shall be required for the changes, including evaluation of the effects of these changes on h(1) and (2) above.

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j. Documentation of design analyses shall include:

- (1) Definition of the objective(s) of the analyses;
- (2) Definition of design inputs and their sources;
- (3) Results of literature searches or other background data;
- (4) Identification of assumptions and indication of those that must be verified as the design proceeds;
- (5) Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem; and
- (6) Review and approval.

3.2.4 The requirements for the control of design verification are described below.

a. The MDE Manager is responsible for assuring that design controls are applied to verify the adequacy of design. As a minimum, design verification shall be accomplished by one or more of the following:

- (1) Design reviews which shall verify the following as a minimum:
 - Design inputs are correctly selected;
 - Assumptions necessary to perform the design activity are described and assumptions are identified for subsequent verifications when the detailed design activities are completed;
 - An appropriate design method was used;
 - Design output is reasonable compared to design inputs;



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- The necessary design input and verification requirements for interfacing organizations are specified in the design documents or in supporting procedures.
 - (2) Calculations or analyses using alternate methods to verify the results of the original calculation or analysis.
 - (3) Peer Review. Due to the investigative nature of geologic studies which involve state-of-the-art test procedures, data acquisition, data reduction, and interpretation of results, it shall be required that an independent review of the procedures, tests, data acquisition and reductions, analysis and interpretation of data for each investigation activity be conducted by a technically qualified peer or group.
 - (4) Qualification Tests. When qualification tests are used to verify the adequacy of design, the following shall be addressed:
 - The tests to be accomplished shall be clearly identified and documented;
 - Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions;
 - When testing is intended to verify only specific design features, the other features of the design shall be verified by other means;
 - Test results shall be documented and evaluated by the design organization and reviewed by Quality Assurance;
 - When qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance; and
 - When tests are performed on models or mockups, scaling laws shall be established, verified, and subject to error analysis.
- #15 b. Design verification shall be performed by an individual or group other than those who performed the original design. Design verification may be performed by the originator's supervisor



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provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or provided the supervisor is the only individual in the organization competent to perform the verification. cursory supervisory reviews do not satisfy the intent of design verification.

- c. The MDE Manager shall assure that the particular method of design verification used for each design is identified and the results of verification clearly documented.
- d. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exists. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, or structure to perform its function.
- e. Where changes to previously verified designs are made, design verification is required for the changes, including an evaluation of the effects of those changes on the overall design.

3.2.5 The requirements for design drawings are described below.

- a. Completed design drawings are reviewed by the MDE Manager or a designated alternate to assure they meet the requirements of the design specification, and if acceptable, approval is documented on the drawings. Drawings are then forwarded to Quality Assurance for review.
- b. Quality Assurance reviews design drawings for quality requirements; and if acceptable, Quality Assurance approval is documented on the design drawings.
- c. Changes to design drawings are handled in the same manner as the original issues.

3.2.6 The MDE Manager is responsible for assuring that changes to final designs, including field changes, are justified and subject to design control measures commensurate with those applied to the original design. Changes to final design shall be reviewed and approved by the originating group, organization, or an approved alternate designated by the MDE Manager.



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3.2.7 The requirements for design interface control are described below.

- a. The MDE Manager is responsible for identifying, controlling, and documenting design interfaces, both internal and external, among participating design organizations.
- b. Interface controls include assigning responsibility and establishing procedures for review, approval, release distribution, and revision of documents between participating design organizations.
- c. Design information transmitted across interfaces shall be documented and controlled.
- d. Design information initially transmitted orally or by informal means across interfaces shall be confirmed by a controlled document.
- e. Controls shall be established to assure that documentation and records which provide evidence that design and verification processes were performed in accordance with the requirements of this manual are assembled, stored, and maintained in a manner which would preclude loss or damage by any means. The controls shall also provide documented evidence that all applicable data which applies to the design has been included in the design.

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