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## INSPECTION PROCEDURE 78060

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### DESIGN CONTROL (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: MC 2300

#### 78060-01 INSPECTION OBJECTIVES

01.01 To determine if the design program is adequately defined and includes effective procedures that identify design interfaces, translate quality standards into design documents, and control deviations from standards.

01.02 To determine if the design process is controlled to ensure correct design; proper classification of structures, systems, and components (SSCs); suitable application of materials, parts, equipment, and processes; and accurate translation of requirements into specifications, drawings, procedures, and instructions.

01.03 To determine if design verification is adequate through effective qualification testing or independent verification.

01.04 To determine if design changes are controlled and are subject to design control measures commensurate with those applied to the original design.

#### 78060-02 INSPECTION REQUIREMENTS

02.01 Design Standards. Determine if appropriate quality standards are specified and included in design documents, and that deviations from such standards are controlled.

02.02 Design Interfaces. Determine if design interfaces are identified, controlled, and coordinated among participating design organizations.

02.03 Design Interface Procedures. Determine if procedures are established among design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

02.04 Classification and Design of SSCs. Determine if SSCs important to safety and waste isolation have been correctly identified and are designed in accordance with the Safety Analysis Report (SAR). Determine if applicable regulatory requirements and the design basis, as defined in 10 CFR 63.2 and specified in the license application, are translated into specifications, drawings, procedures, and instructions for the SSCs.

02.05 Design Controls. Determine if design control measures are applied to SSCs, including items such as:

- a. Criticality physics, stress, thermal, hydraulic, and preclosure and postclosure analysis;
- b. Compatibility of material;
- c. Accessibility for in-service inspection, maintenance, and repair; and
- d. Delineation of acceptance criteria for inspections and tests.

02.06 Suitability of Material Application. Determine if provisions have been established for the selection and review for the suitability of application of materials, parts, equipment, and processes.

02.07 Design Verification. Determine if measures are provided for verifying or checking the adequacy of design, such as by the performance of design reviews, use of alternate or simplified calculational methods, or suitable testing programs.

02.08 Test Program. Determine if suitable qualifications testing is applied to a prototype unit under the most adverse design conditions if a test program is used to verify the adequacy of a specific design.

02.09 Independent Verification. Determine if individuals or groups who perform design verifications or checking processes are not those that developed the original design.

02.10 Design Changes. Determine if design changes, including field changes, are subject to design control measures commensurate with those applied to the original design, and are approved by the organization that performed the original design, or another designated responsible organization.

## 78060-03 INSPECTION GUIDANCE

### General Guidance

This inspection procedure applies to the implementation of the U.S. Department of Energy's (DOE's) quality assurance (QA) program during the design and construction of a geologic repository at Yucca Mountain. The DOE QA program is described in the Quality Assurance Requirements and Description Manual, DOE/RW-0333P (QARD). This inspection procedure applies to SSCs important to safety, to design, characterization, and construction of barriers important to waste isolation, and to related activities described in the SAR.

Selection of areas for evaluation during inspections shall be based on the risk significance of the SSCs, related activities, and past performance. The scope of inspections should also consider the cumulative effect of failures related to low-risk-significant SSCs regarding their potential effects on overall system performance and reliability.

The term “design” includes specifications; drawings; design criteria; design bases; SSC performance requirements for preclosure; natural and engineered barriers of the repository system; inputs and outputs at each stage of design development; data collection and analyses; and computer software that is used to support design development and verification.

### Specific Guidance

03.01 Design Standards. Review the design basis documents, specifications, and drawings for several SSCs to identify applicable quality standards. Verify that appropriate quality standards are identified for the SSCs and are documented in the design documents. Verify that the quality standards are reviewed and approved for use with the particular SSCs. Verify that the quality standards and regulatory requirements are correctly translated into the design, procurement, and procedural documents. Verify that deviations from quality standards are identified, documented, and controlled in accordance with established procedures.

03.02 Design Interfaces. Verify that interfaces between participating design organizations are identified and a process for coordinating and controlling these interfaces is established. Review the controls established by several of the design organizations. Verify that there is adequate coordination between the organizations and determine if any discrepancies exist from one organization to another concerning design interface activities.

Select several design packages that have been transmitted between design organizations. Verify that design information transmitted between the organizations is documented and controlled. Verify that the documentation provides a status of the design information. Review the design packages for any design information that was initially provided informally and verify that formal documentation is provided.

03.03 Design Interface Procedures. Verify that each design organization has established implementing procedures to control the review, approval, release, distribution, and revision of documents involving design interfaces. Verify that procedures include a description of both internal and external interfaces, as appropriate.

03.04 Classification and Design of SSCs. Review the procedure for classifying SSCs according to their importance to safety and waste isolation. Verify that the process described in the procedure is consistent with the requirements in 10 CFR Part 63, the QARD, and the SAR. Verify that the current listing of SSCs that are important to safety and waste isolation is documented on a Q-list. Select a number of SSCs not on the Q-list and verify that the engineering basis for not including them is adequately documented.

Select several Q-list items and verify that adequate analysis was performed to demonstrate that the SSCs meet the design basis established in the SAR, license, technical specifications, engineering documents, system descriptions, applicable regulatory requirements, or other design basis documents. Verify that requirements for the Q-list items are adequately translated into specifications, drawings, procedures, and instructions.

Verify that design work for the Q-list items selected are completed and documented on a timely basis and to the level of detail to support the overall design process and to support fabrication, construction, and operation. Verify that the design documents have sufficient

detail regarding purpose, method, assumptions, design input, references, and units that a person technically qualified in the subject can understand the documents and verify their adequacy without recourse to the originator. Verify that documentation of design analysis includes the definition of the objectives of the analysis; definition of design inputs and their sources; results of literature searches; identification of assumptions; identification of computer calculations; and identification of the originator, reviewer, and approver for the Q-list items selected. Verify that the design analysis documents are legible and in a form suitable for reproduction, filing, and retrieval.

Verify that procedures are established that require documented verification of dimensional accuracy and completeness of design drawings and specifications. Verify that procedures are established requiring design drawings and specifications to be reviewed by the QA organization, to assure that the documents are; (a) prepared, reviewed, and approved in accordance with documented procedures; and (b) contain the necessary QA requirements such as inspection and test requirements, acceptance requirements, and the extent to which inspections and test results are required to be documented.

Verify that design procedures are prepared, reviewed, and approved in accordance with the document control program.

Select several calculations completed to support the design of SSCs on the Q-list. Verify that the calculations are identified by subject (including the SSC to which the calculation applies), originator, reviewer, and date or by other designators, such that the calculations are traceable.

**03.05 Design Controls.** Select several of the following areas to find examples of the programs that verify design controls are applied: field design engineering; physics, including criticality physics; seismic, stress, thermal, and hydraulic analysis; radiation shielding; compatibility of materials; delineation of acceptance criteria for inspections and tests; the SAR accident analysis; features to facilitate decontamination; suitability and compatibility of materials; accessibility for in-service inspections; maintenance and repair; and quality standards. Other design areas not listed above may also be subject to inspection as defined by the inspection team leader. Design controls include identification of organizational responsibilities for preparing, reviewing, approving, and verifying design documents and actions to take to ensure that all errors and deficiencies are corrected. Verify that design documents reviewed include system descriptions, design inputs and criteria, design drawings, and design analysis.

Verify that design inputs are identified and documented and that their selection is reviewed and approved by those responsible for the design. Verify that design inputs are specified and approved on a timely basis and to an adequate level of detail to permit the design work to be performed correctly. Verify that design inputs based on assumptions that require confirmation are identified and controlled. Verify that the design analysis is planned, controlled, and documented.

Verify that computer software used to perform design analysis is developed or qualified, and used in accordance with the QARD. The requirements in the QARD are quite extensive. Either take one software package and complete a detailed review against the requirements or take several software packages and randomly select requirements in the QARD to verify compliance of the software.

Select several personnel who have approved design documents, design inputs, software packages, or calculation packages. Verify that selected personnel are qualified. Verify that position descriptions are established for these personnel and that documentation has been completed to confirm that they meet the requirements established for education and experience. Verify that any required training is completed and is being maintained.

Select several Q-list SSCs that require periodic inspection, maintenance, or testing. Verify that drawings, specifications, and other relevant design documents contain the appropriate inspection, maintenance, and testing acceptance criteria. Verify that the QA organization reviewed the design documents related to the inspection and testing requirements and acceptance requirements.

For any significant design changes necessary because of an incorrect design, error, or deficiency, verify that the design process, design verification methods, and implementing documents are reviewed and modified. Verify that any design deficiencies are documented in the corrective action program. If the incorrect design caused SSCs to be nonconforming, verify that the nonconformance is controlled and documented.

03.06 Suitability of Material Application. Select several SSCs listed on the Q-list. Verify that the planned use of the SSCs is appropriate and consistent with the manufacturer's recommended uses or the specifications for the purchase order. Verify that the material and functionality of the SSCs are suitable for the environment that they will be used in.

Determine if there is a process to provide information, derived from industry experience with the SSCs or similar SSCs, to the cognizant design personnel. Interview selected design engineers to verify their familiarity with industry experience with the SSCs or equipment they are involved with. Verify that the design personnel are aware of limitations for the use of the SSCs or how they would obtain information concerning industry problems with the SSCs or equipment.

Verify that design personnel are aware of 10 CFR Part 21 requirements related to reporting defects. Verify that there is a process to provide relevant 10 CFR Part 21 information, reported by the industry, to cognizant design personnel. Verify that the design personnel understand that if they discover a failure or defect, it should be reported to their management in accordance with their 10 CFR Part 21 procedure.

Select design packages for several systems that include numerous components. Identify any commercial grade assemblies or components that are modified or selected by special inspection or testing to meet requirements more restrictive than the published product description. Verify that the design package identifies the component as different than the commercial grade item, in a manner traceable to a documented description of the difference.

03.07 Design Verification. Verify that a process is established for verifying the adequacy of SSC designs, including defining criteria for when formal design verification by a team, versus review by an individual, is required. Verify that procedures are established that specify the responsibilities of verifiers and the documentation required as a result of the verification process. Verify that the adequacy of the design is determined by using one or a combination of design reviews, alternate calculations, or qualification testing. Verify that guidelines are established for determining which method is to be used. Verify the adequacy

of alternate or simplified calculation methods, if they are used in any of the design packages to verify original calculations.

Review documentation for several design verifications. Verify that documentation includes the design verification process used, the results of the verification, and identification of the verifier. Verify that the verification is performed before release for procurement, manufacture, construction, or release to another organization for use in other design work. Confirm that unverified portions of the design are clearly identified and controlled and that justification for this action is documented. Verify that the extent of the design verification is appropriate for the importance to safety and waste isolation of the SSC, the complexity of the design, degree of standardization, state of the art, and similarity with previously proven designs.

Verify that, if any previously verified designs are changed, the design is re-verified, including an evaluation of the effects of the changes on the overall previously verified design and on any design analysis which the design is based.

Review several design packages and verify that design inputs are correctly selected; assumptions necessary to perform the design are adequately described and are reasonable; appropriate design methods and computer programs are used; design outputs are reasonable compared to design inputs; and the necessary design inputs for interfacing organizations are specified in the design documents.

03.08 Test Program. Verify that requirements are established for qualification testing to be conducted in accordance with the test program requirements established in the QARD. Verify that procedures provide criteria for when verification by testing is to be performed. Verify that verification tests simulate the full range of conditions, including the most adverse condition anticipated that could be experienced by the equipment.

If any designs are verified by testing, verify that an adequate test plan is established and followed. Verify that the test configurations are defined and documented. Verify that the testing is performed under conditions that simulate the most adverse design conditions, including operating modes and environmental conditions. If the tests verified only specific design features, then verify that other features of the design are verified by other means. Verify that test results are documented and evaluated to ensure that the test requirements are met.

If any SSCs are modified to obtain acceptable performance, verify that the modifications are documented and that the SSCs are retested or otherwise verified to ensure satisfactory performance.

If tests are performed on SSC models or mock-ups, verify that scaling laws are established, reviewed, and approved. Verify that the results of model test work are subject to error analysis, before using the results in final design work.

03.09 Independent Verification. Verify that design verifications are performed by qualified individuals other than those who performed the original design, though they may be from the same organization. Verify that if the originator's supervisor performs the verification, it is done under the conditions established in the QARD for independent verification by supervisors.

03.10 Design Changes. Review several design change packages and verify that the appropriate forms are used to document the changes; the forms include the reason for the change and approvals signatures; the design change packages are controlled; the design changes include an assessment of the effect of the change on the design; and the original design analysis for the item is still valid. Verify that design changes are approved by the same organizations that approved the original design, or another organization competent in the design area.

Review several field changes and verify that the field changes are incorporated into the affected design documents when the field change is approved.

Verify that any changes made to final designs, field changes, and nonconforming items dispositioned "use-as-is" or "repair" are justified and subject to the same design control measures as the original design.

For any design changes that impact related implementing documents, other design organizations, or training programs, verify that the change documentation is provided to affected organizations.

#### 78060-04 INSPECTION RESOURCES

An initial inspection of the design control program may be conducted approximately 1 year before submittal of an application. This inspection will consist of two inspectors on site for 1 week. Preparations for the inspection and documentation of the inspection will consist of 3 weeks, for each person. Implementation of the first inspection is 8 inspector-weeks.

After the construction authorization is issued and construction starts, semiannual inspections of the design control program will be conducted by two inspectors, for a total of 16 inspector-weeks per year.

Once construction is complete and the operating license is issued, an annual inspection will be conducted by one inspector for a total of 3 inspector-weeks per year.

#### 78060-05 REFERENCES

NUREG XXXX, "Yucca Mountain Review Plan," Draft Revision 1.

10 CFR Part 63, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada."

U. S. Department of Energy's "Quality Assurance Requirements and Descriptions (QARD)," DOE/RW-0333P, latest revision accepted by NRC.

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