INSPECTION TECHNICAL PROCEDURE

I-104

DESIGN PROCESS ASSESSMENT

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Revision 3

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DESIGN PROCESS ASSESSMENT

1.0   PURPOSE

This procedure assists inspectors in assessing the adequacy of the Contractor's design process and the implementation of the design process procedures.

2.0   OBJECTIVES

Assist inspectors in assessing the adequacy of the design process program for implementing the Contractor's commitments in the authorization basis and implementation of the Contractor's design process procedures in the design of structures, systems, and components (SSCs).

3.0   DEFINITIONS

The definitions included in the following references are incorporated by reference into this inspection procedure:

- DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the River Protection Project Waste Treatment Plant Contractor*, "Glossary."

- The RL/REG-97-05, *Office of Safety Regulation Management Directives*, "Glossary" (the glossary also includes a list of acronyms that are incorporated by reference into this inspection procedure).

4.0   BACKGROUND

The River Protection Project Waste Treatment and Immobilization Plant (WTP) Contract,[1] Section C, paragraph C.6, Standard 7: "Environment, Safety, Quality, and Health," commits the Contractor to implement the requirements of the authorization basis which includes the requirements of an approved Quality Assurance Manual (QAM). The quality assurance requirements are described in the Contractor's QAM.

This inspection will assess the adequacy of the Contractor's design process and the implementation of the design procedures applied to all Quality Level items and activities as described in the QAM, Policy Q-02.1, Section 1.2, Quality Assurance Scope."

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[1] Contract DE-AC27-01RV14136 between the U.S. Department of Energy and Bechtel National, Inc., dated December 11, 2000.

5.0   INSPECTION REQUIREMENTS

The inspectors should assess the adequacy of the Contractor's design process to meet the requirements in the authorization basis by verifying that selected commitments included in the QAM are included in engineering procedures and design documents used to control the design process. The inspectors will assess the level of implementation of these procedures by determining whether these procedures were used in the design of the selected SSCs and by observing activities currently in progress.

5.1   Design Procedures

The inspector should verify that the important-to-safety design process is controlled by and conducted in accordance with documented instructions, procedures, and drawings. (QAM, Policy Q-05.1, Section 3.1.1)

5.2   Design Input

5.2.1   The inspector should verify design inputs are identified and documented, and their selection reviewed and approved by the responsible engineering group. (QAM, Policy Q-03.1, Section 3.2.1; and NQA-1, Supplement 3S-1, paragraph 2)

5.2.2   The inspector should verify design inputs are specified and approved on a timely basis to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. (QAM, Policy Q-03.1, Section 3.2.2; and NQA-1, Supplement 3S-1, paragraph 2)

5.2.4   5.2.3   The inspector should verify the facility is being designed for a set of events that includes normal operations, anticipated operational occurrences, maintenance, and testing; external events; natural phenomena; and postulated accident conditions. With regard to accident conditions, the design will incorporate the expected environmental conditions into the specifications for the SSCs that must function to prevent hazardous situations or mitigate the consequences of accidents. (SRD, SC 4.1-3 and 4.3-2)The inspector should verify changes from approved design inputs and reasons for the changes are identified, approved, documented, and controlled. (QAM, Policy Q-03.1, Section 3.2.3; and NQA-1, Supplement 3S-1, paragraph 2)

5.2.5   The inspector should verify design inputs based on assumptions that require confirmation are identified and controlled as the design proceeds. (QAM, Policy Q-03.1, Section 3.2.4)

5.3   Interface Control

5.3.1   The inspector should verify design effort is coordinated among participating organizations to ensure integration of design and other technical requirements into the design documents. (QAM, Policy Q-03.1, Section 3.3.1; and NQA-1, Supplement 3S-1, paragraph 6)

5.3.2   The inspector should verify design information transmitted across interfaces is identified and controlled. The inspector should verify these controls identify the status of the design information or document provided, and identify designs or portions of designs that require further development, analysis, review, or approval. (QAM, Policy Q-03.1, Section 3.3.2; NQA-1, Supplement 3S-1, paragraph 6; and SRD, Safety Criterion (SC) 4.1-2)

5.3.3   The inspector should verify, where it is necessary to initially transmit design information orally or by other informal means, the transmittal is confirmed promptly by a controlled document. (QAM, Policy Q-03.1, Section 3.3.3; and NQA-1, Supplement 3S-1, paragraph 6)

5.3.4   The inspector should verify interface controls include the assignment of responsibility and the establishment of controls among participating organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. (QAM, Policy Q-03.1, Section 3.3.4; and NQA-1, Supplement 3S-1, paragraph 6)

5.4   Design Process

5.4.1   The inspector should verify the responsible design organization prescribes and documents the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets requirements.. (QAM, Policy Q-03.1, Section 3.4.1; and NQA-1, Supplement 3S-1, paragraph 3)

5.4.2   The inspector should verify the design documents adequately support facility design and construction. (QAM, Policy Q-03.1, Section 3.4.2; and NQA-1, Supplement 3S-1, paragraph 3)

5.4.3   The inspector should verify appropriate standards are identified and documented, and their selection reviewed and approved. The inspector should verify changes from specified standards, including reasons for the changes, are identified, approved, documented, and controlled. (QAM, Policy Q-03.1, Section 3.4.3; and NQA-1, Supplement 3S-1, paragraph 3)

5.4.4   The inspector should verify methods, materials, parts, equipment, and processes, essential to the function of the items, are selected and reviewed for suitability of application. (QAM, Policy Q-03.1, Section 3.4.4; and NQA-1, Supplement 3S-1, paragraph 3)

5.4.5   The inspector should verify the final design, including approved design output documents and approved changes:

- Relates to the design input through documentation in sufficient detail to permit design verification

- Specifies the minimum acceptance requirements

- Identifies assemblies and/or components that are part of the item being designed. (QAM, Policy Q-03.1, Section 3.4.6; and NQA-1, Supplement 3S-1, paragraph 3)

5.4.6   The inspector should verify the final design identifies assemblies or components that are part of the item being designed. (QAM, Policy Q-03.1, Section 3.4.7; and NQA-1, Supplement 3S-1, paragraph 3)

5.5   Design Analysis

5.5.1   The inspector should verify calculations are planned, controlled, and documented, and design documents are legible and in a form suitable for reproduction, filing, and retrieval. (QAM, Policy Q-03.1, Sections 3.5.1 and 3.5.3; and NQA-1, Supplement 3S-1, paragraph 3.1)

5.5.2   The inspector should verify calculations are controlled and identified by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are retrievable. (QAM, Policy Q-03.1, Section 3.5.4; and NQA-1, Supplement 3S-1, paragraph 3.1)

5.5.3   The inspector should verify design analyses documentation includes the objective, inputs and their sources, background data, assumptions, computer calculations and identification of the originator, reviewer and approver. (QAM, Policy Q-03.1, Section 3.5.5; and NQA-1, Supplement 3S-1, paragraph 3.1)

5.5.4   The inspector should verify computer program acceptability has been pre-verified or the results verified with the design analysis for each application. (QAM, Policy Q-03.1, Section 3.5.6; and NQA-1, Supplement 3S-1, paragraph 3.1)

5.5.5   The inspector should verify the computer program is verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. The inspector should verify the encoded mathematical model is shown to produce a valid solution to the physical problem associated with the particular application. (QAM, Policy Q-03.1, Section 3.5.7; and NQA-1, Supplement 3S-1, paragraph 3.1)

5.6   Design Verification

5.6.1   The inspector should verify design verification is performed to determine the adequacy of the design, and the acceptable verification methods include, but are not limited to, any one or a combination of design reviews, alternate calculations, and qualification testing. (QAM, Policy Q-03.1, Section 3.6.1; and NQA-1, Supplement 3S-1, paragraph 4)

5.6.2   The inspector should verify the extent of design verification is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. (QAM, Policy Q-03.1, Section 3.6.2; and NQA-1, Supplement 3S-1, paragraph 4.1)

5.6.3   The inspection should verify design verification has been performed prior to releasing the design to another organization for other design activities. Any unverified portion of the design shall be clearly identified and controlled. (QAM, Policy Q-03.1, Section 3.6.3; NQA-1, Supplement 3S-1, paragraph 4)

5.6.4   The inspector should verify where the design has been subjected to a verification in accordance with this policy, the verification process need not be duplicated for identical designs; however:

- The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.

- Known problems affecting the standard or previously proven designs and their effects on other features shall be considered.

- The original design and associated verification documentation shall be adequately documented and referenced in records of subsequent application of the design. (QAM, Policy Q-03.1, Section 3.6.4; and NQA-1, Supplement 3S-1, paragraph 4.1)

5.6.5   The inspector should verify where changes to previously verified designs have been made, design verification is required for the changes, including evaluation of the effects of those changes on the overall design, and on any design analysis upon which the design is based, that are affected by the change to previously verified design. (QAM, Policy Q-03.1, Sections 3.6.5 and 4.2.4; and NQA-1, Supplement 3S-1, paragraph 4.1)

5.6.6   The inspector should verify design verification is performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization. (QAM, Policy Q-03.1, Sections 3.6.6 and 4.2.3; and NQA-1, Supplement 3S-1, paragraph 4)

5.6.7   The inspector should verify if design verification is performed by the originator's supervisor, the following requirements are complied with:

- The supervisor did not specify a singular design approach or rule out certain design consideration, and did not establish the design inputs used in the design;

or the supervisor is the only individual in the organization competent to perform the verification.

- The verification is not hastily and superficially done.

- The determination to use the supervisor is documented and approved, in advance, with concurrence of the QA organization. (QAM, Policy Q-03.1, Sections 3.6.7 and 4.2.3; and NQA-1, Supplement 3S-1, paragraph 4)

5.6.8 The inspector should verify the responsible design organization identified and documented and justified the particular design verification method(s) used. (QAM, Policy Q-03.1, Sections 3.6.8 and 4.2.2)

5.6.9 The inspector should verify the results of design verification are documented with the identification of the verifier clearly indicated. (QAM, Policy Q-03.1, Section 3.6.9)

5.6.10 The inspector should verify line management established measures for controlling technical modifications to the waste form production process, including:

- Waste form and canistered waste form

- Process control plans and other implementing documents

- Waste Acceptance Product Specifications, Waste Form Compliance Plans, and Waste Form Qualification Reports. (QAM, Policy Q-03.1, Section 4.2.5)

5.7 Design Reviews

The inspector should verify design reviews were controlled per approved procedures and performed to ensure that the following occurred:

- The design inputs were correctly selected and incorporated into the design.

- Assumptions necessary to perform the design activity are adequately described and reasonable.

- Where necessary, the assumptions are identified for subsequent re-verifications when the detailed design activities are completed.

- Appropriate design methods and computer programs, when applicable, were used.

- The design output is reasonable compared to design inputs.

- The necessary design inputs and verification requirements are specified in the design documents or in supporting procedures or instructions. (QAM, Policy Q-03.1, Section 3.7; and NQA-1, Supplement 3S-1, paragraph 4.2.1)

5.8 Alternate Calculations

The inspector should verify alternate calculations used alternate methods to verify the correctness of original calculations or analyses. The inspector should verify the appropriateness of assumptions, input data used, and the computer program, software, or other calculation method used was also reviewed. (QAM, Policy Q-03.1, Section 3.8; and NQA-1, Supplement 3S-1, paragraph 4.2.2)

5.9 Qualification Tests

5.9.1 The inspector should determine if any part of design adequacy is to be verified by qualification tests, and if so, verify the tests will be in accordance with Policy Q-11.1. (QAM, Policy Q-03.1, Section 3.9.1)

5.9.2 The inspector should verify qualification tests demonstrate the adequacy of performance under conditions that simulate the most adverse conditions, and where the test is intended to verify only specific design features, the other features of the design were verified by other means. (QAM, Policy Q-03.1, Section 3.9.2; and NQA-1, Supplement 3S-1, paragraph 4.2.3)

5.9.3 The inspector should verify required tests were controlled under appropriate operating modes and environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and test criteria. (QAM, Policy Q-03.1, Section 3.9.3; and NQA-1, Supplement 3S-1, paragraph 4.2.3)

5.9.4 The inspector should verify test procedures include or reference the test configuration and test objectives. The inspector should verify test procedures include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. (QAM, Policy Q-03.1, Section 3.9.4; and NQA-1, Supplement 3S-1, paragraph 4.2.3)

5.9.5 The inspector should verify test results were documented and evaluated to assure that they satisfy test requirements and conform to acceptance criteria, and the evaluation was documented and included identification of the individual performing the evaluation. (QAM, Policy Q-03.1, Section 3.9.5; and NQA-1, Supplement 3S-1, paragraph 4.2.3)

5.9.6 The inspector should verify when tests are performed on models or mockups, scaling laws were established, reviewed, and approved. (QAM, Policy Q-03.1, Section 3.9.6; and NQA-1, Supplement 3S-1, paragraph 4.2.3)

5.9.7 The inspector should verify model test work is subject to error analysis, where applicable, before using the results in final design work. (QAM, Policy Q-03.1, Section 3.9.7; and NQA-1, Supplement 3S-1, paragraph 4.2.3)

5.9.8 The inspector should verify if qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, the modification was documented

and the item modified and retested or otherwise verified to ensure satisfactory performance. (QAM, Policy Q-03.1, Section 3.9.8; and NQA-1, Supplement 3S-1, paragraph 4.2.3)

5.10   Design Change Control

The inspector should verify design changes were controlled according to the following requirements:

- Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair, shall be justified and shall be subject to design control measures commensurate with those applied to the original design.

- These design control measures shall include provisions to evaluate the effect of the changes on the overall previously verified design and ensure that the design analyses for the item are still valid.

- Changes shall be approved by the same affected groups or organizations that approved the original design documents.

- If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.

- The design organization approving the design shall have demonstrated competence in the specific design area of interest, and have an adequate understanding of the requirements and intent of the original design.

- When a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary. These design deficiencies shall be documented in accordance with QAM Policy Q-16.1, Corrective action. Additionally, if the incorrect design causes constructed or partially constructed SSCs to be nonconforming, the affected items shall be controlled in accordance with QAM Policy Q-15.1, Control of Nonconforming Items.

- Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design change control measures commensurate with those applied to the original design. Required as-built records shall reflect the use-as-is or repair condition.

- Field changes shall be incorporated into affected design documents when such incorporation is appropriate, and when a field change is approved other than by revision to the affected documents.

- Design changes that impact related implementing documents or training programs shall be communicated to organizations affected by the change. (QAM, Policy Q-03.1, Section 3.10; and NQA-1, Supplement 3S-1, paragraph 5)

5.11   Software Design Control

5.11.1 The inspector should verify the software design process is documented, approved by the responsible design organization, and controlled. (QAM, Policy Q-03.1, Section 3.11.1)

5.11.2 The inspector should verify quality-affecting computer software design complies with the requirements of QAM Policy Q-03.2, Software Quality. (QAM, Policy Q-03.2, Section 3.11.2)

5.12   Audits

The inspector should verify audits are performed on selected design documents to ensure the effectiveness of the design program. (QAM, Policy Q-018.1, Section 3.1.1)

6.0   INSPECTION GUIDANCE

The inspector should be familiar with the design related requirements set forth in the QAM and NQA-1.

6.1   Design Procedures

The inspector should gain a broad understanding of the system used to control design. Policies, procedures, instructions, drawings and computer programs all must be integrated together to ensure control and consistent practices. In addition to the general understanding of the system, the review of procedures and other documentation for the inspection attributes listed below will all contribute to a view of the Contractor's program for controlling design. The word "procedures," as used in this inspection guidance should be read as procedures, codes of practice, and/or other appropriate design documents.

6.2   Design Inputs

6.2.1 The inspector should review the procedures used to control the identification, review, documentation, and approval of design inputs to ensure appropriate involvement by the engineering group responsible for the design. Also, the inspector should review three design packages to confirm the procedures were followed.

6.2.2 The inspector should review procedures that control configuration management from the onset of design. The timeliness of inputs and approvals should be addressed. The inspector should also review three design packages. Look at the timeliness of inputs and

the documentation necessary for design decisions, design verification measures, and evaluating design changes.

6.2.3   The inspector should examine a design package which includes equipment which must function during accident conditions to determine if it addresses all of the attributes specified in Section 5.2.3.

6.2.4   The inspector should select and review three changes to design inputs to confirm the reasons for the changes were identified, approved, documented, and controlled.

6.2.5   No additional guidance provided.

6.3.   **Interface Control**

6.3.1   The inspector should review procedures that control design interfaces between organizations. The inspector should verify that the selected procedures address coordination of design inputs among participating organizations. Individuals in a least two different organizations should be interviewed to determine if their practices have followed the procedure.

6.3.2   The inspector should review procedures that control the flow of design requirements from other design functions (e.g., hazards analysis or accident analysis) to the design responsible engineer. The inspector should verify the procedures address identification, review, approval, release, distribution, revision, and control of design information passed between the participating design organizations. Transmittals must also identify the status of the design information and identify any incomplete items that require further evaluation, review or approval.

6.3.3   The inspector should select and review three instances where design information was initially transmitted orally (if possible), and confirm the transmittal was followed up promptly with a controlled document.

6.3.4   No additional guidance provided.

6.4   **Design Process**

6.4.1   The inspector should select and review three design documents for adequacy.

6.4.2   No additional guidance provided.

6.4.3   The inspector should examine three design packages and verify appropriate important-to-safety (ITS) identification, review and approval of standards. Any changes to the selected standards should show the reasons for the change, and that it is properly controlled.

6.4.4   The inspector should review procedures that control the content and distribution of the listed materials, parts, equipment, and processes that are essential to the function of ITS items. The procedures should require that all ITS items and activities are identified in a list, and the list is used across the project for design, procurement, construction, and operation activities. Commercial grade items must be identified with the acceptance criteria defined for such items to be verified.

6.4.5   No additional guidance provided.

6.4.6   No additional guidance provided.

6.5   Design Analysis

6.5.1   The inspector should review design analysis procedures to ensure design analysis calculations are planned, are identified by subject, originator, reviewer, date or other designations, and are legible and in a form suitable for reproduction, filing, and retrieval. Any alternate calculations must meet the requirements of QAM, Policy Q-03.1, Section 3.8.

6.5.2   No additional guidance provided.

6.5.3   The inspector should examine three design packages to determine if they contain all the information specified in the requirement. The documentation should be sufficient that a technically qualified person could verify the results without recourse to the originator.

6.5.4   The inspector should review the Contractor's file for computer program verification to ensure that any programs used for analysis/calculations have been properly verified.

6.5.5   No additional guidance provided.

6.6   Design Verification

6.6.1   No additional guidance provided.

6.6.2   No additional guidance provided.

6.6.3   The inspector should determine if any completed design has been transferred or released to another organization for other design activities, and if so should confirm that the design had been properly verified.

6.6.4   No additional guidance provided.

6.6.5   The inspector should select and review three changes to previously verified designs to confirm they meet the requirements specified in Section 5.6.5.

6.6.6   No additional guidance provided.

6.6.7   The inspector should select and review three designs verified by the originator's supervisor to confirm they comply with the requirements specified in Section 5.6.7.

6.6.8   No additional guidance provided.

6.6.9   No additional guidance provided.

6.6.10 No additional guidance provided.

6.7   Design Reviews

The inspector should select and review three design reviewed to confirm they were conducted in accordance with approved procedures and were in compliance with the requirements specified in Section 5.7.

6.8   Alternate Calculations

The inspector should select and review three alternate calculations to confirm the calculations were performed in accordance with the requirements specified in Section 5.8.

6.9   Qualification Tests

6.9.1   The inspector should determine by discussion if any part of design adequacy is to be verified by qualification testing. If so, the inspector should review any procedures that are pertinent, and review at least one design package. Test requirements and acceptance criteria must be specified, and test results must be evaluated against the acceptance criteria.

6.9.2   No additional guidance provided.

6.9.3   No additional guidance provided.

6.9.4   The inspector should select and review three test procedures to confirm they include or reference the items specified in Section 5.9.4.

6.9.5   No additional guidance provided.

6.9.6   No additional guidance provided.

6.9.7   No additional guidance provided.

6.9.8   No additional guidance provided.

6.10   Design Change Control

The inspector should review procedures for managing changes to control the Authorization Basis and the procedures referenced therein. The inspector should verify that the procedures selected control design criteria and design changes commensurate with the measures applied to the original design. The inspector should select and review three design changes to confirm the items specified in section 5.10 were included. The inspector should confirm whether or not any design deficiencies had been identified and documented in accordance with QAM Policy Q-16.1, Corrective Action. In addition, the inspector should confirm whether or not any design deficiencies caused nonconforming items and were controlled in accordance with QAM Policy Q-15.1, Control of Nonconforming Items.

6.11   Software Design Control

6.11.1 The inspector should review the requirements of QAM, Policy Q-03.2, Software Quality, the Contractor's software QA plan, and any written policies. These should provide for control of any software which is developed by the Contractor or purchased. The Contractor also should provide direction on verification and validation of any software being used. The inspector should refer to the last Configuration Management Assessment conducted for previous reviews in this area.

6.11.2 No additional guidance provided.

6.12   Audits

The inspector should verify that the selected procedures require that QA reviews be performed on selected design documents. These documents normally address appropriate quality requirements, QC inspection requirements, and QA criteria. The inspector should review at least the last QA audit report of the design program and any other surveillances or audits which may have been conducted. The inspector should determine if there were any significant findings, and if so, the corrective actions which were taken.

7.0   REFERENCES

DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the River Protection Project Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

Quality Assurance Manual 24590-WTP-QAM-QA-01-001, Rev. 4, Bechtel National, Inc., Richland, Washington, 2003.

ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*, 1989 Edition

RL/REG-97-05, *Office of Safety Regulation Management Directives*, "Glossary," Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

Safety Requirements Document, 24590-WTP-SRD-01-001-02, Bechtel National, Inc., Richland, Washington, 2003.

8.0   LIST OF TERMS

BNI	Bechtel National, Inc.
ISMP	Integrated Safety Management Plan
ITS	important-to-safety
QA	quality assurance
QAM	Quality Assurance Manual
QC	quality control
QL	Quality Level
SC	Safety Criteria
SRD	Safety Requirements Document
SSC	structures, systems, and components
WTP	Waste Treatment and Immobilization Plant

Attachments: None