NRC INSPECTION MANUAL

QUALITY ASSURANCE: DESIGN AND DOCUMENTATION CONTROL
(PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: 2630

88107-01 INSPECTION OBJECTIVES

01.01 To determine if the design control program is adequately defined and includes effective procedures that identify: (1) design input controls; (2) processes; (3) analyses; (4) verifications; (5) change controls; (6) interface controls; (7) translate quality standards into design documents; and (8) control deviations from standards.

01.02 To determine that applicable design bases and other requirements necessary to assure adequate quality are included or referenced in the applicant's procurement documents for procurement of Quality Level 1 (QL-1) and QL-2 material, equipment, and services.

01.03 To determine that QA records are completed documents that furnish evidence of the quality of items and/or activities affecting quality.

88107-02 INSPECTION REQUIREMENTS

Verify that selected elements associated with the applicant's design and document control systems (as identified in an approved inspection plan) are in accordance with the applicant's approved QA Plan. Elements chosen for inspection may include two or more of the following:

02.01 Design Control. Determine if the QA program and associated QA procedures implement the committed design control requirements.

02.02 Document Control. Determine if the QA program and associated QA procedures implement the committed requirements for control and content of safety-affecting documents.

02.03 Quality Assurance Records. Determine if the QA program records for safety affecting items or activities are being properly generated and controlled.

88107-03 INSPECTION GUIDANCE

03.01 Design Control.

a. Review the applicant's system for control of design inputs (design bases, conceptual design reports, performance requirements, regulatory requirements, codes and standards) to determine if documentation, review, and approval commitments are being met.

b. Review the applicant's design process for translating design inputs into plant design, fabrication, construction, testing, inspection, and examination requirements. Verify that this design process is in accordance with QA plan commitments and requirements. Determine if the design process is controlled to ensure: (1) correct design; (2) proper classification of structures, systems, and components or items relied on for safety; (3) suitable application of materials, parts, equipment, and processes; and (4) accurate translation of requirements into specifications, drawings, procedures, and instructions.

c. Review the applicant's process for design analysis to verify that design analyses are documented in accordance with QA plan commitments and requirements.

d. Review the applicant's program for verifying the adequacy of the design of QL-1 controls. Determine if design verifications, reviews, and qualification tests (or independent verification) were performed in accordance with QA plan commitments and requirements.

e. Review the applicant's design change control program to determine if design changes were controlled in accordance with QA plan commitments and requirements. Verify that design changes are subject to design control measures commensurate with those applied to the original design.

f. Review the applicant's design interface control program to determine if design internal and external interfaces were identified, procedurally controlled, and documented in accordance with QA plan commitments and requirements.

g. Refer to IP 88112, "Software Validation", for inspection requirements pertaining to the applicant's computer software control program.

03.02 Document Control.

a. Review a variety of the applicant's documents that specify quality requirements or prescribe activities affecting quality associated with QL-1 controls. These documents would include project procedures, Design Requirement Documents, Basis-of-Design documents, Engineering Specification, drawings, calculations, and procurement documents. Determine if these documents were prepared, reviewed, approved, and distributed to, and used at, the location where the prescribed activity is performed, in accordance with QA plan commitments and requirements for document control. Verify that changes resulting from applicant evaluations or pre-contract negotiations are incorporated into the procurement documents.

b. When reviewing the applicant's QA program implementing documents (QA procedures, drawings, and specifications), determine if the document contents are in accordance with QA plan commitments and requirements for instructions, procedures, and drawings.

c. Verify that the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance", are delineated, as applicable, on IROFS procurement documents.

03.03 Quality Assurance Records.

a. When reviewing QA program implementing documents, determine if they properly specify the QA records to be generated, supplied, and maintained.

b. Review a variety of the applicant's QA records required by the reviewed implementing documents. Determine if the records have been produced as required by the implementing procedure(s) and determine if the records are received, classified, and processed in accordance with the QA plan commitments and associated implementing procedures for QA records. If corrections have been made to any of the records, determine if the corrections are being performed per the approved QA plan.

c. Observe the applicant's record repositories for both temporary and permanent storage, to determine if they meet QA plan commitments. Determine if record retrieval from, and retention in, each type of repository, is in accordance with the approved QA plan.

88107-04 INSPECTION RESOURCES

Inspection resources necessary to complete this inspection procedure are estimated to be 24-40 hours of inspection per facility visit. Once the construction authorization is issued, the basics of this inspection procedure should be conducted during the construction phase, on an annual basis.

04.01 Design Control. This section should be inspected once per year or when significant design control changes occur. Estimated effort is 16 to 24 hours per occurrence.

04.02 Document Control. This section should be inspected once per year or when significant additions or changes occur. The resource estimate for this section is 4 to 8 hours per occurrence.

04.03 QA Records. This section should be inspected once per year or when significant additions or changes occur. The resource estimate for this section is 4 to 8 hours per occurrence.

88107-05 REFERENCES

Code of Federal Regulations, 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

Duke, Cogema, Stone and Webster, "Mixed-Oxide Fuel Fabrication Facility, MOX Project Quality Assurance Plan (MPQAP)," Docket Number 070-03098, under US Department of Energy Contract DE-AC02-99-CH10888, latest revision accepted by NRC (Sections 3, 4, 5, 6, and 17).

Duke, Cogema, Stone and Webster, "Mixed-Oxide Fuel Fabrication Facility Construction Authorization Request," latest revision accepted by NRC.

U.S. Nuclear Regulatory Commission, NUREG-1718, Standard Review Plan for the Review of an Application for a Mixed-Oxide Fuel Fabrication Facility, August 2000.

END