

Activity: Design Controls

1.0 Purpose: This guideline provides a method to evaluate the practices for the control of design documents.

2.0 Scope: This guideline has been developed for the quality surveillance of the following areas:

Engineering procedures have been established and implemented to ensure that design calculations, drawings and other documents are prepared in a controlled and correct manner.

3.0 References:

3.1 ANSI N45.2.11 - 1974, "Quality Assurance Requirements for the Design of Nuclear Power Plants"

3.2 NRC Inspection Modules 37940B and 37941B, "Design Control, Parts 1 and 2"

4.0 Guidelines:

4.1 In preparation for and during the conduct of this surveillance:

E Obtain and review implementing procedures, instructions and drawings governing this activity.

E Prepare a guide or checklist using the selected items from this guideline.

E Review past surveys, audits, surveillances and other evaluations/ assessments.

- E Ensure that checklists include, where applicable, actual observations of performance, general plant conditions, radiological work practices, housekeeping, work document controls and use, and safety practices.

NOTE: Refer to Guideline A.1, "General Quality Surveillance Guidance," for specific details on the attributes listed above.

4.2 Review and verify a sample of design calculations for each of the following:

- A. Analysis is legible and in a form suitable for reproduction, filing and retrieval.
- B. Analysis is sufficiently detailed as to purpose, method, assumptions, design input, references and units such that a personal technically qualified in the subject can review and understand the analyses and verify the adequacy of the result without recourse to the originator.
- C. Analysis is identifiable by subject (including structure, system or component to which the calculation applies), originator, reviewer and date prepared and review, or by other data such that the calculations are retrievable.
- D. Originators' qualifications (both academic and experience) are in compliance with the position description requirements.
- E. Independent reviewers' qualifications (both academic and experience) are equivalent to or exceed those of the originators'.
- F. Revisions to analysis have been or are being performed with the procedural discipline (including review and approval by the original design organization), as was the original analysis, and

G. Analysis is being stored in a protected and readily retrievable manner.

4.3 Review and verify a sample of design drawings/documents for each of the following:

A. Design documents are legible and in a form suitable for reproduction, filing, and retrieval.

B. Design documents are prepared In accordance with an approved format and include unique identification on an revision status.

C. Design documents are properly interfaced with external and internal organizations:

1. Interfaces and responsibilities are defined in writing.

2. Line of communication are clearly defined.

3. The flow of design information is established and documented.

D. Measures are established to verify the adequacy of design.

1. Design verification methods shall be performed by individuals or groups independent of the original design document preparers.

2. Design verification methods shall be identified and documented. Acceptable verifications methods include design reviews, alternate calculations, or qualification testing.

3. Results of design verification shall be documented clearly identifying the reviewer.

E. Revisions to design documents must be controlled in accordance with established methods.

F. Design documents are being properly retained and stored.

5.0 Other Guidelines for Consideration:

5.1 A.1, "General Quality Surveillance Guidance"

5.2 F.1, "Control of Design Inputs"

5.3 M.8, "Document Control"

5.4 N.3, Design Change Control