

ENGINEERING CHANGE PROCESS

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1.0 SCOPE

This document provides overall controlling guidance for all engineering changes within the Nuclear Power Business Unit (NPBU). All engineering changes should be evaluated using this procedure to determine the type of engineering change involved, and the applicable procedure(s) which should be used in the design and installation of the engineering change. It contains a flowchart that allows the user to determine what design and installation procedures are necessary for the engineering change. The intent of these decisions is to determine what level of design and project controls are needed when performing work at Point Beach Nuclear Plant.

The need for an engineering change originates in numerous places. In addition, the urgency or priority for processing the change varies substantially. For the purpose of this procedure these two important factors are assumed to be pre-determined. First, the need for the development of an engineering change has already been established, and second, its priority has been determined outside of this process.

This procedure covers all engineering changes performed by the Nuclear Power Business Unit (NPBU) at Point Beach Nuclear Plant. The document was developed based on licensing basis requirements, legal requirements by the State of Wisconsin, industry task group guidelines, and good engineering practice.

PBNP is committed to the use of ANSI N45.2.11-1974 per the plant licensing basis. This procedure contains a compliance summary for ANSI N45.2.11-1974. (See Attachment 1) This compliance summary documents NPBU compliance with the requirements of ANSI N45.2.11-1974.

2.0 REFERENCES

- 2.1 NP 1.4.1, Working Drawing System
- 2.2 NP 1.4.2, Permanent Drawing System
- 2.3 NP 1.4.3, Drawing Change Notice Procedure
- 2.4 NP 1.5.2, Computer Software and Data Management
- 2.5 NP 7.2.1, Modification Requests
- 2.6 NP 7.2.2, Design Control
- 2.7 NP 7.2.3, Engineering Change Requests
- 2.8 NP 7.2.4, Calculation Preparation, Review, and Approval
- 2.9 NP 7.3.1, Temporary Modifications

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- 2.10 NP 7.3.8, Instructions for Making Changes to PBNP Setpoint and EOP Setpoint Documents
- 2.11 NP 9.2.1, Specification Preparation, Review, and Approval
- 2.12 NP 9.3.3, Spare Parts Equivalency Evaluation
- 2.13 NP 10.3.1, Authorization of Changes, Tests, and Experiments (10 CFR 50.59 and 72.48 Reviews)
- 2.14 NP 11.4.6, Safety-Related and QA-Scope Classification
- 2.15 DG-G06, Guideline for System, Component, and Part Classification
- 2.16 NQAP, Nuclear Quality Assurance Program
- 2.17 AM 6-3, Systems and Design Functions Covered by the Quality Assurance Program
- 2.18 EPRI Document TR-103586, Guidelines for Optimizing the Engineering Change Process for Nuclear Power Plants
- 2.19 ANSI N18.7-1976, Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants
- 2.20 ANSI N45.2.11-1974, Quality Assurance Requirements for the Design of Nuclear Power Plants
- 2.21 Wisconsin Administrative Code Chapter ILHR 50
- 2.22 Point Beach Nuclear Plant Final Safety Analysis Report (FSAR)
- 2.23 INPO Document 90-009, Guidelines for the Conduct of Design Engineering
- 2.24 Updates to this procedure covered by existing SCR 99-0311

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3.0 DEFINITIONS

The following are definitions provided to ensure a uniform understanding of selected terms as they are used in this procedure.

3.1 Controlled Plant Equipment - Structures, systems, and components that:

- are safety-related, or
- whose functions impact the plant safety analysis, or
- other structures, systems, and components that are subject to special consideration based upon management discretion (e.g., considerations given to licensing basis, Augmented QA, the Maintenance Rule, personnel safety, availability, commercial risk, etc.). (See Reference 2.18)

3.2 Design Basis - Information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values, or ranges of values chosen for controlling parameters as reference bounds for design. (Excerpted from 10 CFR 50.2) (See Reference 2.18)

3.3 Design Change - A change to those bounded technical requirements that 1) ensure performance of design basis functions, or 2) ensure compliance with the plant licensing basis. Design changes include instrument setpoint changes and electronic software changes. (See Reference 2.18)

3.4 Document-only Change - A change to a controlled engineering document that does not involve or result in a change to plant equipment. (See Reference 2.18)

3.5 Engineering Change - Any change to a structure, system, or component including design changes, document-only changes and equivalent changes. (See Reference 2.18)

3.6 Equivalent Change - A hardware change that results in the installation of an item, not identical to the original item, that does not result in a change to those bounded technical requirements that 1) ensure performance of design basis functions, or 2) ensure compliance with the plant licensing basis of either the item(s) or applicable interfaces. (See Reference 2.18)

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4.0 PROCEDURE

4.1 Overall Engineering Change Process Description

4.1.1 The first step in the engineering change process is to apply criteria which effectively categorize engineering changes into logical groups. The types of engineering changes are listed below.

- Non-QA (Not associated with CPE)
- Document-only Change for CPE
- Equivalent Changes for CPE
- Design Changes for CPE

4.1.2 Figure 4-1 outlines the overall change categories and the categorization process. The person performing the engineering change should use Figure 4-1 to determine which type of engineering change is being made. Once this determination has been made, proceed to the applicable section of this procedure (Sections 4.3 through 4.7) to determine what types of controls and the governing procedures to be used to complete the engineering change.

4.1.3 The QA classification of a SSC can be found in the CHAMPS database. This database contains two codes that indicate if an item is safety-related and if the item is QA. If the database for a SSC indicates that it is not safety-related and not QA, the engineering change will be classified as Non-QA. Based on past experience with the CHAMPS database, the user is cautioned to verify the classification of the SSC. If the CHAMPS database does not contain the SSC in question or if the coding of the SSC appears to be incorrect, the engineer should refer to References 2.16 and 2.17 for guidance.

4.2 Non-QA (Not Associated With CPE)

4.2.1 Changes to Non-safety related (Non-SR) and Non-Quality Assurance systems, structures, or components (SSC) will be referred to as Non-QA engineering changes.

4.2.2 Non-QA engineering changes are required to meet design and installation requirements based on legal requirements and good engineering practice. The requirements of ANSI N45.2.11-1974 do not apply to these engineering changes.

4.2.3 The requirements for design and installation of Non-QA engineering changes will vary based on the complexity of the work, the impact on plant operations and the location of the change.

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- 4.2.4 Non-QA Plant Modifications shall be processed with the appropriate level of design and project controls (as determined in NP 7.2.1).
- a. Design control shall be per the requirements of NP 7.2.2. Documentation, installation, and configuration control for Non-QA modifications shall be per the requirements of NP 7.2.1.
  - b. The proposed change may involve interfaces with or "tie-ins" to CPE. The engineering process related to developing detailed design for these tie-ins shall be accomplished per Section 4.6 of this procedure. There may be cases where part of the engineering change is implemented under this section and part under Section 4.6.

- 4.2.5 Non-QA engineering changes, not related to Plant Modifications, should be processed per the requirements specified in their respective procedures for Non-QA work.

4.3 Engineering Changes to Controlled Plant Equipment

The remaining engineering changes outlined below in Sections 4.4 through 4.7 of this procedure have design and installation requirements that are based on legal requirements, good engineering practice and ANSI N45.2.11-1974.

4.4 Document-only Changes to QA SSCs

Document changes for QA SSCs are addressed in the procedure for the specific document (i.e., changes to calculations are addressed in NP 7.2.4). The applicable procedure shall be used for these document changes.

4.5 Equivalent Changes to QA SSCs

The evaluation of an item to determine if it can be considered an "Equivalent Change" is contained in NP 9.3.3, "Spare Parts Equivalency Evaluation". If an item is determined to be equivalent, the requirements of NP 9.3.3 should be used. If an item is determined not to be equivalent, the requirements of Section 4.6 below shall be followed.

4.6 Design Changes to QA SSCs

When the determination has been made that the engineering change involves a design change to a QA SSC, then design and installation shall be done in accordance with the requirements of ANSI N45.2.11-1974. In order to meet the requirements of ANSI N45.2.11 the design shall be done per the QA sections of NP 7.2.2, and the applicable design and project controls of NP 7.2.1 shall be invoked.

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**4.7 Special Condition Changes to QA SSCs**

Special condition changes are changes that have unique criteria and are therefore handled by separate procedures. These items include such things as setpoint changes, computer software changes and temporary modifications.

The procedures listed below shall be used for special condition changes to QA SSCs. These procedures shall be followed in lieu of those shown in Section 4.6 above.

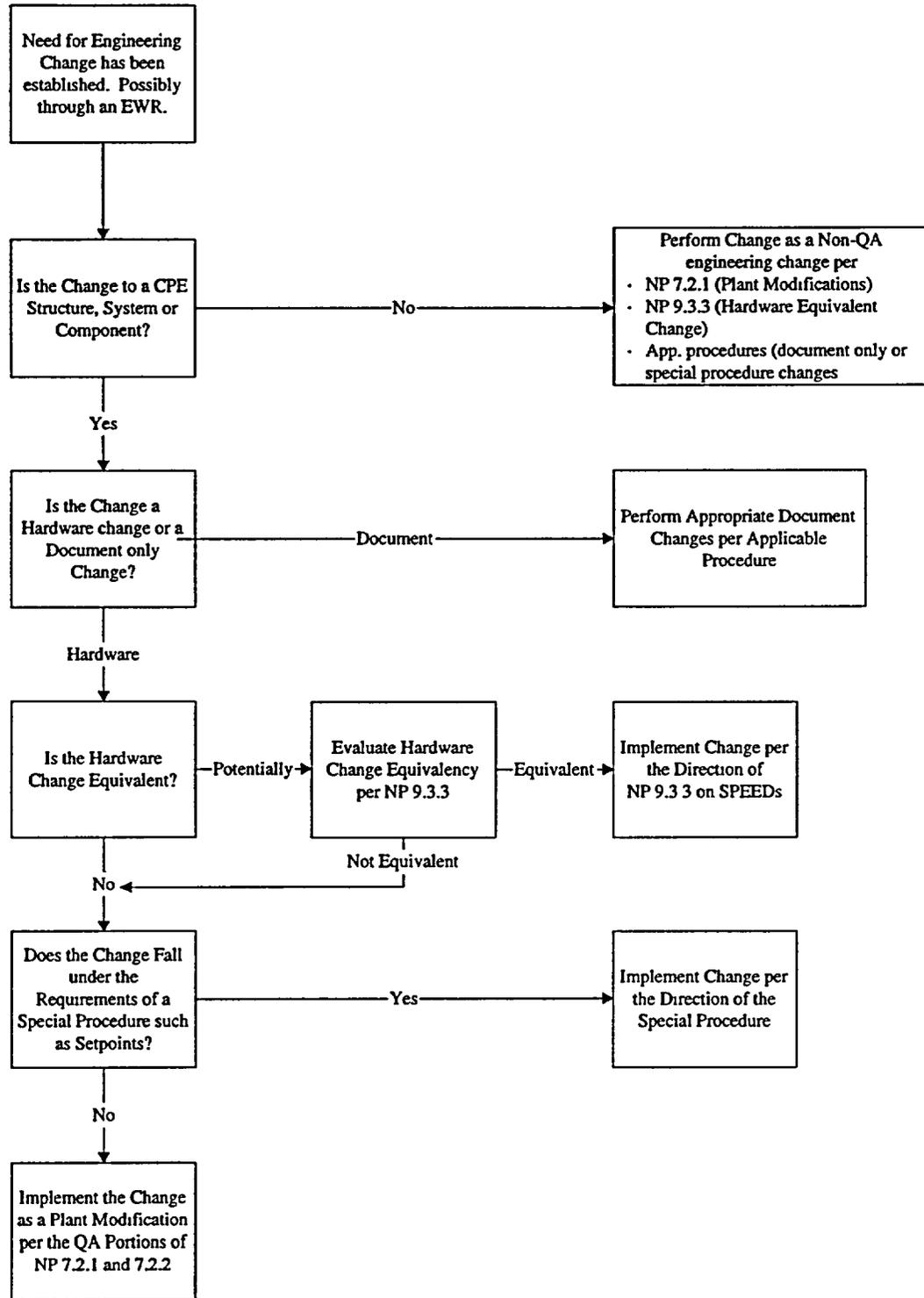
4.7.1 NP 1.5.2, Computer Software and Data Management

4.7.2 NP 7.3.1, Temporary Modifications

4.7.3 NP 7.3.8, Instructions for Making Changes to PBNP Setpoint and EOP Setpoint Documents

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FIGURE 4-1  
OVERALL ENGINEERING CHANGE PROCESS



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ATTACHMENT 1

Wisconsin Electric is committed to perform design changes to the Point Beach Nuclear Plant per Section 8 of ANSI N45.2.11-1974. In order to obtain a higher degree of Quality Assurance and to develop a consistent method of design (both within the Nuclear Power Business Unit and within the industry). The Nuclear Power Business Unit (NPBU) will perform QA design changes per all sections of ANSI N45.2.11-1974 as outlined below.

Below is a compliance summary for ANSI N45.2.11-1974 for NPBU procedures used in safety-related and QA-related design. The sections of ANSI N45.2.11 will be given and then a statement explaining how we comply with that section of the ANSI document will follow in bold italics.

1.0 INTRODUCTION

1.1 Scope

1.1.1 This standard provides requirements and guidance for quality assurance program for the design of nuclear power plant structures, systems and components whose satisfactory and reliable performance is required:

- a. To prevent accidents that could cause undue risk to the health and safety of the public; or
- b. To mitigate the consequences of such accidents if they were to occur.

1.1.2 The requirements of this standard may also be extended to other structures, systems and components in whole or in part as specified by the purchaser.

1.1.3 This standard covers activities which affect the final design.

1.1.4 This standard is intended to be used in conjunction with ANSI N45.2.

1.2 Applicability

This standard applies to the plant owner, nuclear steam supply system (NSSS) designer, architect engineer or plant designer, and other organizations participating in design activities affecting quality of items covered by this standard. The extent to which the individual sections and elements of this standard are applied will depend upon factors such as the nature and scope of the work to be performed and the importance of the structures, systems, and components to safe plant operation.

The ASME Boiler and Pressure Vessel Code (hereafter referred to as the Code) as well as other ANSI Standards, has been considered in the development of this standard, and this standard is intended to be compatible with their requirements.

However, this standard does not apply to activities covered by Section III, Division 1 and 2 and Section XI of the Code for those activities covered by the Code.

*The scope and applicability of ANSI N45.2.11 to work performed by the NPBU is outlined in Section 4.0 of NP 7.2.6.*

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1.3 Responsibility

It is the responsibility of the plant owner to provide for the establishment and execution of a quality assurance program for the plant design consistent with the provisions of this standard. The plant owner may delegate to other organizations the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for overall program effectiveness. It is the responsibility of the plant owner and other organizations invoking this standard to identify the structures, systems and components, and to specify the extent to which the provisions of this standard apply to such structures, systems and components. In no way shall the program operate to diminish the responsibility of any contractor for the quality of services furnished.

*The responsibility of establishment of a QA program to meet the requirements of ANSI N45.2.11 for the Point Beach Nuclear Plant is the ultimate responsibility of Wisconsin Electric. The method for meeting this standard is outlined in this appendix. The requirements for applicability to structures, systems and components is outlined in NP 7.2.6.*

1.4 Definitions

The following definitions are provided to assure a uniform understanding of select terms as they are used in this standard.

Design - Technical and management processes which commence with identification of design input and which lead to and include the issuance of design output documents.

Design Input - Those criteria, parameters, bases or other design requirements upon which detailed final design is based.

Design Output - Documents such as drawings, specifications and other documents defining technical requirements of structures, systems and components as delineated in Section 4.

External Design Interface - Relationship between design groups from different companies. Examples are the interfaces between the plant owner and the architect engineer or the plant owner and the NSSS supplier, or the architect engineer and the NSSS supplier.

Final Design - Approved design output documents and approved changes thereto.

Internal Design Interface - Relationship between design groups or organizations within a company.

Procedures - A document that specifies or describes how an activity is to be performed. It may include methods to be employed, equipment or materials to be used and sequence of operation.

*The definitions are provided in NP 7.2.2.*

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1.5 Referenced Documents

Other documents that are required to be included as part of this standard will be identified at the point of reference and described in Section 12 of this standard. The issue or edition of the referenced document that is required will be specified either at the point of reference or in Section 12 of this standard.

*Not Applicable*

2.0 PROGRAM REQUIREMENTS

2.1 Establishment and Documentation

A quality assurance program for design shall be established and documented to comply with the requirements of this Standard.

The program documents shall define the organizational structure within which the program is to be implemented, and shall delineate the authority and responsibility of the persons and organizations involved performing design activities affecting the quality of design.

The program documents shall identify the items and services and the specific activities to which this standard is applied. The design responsibilities and interfaces among the contributing organizations, both internal and external shall be identified.

Provisions shall be made in the program for periodic audits, review and evaluation of the effectiveness of the program in achieving quality objectives. Correction of deficiencies shall be an integral part of the program.

*Para. 1 - Reference NQAP.*

*Para. 2 - Reference NQAP.*

*Para. 3 - Applicability of this standard is as outlined in Section 4.0 of this procedure and NQAP. Design responsibilities and interfaces are outlined in NQAP.*

*Para. 4 - The provisions for audits, review and evaluation of the program and correction of deficiencies is contained in NQAP.*

2.2 Program Procedures

Procedures shall be employed to assure that design activities are carried out in a planned, controlled, orderly and correct manner. Program procedures shall cover the following as applicable:

2.2.1 Responsibilities of organizations involved in the program, such as owner, A-E, NSSS supplier and other contractors.

2.2.2 Responsibilities within design organizations.

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- 2.2.3 Technical information exchanges across external and internal interfaces.
- 2.2.4 Document control including review, approval, release, distribution, and revision.
- 2.2.5 Maintenance and retention of design documents.
- 2.2.6 Management review of status and adequacy of program.
- 2.2.7 Necessary training of personnel performing activities covered by this standard.
- 2.2.8 Identifying appropriate design input.
- 2.2.9 Preparation of design documents.
- 2.2.10 Specifying quality levels, acceptance standards, and record requirements.
- 2.2.11 Performance of design verifications.
- 2.2.12 Conducting audits of design activities, their reporting and followup.
- 2.2.13 Taking corrective action. (See Section 9 0)
- 2.2.14 Making experience reports available to cognizant design personnel.
- 2.2.15 Controlling design changes.
- 2.2.16 Other procedures as required by this standard.
  - a. *Reference NQAP*
  - b. *Reference NQAP*
  - c. *Reference NP 7.2.2*
  - d. *Reference NQAP*
  - e. *Reference NQAP*
  - f. *Reference NQAP*
  - g. *Per Qualification Card program*
  - h. *Per NP 7.2.2*
  - i. *Per NP 7.2.2*
  - j. *Quality levels per NP 7.2.2, acceptance standards per NP 7.2.2 and Installation document, and record requirements per NP 7.2.1 document update sheet.*
  - k. *Reference NP 7.2.2*
  - l. *Reference NQAP*
  - m. *Reference NQAP*
  - n. *Reference NQAP*
  - o. *Reference NP 7.2.3*
  - p. *This is done as outlined throughout this procedure.*

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2.3 Factors Considered

Some of the factors to be considered in establishing the program include:

- 2.3.1 Nature of the organization such as the plant owner, manufacturer, or architect-engineer, and the nature of the design interfaces among them.
- 2.3.2 Importance of the design activity to plant safety.
- 2.3.3 State of the art such as experimental, developmental, or standard design.
- 2.3.4 Nature of design activity such as conceptual, preliminary, detailed design, or field engineering.

*These items are considered as part of the program.*

3.0 DESIGN INPUT REQUIREMENTS

3.1 General

Applicable design inputs such as design bases, regulatory requirements, codes and standards, shall be identified, documented and their selection reviewed and approved. Changes from specified design inputs including the reasons for the changes shall be identified, approved, documented and controlled.

The design input shall be specified on a timely basis and to the level of detail necessary to permit the design activity 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.

3.2 Requirements

The design input shall include but is not limited to the following, where applicable:

- 3.2.1 Basic functions of each structure, system and component.
- 3.2.2 Performance requirements such as capacity, rating, system output.
- 3.2.3 Codes, standards, and regulatory requirements including the applicable issue and/or addenda.
- 3.2.4 Design conditions such as pressure, temperature, fluid chemistry and voltage.
- 3.2.5 Loads such as seismic, wind, thermal and dynamic.

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- 3.2.6 Environmental conditions anticipated during storage, construction and operation such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation and duration of exposure.
- 3.2.7 Interface requirements including definition of the functional and physical interfaces involving structures, systems and components.
- 3.2.8 Material requirements including such items as compatibility, electrical insulation properties, protective coating and corrosion resistance.
- 3.2.9 Mechanical requirements such as vibration, stress, shock and reaction forces.
- 3.2.10 Structural requirements covering such items as equipment foundations and pipe supports.
- 3.2.11 Hydraulic requirements such as pump net positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities.
- 3.2.12 Chemistry requirements such as provisions for sampling and limitations on water chemistry.
- 3.2.13 Electrical requirements such as source of power, voltage, raceway requirements, electrical insulation and motor requirements.
- 3.2.14 Layout and arrangement requirements.
- 3.2.15 Operational requirements under various conditions, such as plant startup, normal plant operation, plant shutdown, plant emergency operation, special or infrequent operation, and system abnormal or emergency operation.
- 3.2.16 Instrumentation and control requirements including indicating instruments, controls and alarms required for operation, testing, and maintenance. Other requirements such as the type of instrument, installed spares, range of measurement, and location of indication should also be included.
- 3.2.17 Access and administrative control requirements for plant security.
- 3.2.18 Redundancy, diversity and separation requirements of structures, systems and components.
- 3.2.19 Failure effects requirements of structures, systems and components, including a definition of those events and accidents which they must be designed to withstand.

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- 3.2.20 Test requirements including in-plant tests and the conditions under which they will be performed.
- 3.2.21 Accessibility, maintenance, repair and inservice inspection requirements for the plant including the conditions under which these will be performed.
- 3.2.22 Personnel requirements and limitations including the qualification and number of personnel available for plant operation, maintenance, testing and inspection and permissible personnel radiation exposures for specified areas and conditions.
- 3.2.23 Transportability requirements such as size and shipping weight, limitations, I.C.C. regulations.
- 3.2.24 Fire protection or resistance requirements.
- 3.2.25 Handling, storage and shipping requirements.
- 3.2.26 Other requirements to prevent undue risk to the health and safety of the public.
- 3.2.27 Materials, processes, parts and equipment suitable for application.
- 3.2.28 Safety requirements for preventing personnel injury including such items as radiation hazards, restricting the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems.

*These items are specifically addressed in NP 7.2.2*

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4.0 DESIGN PROCESS

4.1 General

Design activities shall be prescribed and accomplished in accordance with procedures of a type sufficient to assure that applicable design inputs are correctly translated into specifications, drawings, procedures or instructions. Appropriate quality standards shall be identified, documented and their selection reviewed and approved. Changes from specified quality standards including reasons for the changes shall be identified, approved, documented and controlled.

The design activities may be prescribed in job specifications, work instructions, planning sheets, procedure manuals, test procedures, or any other type of written form, which provides adequate control and permits reviewing, checking or verifying the results of the activity by personnel who are experienced in the subject activity.

Methods shall provide for relating the final design back to the source of design input. This traceability shall be documented in accordance with the requirements of Section 10.0.

The design activities shall be documented in sufficient detail to permit verification and auditing as required by this standard.

*This section is addressed in NP 7.2.2*

4.2 Design Analyses

Design analyses such as physics, stress, thermal, hydraulic and accident, shall be performed in a planned, controlled and correct manner.

Design analyses shall be legible and be in a form suitable for reproduction, filing and retrieving. Analyses shall be sufficiently detailed as to purpose, method, assumptions, design input, references and units 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. Procedures shall include requirements for:

4.2.1 Identifying documents to permit ready reference and retrieval.

4.2.2 Defining the objective of the analyses.

4.2.3 Definition of design inputs and their sources.

4.2.4 Documenting the results of literature searches or other applicable background data.

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- 4.2.5 Documenting assumptions, and identifying those assumptions that must be verified as the design proceeds.
- 4.2.6 Identification of computer calculations, including computer type, code or programming, inputs and outputs.
- 4.2.7 Review and approval.

*This section is addressed in NP 7.2.4*

4.3 Drawings

Procedures shall be established for the preparation and control of drawings. Typical subjects to be covered by such procedures are:

- 4.3.1 Drafting room standards.
- 4.3.2 Standardized symbols.
- 4.3.3 Identification system.
- 4.3.4 Indication of status.
- 4.3.5 Checking methods.
- 4.3.6 Review and approval requirements.
- 4.3.7 Issuance and distribution.
- 4.3.8 Storage and control of originals or master copies.
- 4.3.9 Revisions.
- 4.3.10 As-built drawings.
- 4.3.11 Nonconformance with drawing requirements.

*This section is addressed by NP 1.4.1, 1.4.2 and 1.4.3.*

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### 4.4 Specifications

Procedures shall be established for the preparation and control of specifications. Typical subjects to be covered by such procedures are:

- 4.4.1 Format requirements.
- 4.4.2 Identification system.
- 4.4.3 Review and approval requirements.
- 4.4.4 Issuance and distribution.
- 4.4.5 Revisions.
- 4.4.6 Indication of status.
- 4.4.7 Nonconformance with specification requirements.
- 4.4.8 Storage and control of originals or master copies.

*This section is addressed by NP 9.2.1.*

### 4.5 Other Design Documents

Procedures shall be established for the preparation and control of other design documents such as installation instructions and test procedures. Typical subjects to be covered are:

- 4.5.1 Format requirements.
- 4.5.2 Identification system.
- 4.5.3 Review and approval requirements.
- 4.5.4 Issuance and distribution.
- 4.5.5 Revisions.
- 4.5.6 Indication of status.
- 4.5.7 Nonconformance with design document requirements.
- 4.5.8 Storage and control of originals or master copies.

*Other design documents are controlled by the applicable procedures.*

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5.0 INTERFACE CONTROL

5.1 External

- 5.1.1 Identification of Interface - The external interfaces between organizations performing work affecting quality of design shall be identified in writing and shall include those organizations providing criteria, designs, specifications and technical direction.
- 5.1.2 Responsibilities - Responsibilities for organizations shall be defined and documented in sufficient detail to cover the preparation, review and approval of documents involving design interfaces. Responsibilities may be set forth in tabular form or flowcharts accompanied by appropriate text to clarify the intent. Appendices A and B provide examples.
- 5.1.3 Lines of Communication - Systematic methods shall be established for communicating needed design information across external design interfaces, including changes to the design information as work progresses. Documents shall identify the positions and titles of key personnel in the communication channels and their responsibilities for decision-making, for resolution of problems, for providing and reviewing information, and for taking other action within the scope of this standard.
- 5.1.4 Documentation - Procedures shall be established to control the flow of design information between organizations. Design information transmitted from one organization to another shall be documented in specifications, drawings, or other controlled documents which are uniquely identified and issued by authorized persons. The procedures shall provide that design interface information be transmitted to affected organizations and that any information requested in the design interface transmittal be transmitted back to the originator. Documentation requesting information or action shall be controlled by a system which assures that the response and the request can be related. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

*5.1.1 - Reference NP 7.2.2*

*5.1.2 - Reference NP 7.2.2*

*5.1.3 and 5.1.4 - The intent of these sections are met by varying degrees for each engineering change dependant on scope and safety significance. For large safety-related projects formal lines of communications, key personnel and documentation transmittal are documented in a project procedures manual. For smaller projects these items are done in a less formal manner and may consist of a team charter in the case of a Plant Modification or verbal instructions from the Project Manager.*

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5.2 Internal

- 5.2.1 Identification of Interface - Each organization performing work affecting quality of design shall identify in writing its internal design interfaces for managing the flow of design information between organizational units.
- 5.2.2 Responsibilities - Responsibilities for each organizational unit shall be defined and documented in sufficient detail to cover the preparation, review, approval, distribution and revision of documents involving design interfaces.
- 5.2.3 Lines of Communication - Systematic methods shall be established for communicating needed design information across the internal design interfaces, including changes to the design information as work progresses.
- 5.2.4 Documentation. Procedures shall be established to control the flow of design information between organizational units. Design information transmitted from one organizational unit to another shall be documented and controlled. Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

*5.2.1 - Per NP 7.2.2*

*5.2.2 - Per NP 7.2.2*

*5.2.3 and 5.2.4 - The intent of these sections are met by varying degrees for each engineering change dependant on scope and safety significance. For large safety-related projects formal lines of communications, key personnel and documentation transmittal are documented in a project procedures manual. For smaller projects these items are done in a less formal manner and may consist of a team charter in the case of a Mod Request or verbal instructions from the Project Manager.*

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### 6.0 DESIGN VERIFICATION

#### 6.1 General

Measures shall be applied to verify the adequacy of design. Design verification is the process of reviewing, confirming, or substantiating the design by one or more methods to provide assurance that the design meets the specified design inputs.

Design verification shall be performed by any competent individuals or groups other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor 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 if the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this standard. Design verification may vary from spot checking of calculations to actual tests in the field.

The results of design verification efforts shall be clearly documented, with the identification of the verifier clearly indicated thereon, and filed. Documentation of results shall be auditable against the verification methods identified by the responsible design organization.

#### 6.2 Extent

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, including environmental conditions, shall be verified for each application. Where the design of a particular structure, system, or component for a particular nuclear power plant has been subjected to a verification process in accordance with this standard, the verification process need not be duplicated for identical designs. However, known problems affecting the standardized design and their effects on other features shall be considered. The original design and associated verification measures shall, however, be adequately documented and referenced in the files of subsequent application of the design.

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design.

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6.3 Methods

The responsible design organization shall identify and document the particular design verification methods to be used. Acceptable verification methods include but are not limited to:

- Design reviews
- Alternate calculations
- Qualification testing

6.3.1 Design Reviews - Design reviews are critical reviews to provide assurance that design documents such as drawings, calculations, analyses or specifications are correct and satisfactory. Design reviews can range from multi-organization reviews to single-person reviews. The depth of review can range from a detailed check of the complete design to a limited check of such things as the design approach and the results obtained. The results of the review shall be documented and measures taken to ensure that the findings are implemented. Whether the review is conducted by one individual or a multi-organization there are a number of basis questions that shall be addressed such as:

- a. Were the inputs correctly selected and incorporated into design? (See Paragraph 3.2).
- b. Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent re-verifications when the detailed design activities are completed?
- c. Are the appropriate quality and quality assurance requirements specified?
- d. Are the applicable codes, standards and regulatory requirements including issue and addenda properly identified and are their requirements for design met?
- e. Have applicable construction and operating experience been considered?
- f. Have the design interface requirements been satisfied?
- g. Was an appropriate design method used?
- h. Is the output reasonable compared to inputs?
- i. Are the specified parts, equipment, and processes suitable for the required application?

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- j. Are the specified materials compatible with each other and the design environmental conditions to which the material will be exposed?
- k. Have adequate maintenance features and requirements been specified?
- l. Are accessibility and other design provisions adequate for performance of needed maintenance and repair?
- m. Has adequate accessibility been provided to perform the in-service inspection expected to be required during the plant life?
- n. Has the design properly considered radiation exposure to the public and plant personnel?
- o. Are the acceptance criteria incorporated in the design documents sufficient to allow verification that design requirements have been satisfactorily accomplished?
- p. Have adequate pre-operational and subsequent periodic test requirements been appropriately specified?
- q. Are adequate handling, storage, cleaning and shipping requirements specified?
- r. Are adequate identification requirements specified?
- s. Are requirements for record preparation review, approval, retention, etc., adequately specified?

6.3.2 Alternate Calculations - Verification of some types of calculations or analyses may be achieved by comparison with alternate methods of calculation or analyses. This shall be performed by a person or persons other than those who performed the original calculation. Where alternate calculations are performed to verify the correctness of the original calculation a review shall also be performed to address the appropriateness of assumptions, input data, and the code or other calculation method used.

The alternate method used for comparison may be a more simplified approach or less rigorous, such as when a hand calculation is used to check the computer code output. Although the simplified or less rigorous method may not exactly check the original calculation or analysis, it must provide results consistent with the original calculation or analyses.

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- 6.3.3 Qualification Testing - Design verification for some designs or specific design features can be achieved by suitable qualification testing of a prototype or initial production unit.

In those cases where the adequacy of a design is to be verified by a qualification test, the testing shall be identified and documented. Testing shall demonstrate adequacy of performance under the most adverse design conditions. All pertinent operating modes shall be considered in determining these design conditions where it is intended that the test program confirm the adequacy of the overall design. Where the test is only intended to verify a specific design feature, the other features of the design shall be verified by other means. For example, it may be most effective to verify that an instrumentation cabinet is designed to withstand the maximum earthquake-caused vibratory motions by actually subjecting the cabinet and its associated components to shaker tests which correspond to these vibratory motions. The shaker tests will not, however, verify that the circuitry is designed correctly, or that the component in the cabinet will perform its intended function. Other tests or verification means are required to confirm that remaining design functions are adequately performed by the instrumentation and that those components perform the intended functions for the varying design conditions to which they are subjected.

Qualification testing shall be performed in accordance with written test procedures which incorporate or reference the requirements and acceptance limits contained in applicable design documents. The test procedures shall include provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation of the required range and accuracy is available and used, and that necessary monitoring is performed. Prerequisites include such items as calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions and provisions for data acquisition. Test results shall be documented and evaluated by the responsible designer to assure that test requirements have been satisfied.

If 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. When tests are being performed on models or mock-ups, scaling laws shall be established and verified. The test configuration shall be clearly defined and documented. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.

*Reference NP 7.2.2*

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7.0 DOCUMENT CONTROL

7.1 Document Preparation, Approval and Issue

Personnel shall be made aware of and use proper and current instructions, procedures, drawings and design inputs. Participating organizations shall have documented procedures for control of design documents and changes thereto to assure that current and appropriate documents are available for use. The document control procedures shall provide for:

- 7.1.1 Identification of personnel positions or organizations responsible for preparing, reviewing, approving and issuing documents and revisions thereto. This identification may take the form of Project General Instructions, design organization Policy Statements, a matrix showing document type against function, or other written forms appropriate to the organizational method of performing the design process.
- 7.1.2 Identification of the proper documents to be used in performing the design. The identification should include title applicable revisions, date of issue or any other relevant information that would precisely identify the document to be used.
- 7.1.3 Coordination and control of design (internal and external) interface documents. These interface documents should be mutually agreed to and prepared in sufficient detail to assure that the required reviews and approvals are accomplished.
- 7.1.4 Ascertaining that proper documents are accessible and are in fact being used. This might be accomplished by several schemes including the following examples: periodic issuance of master drawing or specification lists showing the latest applicable revision (such lists could provide a reference for auditing the accessibility and use of the latest documents); or some type of receipting system can provide assurance that the latest documents have been received and obsolete revisions recalled. An example of such a receipting system is Appendix C, Drawing Issue Check List.
- 7.1.5 Establishing distribution lists which are updated and maintained current to assure that the proper personnel are sent all the required documents to perform the work.

*This information is contained in the procedure governing the design document. See the list of references for the specific procedures.*

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7.2 Document Revision

Significant changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organizations shall have access to pertinent background data information upon which to base their approval. However, minor changes to design documents, such as inconsequential editorial corrections or changes to commercial terms and conditions, may not require that the revised document receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes which do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated in the document control procedures.

*This information is contained in Section 4.0 of NP 7.2.6 and the procedure governing the design document. See the list of references for the specific procedures.*

8.0 DESIGN CHANGE CONTROL

Documented procedures shall be provided for design changes to approved design documents, including field changes, which assure that the impact of the change is carefully considered, required actions documented and information concerning the change is transmitted to all affected persons and organizations. These changes shall be justified and subjected to design control measures commensurate with those applied to the original design.

8.1 Reasons for Changes

Design changes frequently result from such things as the following:

- 8.1.1 Qualification, preoperational, or operational test results are not satisfactory.
- 8.1.2 Interference problems discovered during construction.
- 8.1.3 Failures of structures, systems, or components to meet functional requirements.
- 8.1.4 Disposition of nonconforming items.
- 8.1.5 Changes in regulatory or other requirements.
- 8.1.6 Operational experience.
- 8.1.7 Design improvements.

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### 8.2 Review of Changes

Normally, the procedures for effecting design changes shall require that the documents which reflect the design change be reviewed and approved by the same groups or organizations which reviewed and approved the original design documents. Where an organization which originally was responsible for approving a particular design document is no longer responsible, the plant owner shall designate the new responsible organization which may be the owner's own engineering organization. The designated organization shall have access to pertinent background information, have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

*Reference NP 7.2.3 and the specific procedures for the design documents.*

### 9.0 CORRECTIVE ACTION

In addition to correcting a deficiency (or error), corrective action also includes, for significant or recurring deficiencies (or errors), determining the cause and instituting appropriate changes in the design process and the quality assurance program to prevent similar types of deficiencies (or errors) from recurring. A procedure shall be employed for providing such corrective action. This procedure shall also contain provisions for reporting the deficiency and corrective action to appropriate levels of supervision and management. The procedure shall also include follow-up actions that cannot be immediately completed to assure timely resolution and/or completion of the corrective action.

#### 9.1 Detection of Errors

Deficiencies or error in the design or the design quality assurance program may be detected by:

- 9.1.1 Design verification measures.
- 9.1.2 Personnel using the design documents.
- 9.1.3 Audits.
- 9.1.4 Tests conducted.
- 9.1.5 Actual failure during operation.
- 9.1.6 Other means.

#### 9.2 Review of Procedure

Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

*Reference NQAP*

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### 10.0 RECORDS

Design documentation and records which provide evidence that the design and review process was performed in accordance with the requirements of this standard shall be collected, stored and maintained in accordance with the requirements of ANSI N45.2.9.

The documentation shall include not only the final design documents such as drawings and specifications, and revisions thereto but also records of the important steps including sources of design inputs, which support the final design. The records shall be legible, identifiable and retrievable.

Documentation and records will be either of the lifetime or nonpermanent category as defined in ANSI N45.2.9.

*Reference NQAP*

### 11.0 AUDITS

A comprehensive system of planned and documented audits shall be carried out to verify compliance with all aspects of the Quality Assurance program for design including those procedures delineating quality assurance actions required during the design process.

#### 11.1 Personnel

These audits shall be performed in accordance with written procedures or check list by personnel not having direct responsibilities in the areas being audited. For example, the person who performs an audit on design verification should not have been responsible for performing the design verification. The personnel performing audits shall be of a level of competency and have sufficient authority and organizational freedom to make the audit process meaningful and effective.

#### 11.2 Internal Audits

Design organizations performing work in accordance with the requirements of this standard shall be audited to assure that their design quality assurance programs are being implemented. Audits may be conducted internally by the design organization or by a unit independent of the design organization.

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**11.3 External Audits**

Organizations shall conduct or delegate the conduct of external audits of design organizations performing work for them to assure that specified design quality assurance program requirements are being implemented and are effective.

**11.3.1** Audits shall include an evaluation of design quality assurance policies, practices, procedures and instructions; the effectiveness of implementation; and actions taken to correct deficiencies in the program. The audits should include the examination of design activities, processes and documents and records. An audit plan shall be developed and should identify the functional areas to be audited, the extent of audit within these areas to determine effectiveness, the names and assignments of those who will perform the audit, the scheduling arrangements and the methods of reporting findings and recommendations.

**11.3.2** Audit Schedule

Audits should be conducted on a routine basis to establish the adequacy of and conformance to the design quality assurance requirements. Audits should also be conducted when one or more of the following conditions exists:

- a. When it is necessary to determine the capability of a subcontractor's quality assurance program prior to awarding of contract or purchase order for design services.
- b. When, after award of contract, sufficient time has elapsed for the implementation of the quality assurance program for design and it is appropriate to determine that the organization is performing the functions as defined in the quality assurance program description, codes, standards and other contract documents.
- c. When significant changes are made in functional areas of the quality assurance program for design including significant reorganizations and procedure revisions.
- d. When it is suspected that safety related performance of the item is in jeopardy due to deficiencies and nonconformances in the quality assurance program.
- e. When a systematic, independent assessment of program effectiveness or item quality or both is considered necessary.
- f. When it is considered necessary to verify implementation of required corrective actions.

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11.4 Results

Audit results shall be documented and reviewed by management having responsibility in the areas audited. Audit reports shall be in sufficient detail to permit management evaluation of the breadth of the audit as well as the validity of the findings.

11.5 Follow-up

Appropriate corrective action and timely follow-up action, including re-audit of deficient areas, shall be taken where indicated by the audit findings.

*Reference NQAP*

12.0 AMERICAN NATIONAL STANDARDS REFERRED TO IN THIS DOCUMENT

When the following standards referred to in this document are superseded by a revision approved by the American National Standards Institute, the revision shall apply.

N45.2 Quality Assurance Requirements for Nuclear Power Plants.

N45.2.9 Requirements for Collection, Storage and Maintenance of Quality Assurance Records for Nuclear Power Plants.

N45.2.10 Quality Assurance Terms and Definitions.

*No Compliance summary is required for this section.*