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Our Topic today:
Nuclear Quality Assurance
ASME NQA-1

CIS GmbH
Experts in ASME Code

Consulting

3rd Party Inspection

Training
Design
Audits

CIS GmbH Consulting Inspection Services
Hierarchy Structure

Regulatory Authorities: Nuclear Regulatory Commission [NRC]

Code of Federal Regulations [CFR]
Regulatory Guides [Reg]
http://www.nrc.gov/

Jurisdictional Authorities: US-States and Canadian Provinces

IEEE Standards
IEEE 323
IEEE 334
IEEE 572

Referenced Codes and Standards
NQA-1: Quality Assurance Requirements for Nuclear Facility Applications
QAI-1: Qualifications for Authorized Inspection
ASME ; ANSI ; ASNT
§ 50.49 Environmental qualification of electric equipment important to safety for nuclear power plants.

(a) Each holder of or an applicant for an operating license issued under this part,..., shall establish a program for qualifying the electric equipment defined in paragraph (b) of this section. ...

(b) Electric equipment important to safety covered by this section is:
   (1) Safety-related electric equipment. ³

   ³ Safety-related electric equipment is referred to as "Class 1E" equipment in IEEE 323-1974.

   (2) Nonsafety-related electric equipment whose failure under postulated environmental conditions could prevent satisfactory accomplishment of safety functions specified in subparagraphs (b)(1)(i)(A) through (C) of this section by the safety-related equipment.

   (3) Certain post-accident monitoring equipment. ⁴

   ⁴ See Reg Guide 1.96
§ 50.49 Environmental qualification of electric equipment important to safety for nuclear power plants.

(c) Requirements for (1) dynamic and seismic qualification of electric equipment important to safety, (2) protection of electric equipment important to safety against other natural phenomena and external events, and (3) environmental qualification of electric equipment important to safety located in a mild environment are not included within the scope of this section. A mild environment is an environment that would at no time be significantly more severe than the environment that would occur during normal plant operation, including anticipated operational occurrences.

(d) The applicant or licensee shall prepare a list of electric equipment important to safety covered by this section. In addition, the applicant or licensee shall include the information in paragraphs (d)(1), (2), and (3) of this section for this electric equipment important to safety in a qualification file. The applicant or licensee shall keep the list and information in the file current and retain the file in auditable form for the entire period during which the covered item is installed in the nuclear power plant or is stored for future use to permit verification that each item of electric equipment is important to safely meet the requirements of paragraph (j) of this section.

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(d)

(1) The performance specifications under conditions existing during and following design basis accidents.
(2) The voltage, frequency, load, and other electrical characteristics for which the performance specified in accordance with paragraph (d)(1) of this section can be ensured.
(3) The environmental conditions, including temperature, pressure, humidity, radiation, chemicals, and submergence at the location where the equipment must perform as specified in accordance with paragraphs (d)(1) and (2) of this section.
(e) The electric equipment qualification program must include and be based on the following:

1. **Temperature and pressure.** The time-dependent temperature and pressure at the location of the electric equipment important to safety must be established for the most severe design basis accident during or following which this equipment is required to remain functional.

2. **Humidity.** Humidity during design basis accidents must be considered.

3. **Chemical effects.** The composition of chemicals used must be at least as severe as that resulting from the most limiting mode of plant operation (e.g., containment spray, emergency core cooling, or recirculation from containment sump).

4. **Radiation.** The radiation environment must be based on the type of radiation, the total dose expected during normal operation over the installed life of the equipment, and the radiation environment associated with the most severe design basis accident during or following which the equipment is required to remain functional, including the radiation resulting from recirculating fluids for equipment located near the recirculating lines and including dose-rate effects.

5. **Aging.** Equipment qualified by test must be preconditioned by natural or artificial (accelerated) aging to its end-of-installed life condition.

6. **Submergence** (if subject to being submerged).

7. **Synergistic effects.** Synergistic effects must be considered.

8. **Margins.** Margins must be applied to account for unquantified uncertainty, such as the effects of production variations and inaccuracies in test instruments. These margins are in addition to any conservatisms applied during the derivation of local environmental conditions of the equipment unless these conservatisms can be quantified and shown to contain appropriate margins.

(f) Each item of electric equipment important to safety must be qualified by one of the following methods:

1. **Testing an identical item of equipment** under identical conditions or under similar conditions with a supporting analysis to show that the equipment to be qualified is acceptable.

2. **Testing a similar item of equipment** with a supporting analysis to show that the equipment to be qualified is acceptable.

3. **Experience** with identical or similar equipment under similar conditions with a supporting analysis to show that the equipment to be qualified is acceptable.

4. **Analysis in combination with partial type test data** that supports the analytical assumptions and conclusions.
Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.

Every applicant for a combined license under part 52 of this chapter is required by the provisions of § 52.79 of this chapter to include in its final safety analysis report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation.

For applications submitted after September 27, 2007, every applicant for an early site permit under part 52 of this chapter is required by the provisions of § 52.17 of this chapter to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the structures, systems, and components of the facility or facilities that may be constructed on the site.

Every applicant for a design approval or design certification under part 52 of this chapter is required by the provisions of 10 CFR 52.137 and 52.47, respectively, to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility.

Every applicant for a manufacturing license under part 52 of this chapter is required by the provisions of 10 CFR 52.157 to include in its final safety analysis report a description of the quality assurance program applied to the design and manufacture of the structures, systems, and components of the reactor, nuclear power plants and fuel reprocessing plants that include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

I. Organization
II. Quality Assurance Program
III. Design Control
IV. Procurement Document Control
V. Instructions, Procedures, and Drawings
VI. Document Control
VII. Control of Purchased Items and Services
VIII. Identification and Control of Items
IX. Control of Processes
X. Inspection
XI. Test Control
XII. Control of Measuring and Test Equipment
XIII. Handling, Storage, and Shipping
XIV. Inspection, Test, and Operating Status
XV. Nonconforming Materials, Parts, or Components
XVI. Corrective Action
XVII. Quality Assurance Records
XVIII. Audits
IV. Procurement Document Control
Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

VII. Control of Purchased Material, Equipment, and Services
Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation, objective evidence of quality furnished by the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear powerplant or fuel reprocessing plant site prior to installation or use of such material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.
B. DISCUSSION
Institute of Electrical and Electronics Engineers (IEEE) Standard (Std.) 572-2006, “Qualification of Class 1E Connection Assemblies for Nuclear Power Generating Stations,” issued June 2007 (Ref. 2), was prepared by Subcommittee 2 (Qualification) of the IEEE Nuclear Power Engineering Committee and was approved by the IEEE Standards Board on December 6, 2006. This standard describes basic procedures for qualifying connection assemblies (e.g., connectors, terminations, and environmental seals in combination with related cables or wires as assemblies). The qualification requirements in this standard, when followed, demonstrate and document the ability of the equipment to perform safety functions under applicable service conditions, including design-basis events.

C. REGULATORY POSITION
The NRC considers the use of the procedures in IEEE Std. 572-2006, when used in conjunction with Regulatory Guide 1.89, “Environmental Qualification of Certain Electric Equipment Important to Safety for Nuclear Power Plants” (Ref. 4), as an acceptable method for demonstrating compliance with the NRC regulations pertaining to the environmental qualification of connectors, terminations, and environmental seals in combination with cables or wires as assemblies for service in nuclear power plants to ensure that the connection assemblies can perform their safety functions.

Other Methods may be used as well!
ANSI/ASME NQA-1-1979 Quality Assurance Program Requirements for Nuclear Power Plants
intended to meet and implement the 18 criteria of
10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants.

ANSI/ASME NQA-2-1979 Quality Assurance Requirements for Nuclear Power Plants
based upon ANSI/ASME N45.2-1977, Quality Assurance Program Requirements for Nuclear Facilities;
ANSI N45.2, Revision 1, Quality Assurance Program Requirements for Post-Reactor Nuclear Fuel Cycle Facilities;
N45.2.6-1978 Qualifications of Inspection, Examination, and Testing Personnel for Nuclear Power Plants
N45.2.9-1979 Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants
N45.2.10-1973 Quality Assurance Terms and Definitions
N45.2.11-1974 Quality Assurance Requirements for the Design of Nuclear Power Plants
N45.2.12-1977 Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants
N45.2.13-1976 Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants
N45.2.23-1978 Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants


**NQA-1 Part 1 Requirements**

1. Organization
2. Quality Assurance Program
3. Design Control
4. Procurement Document Control
5. Instructions, Procedures, and Drawings
6. Document Control
7. Control of Purchased Items and Services
8. Identification and Control of Items
9. Control of Processes
10. Inspection
11. Test Control
12. Control of Measuring and Test Equipment
13. Handling, Storage, and Shipping
14. Inspection, Test, and Operating Status
15. Control of Nonconforming Items
16. Corrective Action
17. Quality Assurance Records
18. Audits
NQA-1  Requirement 1

**Requirement 1**

**Organization**

100  **GENERAL**
Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be defined.

200  **STRUCTURE AND RESPONSIBILITY**

201  General

The organization of organizational units and assignment shall be such that:

(a) senior management shall establish and verify requirements for the QA program and the desired end result
(b) quality is achieved by assigned responsibility for performing the work
(c) those responsible for assuring that an appropriate quality assurance program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to

202  Operations

Organization Chart Required

Summary:

- Senior Management shall establish and verify requirements for the QA program
- Responsibility and Authority in case of Problems
- No shipment with open NCRs
- Interface Controls required

NQA-1  2 – QA Program

100  **GENERAL BASIC**

(a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities. The program shall provide for the establishment of activities affecting quality under suitable conditions.

(b) The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and maintained.

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100 GENERAL BASIC
The design shall be
• defined,
• controlled, and
• verified.

Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.

200 DESIGN INPUT
Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary 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.

400 DESIGN ANALYSES
Design analyses shall be sufficiently detailed 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.

401 Use of Computer Programs
To the extent required in paras. 401(a) and (b) of this Requirement, computer program acceptability shall be preverified or the results verified with the design analysis for each application.

Preverified computer programs
(a) The computer program
(b) The encoded mathematical problem associated with the computer program

402 Documentation of Design Analyses
Documentation of design analyses shall include the following:
(a) the objective of the analyses
(b) design inputs and their sources
(c) results of literature searches or other applicable background data
(d) assumptions and indication of those assumptions that must be verified as the design proceeds
(e) identification of any computer calculations, including identification of

900 DOCUMENTATION AND RECORDS
Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.
NQA-1 4– Procurement

200 CONTENT OF THE PROCUREMENT DOCUMENTS
Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.
201 Scope of Work
202 Technical Requirements
203 Quality Assurance Program Requirements
204 Right of Access
205 Documentation Requirements
206 Nonconformances
207 Spare and Replacement Parts

300 PROCUREMENT DOCUMENT REVIEW
A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents transmitted to prospective Supplier(s) include appropriate provisions that items or services will meet the specified requirements.

400 PROCUREMENT DOCUMENT CHANGES
Summary:
- Procurement process shall be documented
- QA shall be extended to subtier suppliers
- PO shall be reviewed for approval prior to procurement
- Changes shall be controlled in the same way.

NQA-1 7– Purchased Items and Services

100 GENERAL BASIC
The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such controls shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.

200 SUPPLIER EVALUATION AND SELECTION
Prior to award of a contract, the Purchaser shall evaluate the Supplier’s capability by:
(a) Supplier’s history of providing an identical or similar product that performs satisfactorily in actual use. The Supplier’s history shall reflect current capability.
(b) Supplier’s current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.
(c) Supplier’s technical and quality capabilities as determined by direct evaluation of the Supplier’s technical, personnel, and quality assurance program, and the implementation of the Supplier’s quality assurance program.

300 BID EVALUATION

400 CONTROL OF SUPPLIER DOCUMENTS

500 ACCEPTANCE OF ITEMS

503 Certificate of Conformance

504 Source Verification

505 Receiving Inspection

600 CONTROL OF SUPPLIER NONCONFORMANCES

Summary:
- Suppliers shall be audited
- Receiving inspection shall be performed
- Nonconformances shall be controlled
- Records shall be maintained

Alternative:

UTILIZATION OF COMMERCIAL GRADE ITEMS

Records shall be established and maintained to indicate the performance of the following functions:
(a) supplier evaluation and selection
(b) acceptance of items or services
(c) supplier nonconformances to procurement document requirements, including their evaluation and disposition
(d) utilization and acceptance of commercial grade items
100 GENERAL BASIC
Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

200 IDENTIFICATION
300 SEGREGATION
400 DISPOSITION
A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented. Technical justification for the acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required deviation records shall reflect the use or repair condition.

405 Reexamination
Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria. Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria if the disposition has established alternate acceptance criteria.

Summary:
• No Nonconforming Item may be supplied
• Structured Process to resolve
• Design / Engineering Concurrence
• Documentation for Lifetime
• 10CFR21: Applies even after supply!

NQA-1 17– QA Records

100 GENERAL
The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities. Quality assurance records shall provide documentary evidence that items or activities modified quality requirements. Quality assurance records shall be identified, generated, authenticated, maintained, and their final disposition controlled requirements and the controls applied shall be documented.

200 GENERALIZATION OF RECORDS
(a) Records shall be legible
(b) Records shall be maintained
(c) Records to be generated: design specifications, procurement documents, test procedures, and operational procedures.

Summary:
• Owner shall keep Lifetime Records
• Nonpermanent Records by Manufacturer
• Storage Facility clearly defined (requirements)
• Records shall be legible and protected
• Retention time
• Electronic records are difficult!
Any questions?
We have answers!

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