

Attachment 2

Quality Assurance Program
Topical Report Duke-1
Amendment 21

Revised Pages 17-10 and 17-27

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Table 17-1 (Page 6 of 7). Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.146 Rev (0) - Qualification of QA Program Audit Personnel for Nuclear Power Plants	Alternative	Duke Program conforms to ANSI/ASME N25.2.23 - 1979 except section 2.3.4. In lieu of prospective lead auditors participating in a minimum of five quality assurance audits within a period of three years prior to date of certification, prospective lead auditors shall demonstrate their ability to effectively lead an audit team and shall have participated in at least one nuclear quality assurance audit within two years preceding the individual's effective date of qualification. Upon successful demonstration of the ability to lead audits, and having met the other provisions of ANSI N45.2.23-1977, the individual may be certified as being qualified to lead audits. This process is described in approved procedures which require documentation of the evaluation and demonstration of results.
Regulatory Guide 1.152 Rev (0) - Criteria For Programmatic Digital Computer System Software In safety-Related Systems of Nuclear Power Plants	Not applicable	Regulatory Guide does not apply to plants prior to 11/85
Regulatory Guide 4.15 Rev (1) - Quality Assurance For Radiological Monitoring Program (Normal Operations) - Effluent Streams and the Environment	Adopted	Adopted at Oconee, McGuire, and Catawba via various site procedures that meet the intent of the Regulatory Guide.
Regulatory Guide 7.10 Rev (1) - Establishing Quality Assurance Programs For Packaging Used In The Transport of Radioactive Material	Alternative	Duke Program conforms to the intent of this Regulatory Guide as addressed in each Station's FSAR
Criteria 1 of Appendix A to 10CFR 50	Conforms	-----
10CFR 50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants	Conforms	-----

Table 17-1 (Page 5 of 7). Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.143 Rev (1) - Design Guidance For Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants	Conforms	-----
Regulatory Guide 1.144 Rev (1) - Auditing of Quality Assurance Programs for Nuclear Power Plants	Alternative	RG 1.144 Rev (1) incorporates ANSI N45.2-12, (1977). Duke Program conforms to ANSI N45.2.12-1977 for internal/external audits except Section 4.4.6. In lieu of making recommendations for correcting program deficiencies we will identify the deficiencies to the audited organization. For external audits, the results of the audit will be provided to the audited organization in lieu of the audit report. Also, the re-evaluation may be extended to 15 months and the triennial period as specified in the Reg. Guide may be extended by 3 months as described in Section 17.3.2.4, "Procurement Control." Self Initiated Technical Audits (Section 17.3.3.2.6, "Self-Initiated Technical Audits") shall require a response describing corrective action and implementation schedule as requested by the audit report but not to exceed sixty days of receipt of the audit report.

holds an appropriate ASME Certificate of Authorization or Quality Systems Certificate issued by the ASME. Surveillance, test or inspection activities shall be performed to verify that applicable portions of the supplier's QA program are being effectively implemented.

When QA Condition 1 basic components and services are procured from a supplier whose quality performance has not been verified by audit, additional assurance of product quality shall be obtained by supplier surveillance, inspection or test.

The Supplier Verification Manager may place a supplier on the Approved Suppliers list following review, approval and acceptance of an audit performed by another licensed nuclear utility or joint utility audit team. Review of such third party audits shall ensure that items to be procured are within the audit scope and any unique plant quality and technical requirements are adequately addressed by such audits.

The Supplier Verification Section shall complete a satisfactory re-evaluation of a supplier every 12 months in order to maintain the supplier on the Approved Suppliers List. Annual re-evaluations may be extended by 3 months, from 12 to 15 months, with written approval of the Supplier Verification Manager. Additionally, suppliers shall be re-evaluated by means of an audit at least triennially, if initial approval was by audit or survey. The triennial audit requirement may be extended by 3 months, from 36 to 39 months, with written approval of the Supplier Verification Manager. Extensions would be on an infrequent basis for reasons such as: accommodating manufacturing schedules, synchronizing with other utility audits, or allowing time for implementation of supplier QA program changes.

Materials, parts and components shall be procured to specified technical and quality requirements at least equivalent to those applicable to the original equipment or those specified by a properly reviewed and approved revision. As required by the applicable purchase documents, suppliers furnish documentation which identifies the material and equipment purchased and the specific procurement requirements met by the items. Also, as required by the applicable purchase documents, suppliers will provide documentation which identifies any procurement requirements which have not been complied with, together with a description of any deviations and repair records.

When QA Condition 1 products/services are not supplied as a basic component and meet the definition of commercial grade, the item may be procured without the performance of a supplier qualification audit or the existence of a documented supplier Quality Assurance Program. These commercial grade items used in QA Condition 1 applications require evaluation, dedication and approval by Nuclear Generation Department personnel. Supplier selection for commercial grade items is the responsibility of the responsible engineering personnel. These items are subject to the same verification and checking process for suitability of application as other QA Condition 1 items.

Critical characteristics for the dedication of Commercial Grade Items are determined by engineering technical sponsors and approved by the responsible engineering personnel based on the manufacturer's published specifications and the intended safety function for the items. Critical characteristics used for acceptance and dedication of commercial grade items are selected to provide reasonable assurance that the items will meet their catalog or manufacturer specifications and will perform the necessary safety functions in the intended applications. Verification of critical characteristic acceptability will be by manufacturer/supplier survey, manufacturing surveillance, receipt tests or inspections, or post installation testing. Historical data, when documented, will represent industry wide experience.

If verification of a critical characteristic is to be by supplier survey, Supplier Verification is responsible for verifying the acceptability of the supplier control of the identified critical characteristic.

Procurement of materials, parts, components and services associated with a station's QA Condition 1 structures, systems, and components is controlled during the operational life of the station so as to assure the suitability for their intended service and that the safety and reliability of the station are not compromised.

Each procurement information for materials, parts, and components associated with QA Condition 1 structures, systems and components is identifiably designated as such. The procurement requirements applicable to each item are determined by a cognizant individual. This determination is reviewed by another cognizant individual who may be from the same organization as the individual/group making the determination.

Procurement information must include or reference other documents such that to assure sufficient information is fully identified to specify the items being procured. Subsequent to preparation, procurement information is approved by the Procurement Engineering Manager or designee who is qualified by experience and training for the function.

Procurement information for QA Condition 1 materials, parts and components is reviewed to assure that quality assurance, technical and regulatory requirements including supplier documentation requirements are adequately incorporated into the purchase document(s). Significant changes to the content of such purchasing information are reviewed and approved in a manner consistent with the original.

Where necessary, procurement documents require that QA Condition 1 materials, parts, and components be acquired from suppliers determined to be acceptable by the Nuclear General Office, Supplier Verification Section - see Section 17.3.3.2.7. Determination of acceptability requires that a supplier provide Duke the right of access to the supplier's facilities and records for inspection and audit.

Except for some commercial grade items each shipment of items procured from a supplier must be accompanied by a certificate of conformance (or equivalent) which identifies the applicable procurement documents and item(s). The certificate and supplier documentation specifies that the item meets the procurement requirements and includes repair records and a description of any deviations. This documentary evidence must be on site (any location under the QA Program) and all procurement, inspection, and testing requirements satisfied before the item is placed in service or used.

Nuclear Generation Department or Electric System Support Department personnel will review and approve this documentary evidence of item conformance with procurement requirements.

17.3.2.5 Procurement Verification

The approved procurement documents along with all quality and technical requirements are provided to the supplier by the Nuclear Generation and/or PSM Department. Procurement information is provided to the Supplier Verification Section and the receiving location.