QA PROGRAM EVALUATION OF ENGINEERING ORGANIZATION

PROGRAM APPLICABILITY: 2512

SALP FUNCTIONAL AREA: SAFETY ASSESSMENT/ QUALITY VERIFICATION (SCSAQV-C)

35960-01

To determine whether QA Program policies and procedures are established and implemented consistent with applicable procurement requirements for items and services that are important to the safety of a nuclear facility.

35960-02 INSPECTION REQUIREMENTS

02.01 <u>QA Program</u>

a. <u>QA Manual Review</u>. Determine if the QA Manual includes basic QA Program provisions to cover the following:

1. Management policy statement implementing QA Program commitments within the organization and endorsing the provisions of the QA Manual as an authoritative document by which stated policies and objectives are to be obtained by management and staff responsible for execution of quality-related activities.

2. Appropriate identification and completion of prerequisites required to attain quality objectives such as staffing, qualification, and training requirements.

3. Indoctrination and training on stated policy, objectives, scope, and execution of QA Program provisions consistent with assigned responsibilities.

4. Periodic management review of status and adequacy of implementation (development and execution) of QA Manual provisions for which they have designated responsibility.

5. Identification of management and staff assigned responsibilities for planning and implementation of QA Program and QA Manual document control responsibilities.

6. Identification of services subject to provisions of the QA Program and participating organizations having responsibilities in these areas.

b. QA Program Implementation

1. Verify that the schedule for development and execution of QA Program commitments related to engineering and procurement activities is consistent with ongoing work and is being adhered to.

2. Verify that training and indoctrination procedures and instructions on the use of QA Manual provisions have been implemented by inspection of training records and interview of personnel for:

    (a) three QA/QC staff personnel at different organizational levels; and

    (b) two engineering and two procurement personnel performing activities affecting quality.

3. Inspect the documented evidence of the last review to verify that QA, engineering, and procurement management personnel, who have assigned quality responsibilities, have reviewed the work.

4. Verify that the last corporate management evaluation related to an assessment of QA Program effectiveness was conducted in accordance with established procedures.

5. Verify that corporate document control procedures for control of QA Manual documents have been implemented by inspection of the activities associated with review, approval, and distribution of three QA Manual documents of which one is primarily used by engineering, one by procurement, and one by QA.

02.02 Organization

a. QA Manual Review. Determine if the QA Manual includes basic QA Program provisions to cover:

1. identification of authorities and responsibilities of organizations, groups, and individuals performing quality related activities; and

2. degree of organizational independence of each group or person performing quality assurance functions.

b. QA Program Implementation

1. Verify that personnel and groups performing verification of conformance to established quality requirements do not have direct responsibility for performing the work by examination of organization charts, assigned responsibilities, and work activities for a minimum of three such designated individuals or group representatives.

2. Determine if personnel (select two) assigned principal QA interface responsibilities and assigned project technical interface responsibilities have carried out those responsibilities per prescribed procedures.

02.03 Engineering Control

a. <u>QA Manual Review</u>. Determine that provisions of the QA Manual include sufficient quantitative/qualitative criteria to assure adequate execution in the following areas:

   1. Identification of groups, positions, and names of management and staff filling key positions within the engineering organization including those responsible for interface responsibilities.

   2. Procedures for the review, approval, release, distribution, and revision of documents involving engineering interfaces.

   3. Identification of engineering procedures necessary to assure uniform and effective translation of requirements and execution of engineering and engineering control activities such as:

      (a) identification of inputs;

      (b) specification and inclusion of appropriate quality standards in engineering documents;

      (c) performance of analyses utilizing basic engineering inputs;

      (d) preparation of drawings and specifications;

      (e) "reviews" or "alternate calculations" as a means of independent verification for calculations and analyses, drawings, and specifications;

      (f) reviews to establish need for "qualification testing" as a means of independent verification;

      (g) review, approval and/or distribution of changes to engineering documents;

      (h) programmatic corrective actions for significant or recurring errors or deficiencies: and

      (i) identification of interim and permanent records and system for filing, retention and retrieval of records.

b. QA Program Implementation

   1. Verify that procedures for the review, approval, release, distribution, and revision of documents involving interfaces have been implemented for a minimum of three such documents.

   2. Verify that procedures for accomplishing engineering work have been implemented by inspecting the following:

      (a) three analyses or calculations

      (b) two specifications

      (c) four drawings

      (d) four reviews or alternate calculations (at least one of which is a review) used for independent verification

3. Verify that changes to a minimum of three documents receive prescribed control and independent verification.

4. Verify that design bases have been correctly translated into design output documents through interview of design personnel and/or alternate calculations

02.04   Procurement Control

a.   QA Manual Review. Determine if the QA Manual includes basic QA Program provisions to ensure the following:

1. Applicable regulatory requirements, design bases, and other requirements necessary to obtain adequate quality and performance are included or referenced in documents for procurement of items and services.

2. Changes to procurement documents are subjected to the same degree of control as the original document.

3. Requirements which are applicable to lower tier procurements are passed on to the respective vendors.

4. Purchased services or items conform with procurement documents

5. Source evaluation and selection.

6. Documented evidence of conformance with procurement document quality objectives.

7. Surveillance (reviews, inspections, audits) consistent with the safety significance of purchased item or service.

8. Imposition of 10 CFR Part 21, when applicable, e.g. for consulting services that are important to safety of a nuclear power reactor.

b.   QA Program Implementation

1. Inspect a minimum of two procurement documents to assure that they contain regulatory requirements, design bases, and other requirements as prescribed by procedures.

2. Verify that the above procurement documents provide for extension of appropriate requirements to lower tier procurements.

3. Verify that the proscribed procurement document reviews have been performed per procedure for the above documents.

4. Select one change to each of the above documents. Verify that the changes were subjected to the same degree of control as the original document.

5. Verify that the bid evaluation and award procedures have been followed.

6. Verify that purchaser methods for evaluation of supplier performance have been implemented.

7. Verify that procedures for supplier audit and/or surveillance have been implemented.

8. Inspect records of supplier nonconformances to verify that procedures for disposition, including corrective action and maintenance of records, are being implemented.

02.05 Quality Assurance Records

a. QA Manual Review. Determine if the QA Manual includes basic QA Program provisions to cover:

1. Maintenance of records to furnish evidence of activities affecting quality.

2. Identification, retrieval, and retention of records.

b. QA Program Implementation

1. Verify by inspection of indexes or listings of-records ~ maintained that they are sufficient to provide documentary evidence of quality.

2. Verify by sampling that records,are classified into lifetime and nonpermanent categories per procedures.

3. Inspect records retention practices such as storage, preservation, fire protection, safekeeping and maintenance against QA Manual requirements.

4. Verify for a minimum of two records that they contain the required information.
5. Verify that the construction, location, and securing of record storage facilities to prevent destruction by fire, flooding, theft, and deterioration conforms with requirements.

02.06 Audits

a. QA Manual Review. Determine if the QA Manual includes basic QA Program provisions to cover:

1. The system of audits to verify compliance with all aspects of the QA Program and to determine the effectiveness of the QA Program.

2. Documenting responsibilities and procedures for auditing, the required frequency of audits, documenting and reviewing audits results, and designating management levels to review and assess audit results.

b. QA Program Implementation

1. For a minimum of four audits (two internal and two external), verify that they were conducted in accordance with procedures.

2. Verify that audit personnel involved were qualified in accordance with procedures.

3. Verify that corrective actions were obtained for the audits with followup to verify implementation of corrective action.

4.   Verify that the audit program covers objective evaluation of quality-related practices, procedures, activities, work areas, review of documents and records, including effectiveness of implementation by inspection of audit schedules and scopes. Verify that audits were regularly scheduled based on work status and safety importance of activities being performed.

5.   Verify that audit data are analyzed and the results, which indicate quality trends and the effectiveness of the QA program, are reported to management for review and assessment.

35960-03   INSPECTION GUIDANCE

General Guidance

Prerequisites and Planning

The inspection of the Engineering Service Organization (ESO) should have been approved by Regional management, Branch Chief, or above.

The inspection of an ESO may be approved based on need, as justified by any Regional Office, or based on the knowledge that a particular ESO is used extensively by the licensee, Architect Engineer (AE) or Nuclear Steam Supply System (NSSS), organizations in providing services important, to nuclear safety.

The structure and size of organizations inspected under this procedure should be the prime factor in assessing the adequacy of their QA program and implementing procedures. As a general rule, if the size of the organization (number of personnel plus separate discrete functions) is such that an organization chart has been established to delineate these functions, then a QA program and detailed implementing procedures should have been established.

Review of QA Manual and Program Implementation

As used herein, the term "Quality Assurance Manual" includes those procedures and manuals issued by various departments and groups to implement QA Program commitments. Such procedures and manuals are often referred to by various designations other than QA Manual. Examples are Product Assurance Manual, Quality or QA Policy or Procedures Manuals, etc. Different manuals and/or procedures are often used to implement basic QA Program commitments by the engineering, procurement, and QA organizations. This inspection procedure includes a review of all such procedures regardless of their designated title.

These reviews should determine if (a) procedures and instructions included or referenced by the QA Manual are consistent with quality requirements specified in applicable codes, standards, regulations and guides, and (b) the implementation of the QA Program is consistent with the scope and status of design and procurement activities in progress and in a manner that should result in producing quality items and services.

The following ANSI standards should be referred to for specific QA Manual requirements: ANSI N45.2, N45.2.g, N45.2.11, N45.2.12, N45.2.13 and N45.2.23. However, only ANSI standards to which organizations are committed in the contract should be used in enforcement actions.

The procedures to implement QA Program commitments should be evaluated for:

a.   Content (i.e., do they meet the regulations and contract commitments to regulatory guides, ANSI standards, codes, etc.?)

b.   Implementation (i.e., are procedures utilized effectively and do they fit into a plan of action that is being implemented?)

c.   Management support (i.e., do QA Manual procedures have adequate review, approval, and endorsement of management?)

During the conduct of each section of this procedure, the inspector should verify that measures have been established and implemented to assure that those participating in an activity are aware of and use proper and current documents.

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