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| Nuklearna Elektrarna Krško MASTER DOCUMENT | |
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NE KRŠKO

QUALITY SPECIFICATION QS 600

**QUALITY ASSURANCE PROGRAM SPECIFICATION
FOR
SOFTWARE**

Rev. No. 0, 18/08/1989.

APPROVED: _____

QA Manager

1.0 GENERAL

- 1.1 This specification establishes the Supplier's quality assurance program requirements that shall apply to all activities affecting the quality of the items or services provided.
- 1.2 Supplier shall assure that its Subsuppliers conform to the applicable requirements of this specification.
- 1.3 Supplier shall assure compliance with the requirements of Title 10, Code of Federal Regulations, Part 50, Appendix B (10CFR50, Appendix B), "Quality Assurance Criteria for Nuclear Power Plants"; ANSI N45.2-1971, "Quality Assurance Program Requirements for Nuclear Power Plants"; and all other codes or standards referenced herein and in the purchase order.
- 1.4 The reporting and posting requirements of Title 10, Code of Federal Regulations, Part 21 (10CFR21), "Reporting of Defects and Noncompliance", shall apply.
- 1.5 The Purchaser shall have the right of access to enter the premises of the Supplier to witness inspection/test activities or to conduct surveillances or quality assurance audits.

2.0 DEFINITIONS

- 2.1 Audit - An independent review for the purpose of assessing compliance with software requirements, specifications, baselines, standards, procedures, instructions, codes, and contractual and licensing requirements.
- 2.2 Application Software - Software specifically produced for the functional use of a computer system; software for structural analysis, process control, etc.
- 2.3 Purchaser - Utility issuing the procurement document.
- 2.4 Quality Assurance - A planned and systematic pattern of all actions necessary to provide adequate confidence that the computer software conforms to established technical requirements.
- 2.5 Testing - The process of exercising or evaluating a system or system component by manual or automated means, to verify that it satisfies specified requirements or to identify differences between expected and actual results.
- 2.6 Verification - Testing that provides evidence that the software program can produce results in agreement with those obtained from one or more of the following: hand calculation, published technical solution, solution obtained from another verified software program, or visual inspection (graphics software program).
- 2.7 Configuration Management - The process of identifying and defining the configuration items in a system, controlling the release and change of these items throughout the system life cycle, recording and reporting the status of configuration items and change requests.
- 2.8 Software Error - A discrepancy between a computed, observed, or measured value or condition, and the true, specified, or theoretically correct value or condition.

3.0 DOCUMENTS FOR SUBMISSION

Supplier shall submit one controlled copy of the final approved Supplier's quality assurance program for the scope of work to be performed for Purchaser's review.

4.0 QUALITY ASSURANCE PROGRAM REQUIREMENTS

Supplier shall develop and implement a quality assurance program consistent with the requirements defined herein. As a minimum, the program shall address the following quality assurance criteria:

4.1 Organization

The organizational structure, functional responsibilities, levels of authority, and lines of communication for personnel performing activities affecting quality shall be documented in organizational charts and/or written procedures.

- 4.1.1 Quality Assurance personnel shall have sufficient and well-defined responsibility, authority, and organizational freedom to identify and evaluate quality problems, to require implementation of approved corrective action, and to verify implementation of corrective actions. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.
- 4.1.2 Personnel responsible for verifying that Supplier's work conforms to established requirements shall not have direct responsibility for the work performed.

4.2 Quality Assurance Program

The documented quality assurance program shall be planned, implemented, and maintained to identify the items and services to which it applies.

- 4.2.1 The program shall provide for planning and accomplishing activities affecting quality under suitably controlled conditions.
- 4.2.2 The program shall provide for any special controls, processes, and skills necessary to attain the required quality and provide for verification of quality by test, as necessary.
- 4.2.3 The program shall provide for indoctrination and training of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.
- 4.2.4 Supplier's management shall regularly review the status and adequacy of the documented quality assurance program.
- 4.2.5 Measures shall be established for the control and distribution of the documented quality assurance program.

4.3 Software Design Control

Supplier's program for controlling design activities shall satisfy the following requirements:

- 4.3.1 Computer Program Design - The program shall identify and document the procedures by which technical and management reviews are conducted and documented to verify the activities utilized to demonstrate acceptable performance and the correctness of documentation, prior to the delivery of program capabilities to the customer.
- 4.3.2 Verification - The program shall identify and document the procedures used to formally approve or certify the acceptability of performance, correctness of documentation and attainment of program requirements. The program shall require monitoring to assure compliance with its procedures.
- 4.3.3 Documentation - Documentation standards and practices to be used for all software shall be referenced or documented in the program. The program shall reference or document the procedures to be applied to assure compliance with standards, practices, and delivery of correct documentation and change information to the Purchaser. In addition, the program shall provide for the independent review of documentation and designation of Supplier approval authority.
- 4.3.4 Configuration Management - The program shall reference or document the Supplier's procedures and controls for the handling of the object code and related data in their various forms and versions, from the time of their initial approval or acceptance until they have been incorporated into the final media. The objective of these controls is to ensure that different computer program versions are accurately identified and documented, that no unauthorized modifications are made, that all approved modifications are properly incorporated, and that software submitted for testing is the correct version.
- 4.3.5 Testing - The program shall reference or document procedures for assuring the accomplishment of the following:
 - 1. Analysis of software requirements to determine testability.
 - 2. Review of test requirements and criteria for adequacy, feasibility, and traceability and satisfaction of requirements.
 - 3. Review of test plans, procedures, and specifications to determine that the level of testing is sufficient to determine acceptable program performance.
 - 4. Verification that tests are conducted in accordance with approved test plans and procedures.
 - 5. Verification that test results are the actual findings of the tests.
 - 6. Review and verification of test reports.
 - 7. Ensuring that test-related media and documentation are maintained to allow repeatability of tests.
 - 8. The Supplier shall test all programs in a hardware and software environmental similar to the operational environment that is used to deliver the capability to the customer.



4.4 Procurement Document Control

Supplier's program for controlling procurement documents shall satisfy the following requirements:

- 4.4.1 Applicable design bases, quality assurance requirements, and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services.
- 4.4.2 Procurement documents shall require Subsuppliers to have a quality assurance program consistent with the applicable requirements of this specification.
- 4.4.3 The procurement documents shall provide for access to the Subsupplier facilities and records for inspection or audit by the Supplier.
- 4.4.4 Procurement documents shall identify the documentation required to be submitted.
- 4.4.5 Procurement documents shall include Supplier's requirements for reporting and approving disposition of nonconformances.
- 4.4.6 A review of the procurement documents shall be performed to assure that the documents include appropriate technical and quality requirements.
- 4.4.7 Procurement document changes that affect technical or quality specifications shall be subject to the same degree of control as used in preparing the original document.

4.5 Instructions, Procedures, and Drawings

Supplier shall assure that all activities affecting quality are prescribed by documented instructions, procedures, or drawings. Such instructions, procedures, or drawings shall include appropriate quantitative or qualitative criteria for determining that activities affecting quality have been satisfactorily accomplished.

4.6 Document Control

Supplier shall assure that quality-related documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and properly distributed to and used at locations where the prescribed activity is performed.

- 4.6.1 Document changes shall be reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated.
- 4.6.2 Procedure governing document control shall be established and provide for:
 - 1. identification of individuals or organizations responsible for preparing, reviewing, approving, and issuing documents and revisions thereto;
 - 2. identifying the proper documents to be used in performing the activity;
 - 3. coordination and control of interface documents;
 - 4. ascertaining that appropriate documents are being used; and
 - 5. establishing distribution lists.

4.7 Control of Purchased Items and Services

Supplier's program for controlling purchased items and services shall satisfy the following requirements:

- 4.7.1 The selection of Subsuppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents.
- 4.7.2 Methods to be utilized in evaluation of Subsuppliers, and the results therefrom, shall be documented and shall include one or more of the following:
 1. Evaluating the Subsupplier's history of providing a product which performs satisfactorily in actual use.
 2. Determining the Subsupplier's technical and quality capability by a review of his quality assurance program, and a direct evaluation of his facilities and the implementation of his quality assurance program.
- 4.7.3 Procedures shall be established and implemented for verification activities (surveillance, receipt inspection, and audit), as appropriate, to assure conformance of procured items and services to identified requirements.
- 4.7.4 Where acceptance is based on certifications from Subsuppliers, the Supplier shall validate the certifications via surveillance, audit, and/or independent tests.

4.8 Corrective Action

Supplier shall assure that conditions adverse to quality are promptly identified and corrected.

- 4.8.1 In the case of significant conditions adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.
- 4.8.2 The identification of significant conditions adverse to quality, the cause of the conditions, and the corrective action taken shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of corrective action.

4.9 Software Errors

- 4.9.1 The Supplier is responsible for analyzing software errors and notifying the Purchaser of confirmed errors detected in Supplier software. The notification shall include a description of the error, advice on work-arounds for error avoidance when applicable, a listing of all versions of the software that contained the error when available, and the date the error was reported. Corrected errors will be noted.
 1. Software error classification shall meet the following functional descriptions:
 - A Problem results in incorrect answers.
 - B Problem causes incomplete program execution or aborts.
 - C Documentation of procedure file errors, inconveniences, or cautions, cannot be classified in either of the above definitions.
 2. A copy of each error notification will be sent to the individual(s) identified in the procurement document.



- 4.9.2 The Supplier shall promptly notify the Purchaser when software errors are confirmed and again when the errors are removed or corrected.
- 4.9.3 The Supplier shall maintain a log of all software errors detected in application software that are made available for use.
- 4.9.4 If errors invalidate any sections of the verification report, such that a program user or calculation checker could not depend on specific sections of a verification report when making engineering designs and analysis, the Supplier shall promptly revise the verification report accordingly.

4.10 Quality Assurance Records

Supplier shall establish procedures to identify the specific records that will be generated and maintained and to prescribe their retention periods and storage requirements.