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NUCLEAR POWER PLANT KRŠKO

QA SPECIFICATION

GENERIC QUALITY ASSURANCE PROGRAM REQUIREMENTS

QS-610, Rev. 2

Safety Related

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1.0 GENERAL

1.1 This specification establishes the requirements for Supplier's QA program that shall apply to all activities affecting the quality of the supplied equipment, materials, or services.

1.2 Supplier shall ensure that its Subsuppliers conform to the applicable requirements of this specification.

1.3 For Safety Related products and services (SR), Supplier shall ensure 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 and Fuel Reprocessing Plants", and ANSI/ASME N45.2-1977, "Quality Assurance Program Requirements for Nuclear Facilities" or ASME NQA-1-2008, Addenda 2009/2011, "Quality Assurance Requirements for Nuclear Facility Applications". Additionally, IAEA GSR part 2, 2016 "Leadership and Management for Safety" and all other codes or standards referenced herein and in the purchase order could be applied.

1.4 For SR ASME Code Section III components, Supplier shall ensure compliance with the requirements of ASME Code Section III, NCA-4000 "Quality Assurance" and NCA-3800 "Metallic Material Organization's Quality System Program". In addition to ASME Code Section III requirements, Supplier shall ensure compliance with the requirements of 10CFR50 Appendix B and 10CFR Part 21.

1.5 The reporting and posting requirements of Title 10, Code of Federal Regulations, Part 21 (l0CFR21), "Reporting of Defects and Noncompliance", shall apply for SR products and services.

1.6 For Non-Safety Related products and services with Augmented Quality requirements (AQ), Supplier shall ensure compliance with the requirements of international standards as ISO 9001, "Quality management systems – Requirements" or ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories" or other relevant recognized standards. Compliance with the requirements of international standards shall be certified by accredited organization. Additional QA requirements to the Supplier commercial QA Program shall be specified and selected in accordance with this Quality Specification and scope of supply referenced in the purchase order.

1.7 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. This right shall extend to the Subsuppliers and will be coordinated through the Supplier.

2.0 DEFINITIONS

2.0 Definitions shall be as stated in ANSI N45.2.10-1973, "Quality Assurance Terms and Definitions" and in other standards referenced herein.

2.1 PURCHASER - Utility issuing the purchase order.

2.2 SUPPLIER - The person or organization to whom a purchase order from the Purchaser has been issued.

2.3 SUBSUPPLIER - The person or organization that furnishes items and services to the Supplier that will be used to complete the Purchaser's purchase order requirements.

2.4 ABREVIATIONS:

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASNT	American Society for Nondestructive Testing
CFR	Code of Federal Regulation, USA
ILAC MRA	International Laboratory Accreditation Cooperation Mutual Recognition Arrangement
ISO	International Organization for Standardization
NEK	Nuclear Power Plant Krško
NRC	Nuclear Regulatory Commission, USA
QA	Quality Assurance
SR	Safety Related
USA	United States of America

3.0 DOCUMENTS FOR SUBMISSION

3.1 The Supplier shall submit a full description of its QA program, proposed for the scope of work to be performed, as controlled copy document, for the Purchaser's review and acceptance/approval.

3.2 If the Purchaser has already approved the Supplier's QA program, it does not have to be submitted for acceptance/approval. However, if the Purchaser's copy of the QA program is not current, all portions of the program that have been revised since the Purchaser's previous approval shall be submitted for review and acceptance/ approval.

4.0 QUALITY ASSURANCE PROGRAM REQUIREMENTS

Supplier shall develop and implement a QA program consistent with the requirements defined herein and in the purchase order. As a minimum, the program shall encompass 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 written procedures.

4.1.1 Quality Assurance and Quality Control inspection and audit 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 so that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.

4.1.2 Personnel responsible for verifying if Supplier's work conforms to established requirements shall not have direct responsibility for the work being performed.

4.1.3 Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented. The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.

4.2 QA Program

The documented QA program shall be planned, implemented, and maintained to identify the items and services to which it applies and to comply with requirements of the relevant Code and/or Standard (See Attachment A).

4.2.1 The program shall provide for planning and accomplishing activities which affect quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.

4.2.2 The program shall provide for any special controls, processes, test equipment, tools, and skills necessary to attain the required quality and provide for verification of quality by inspection and test, as necessary.

4.2.3 The program shall provide for indoctrination and training of personnel, who is performing activities affecting quality, to ensure that suitable proficiency is achieved and maintained.

4.2.4 The Supplier's management shall regularly review the status and adequacy of the documented QA program.

4.2.5 For items which are supplied to the Purchaser as "Commercial Grade," the Supplier's program, as a minimum, shall contain procedures, processes, etc., necessary to ensure the Purchaser that the items being supplied meet

industry standards, purchase order requirements, and performance or technical requirements specified in the Suppliers catalog.

4.3 Design Control

The Supplier's program for controlling design activities shall satisfy the requirements of ANSI N45.2.11-1974, "Quality Assurance Requirements for the Design of Nuclear Power Plants," or requirements of relevant Code and Standard (See Attachment A), and shall include as a minimum, the following:

4.3.1 Design activities shall be prescribed and accomplished in accordance with procedures of a type sufficient to ensure that applicable design inputs are correctly translated into specifications, drawings, procedures, or instructions.

4.3.2 Interface between organizations performing work, affecting quality of design, shall be identified in writing and shall include those organizations that provide criteria, design, specifications, and technical direction.

4.3.3 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.

4.3.4 Documentation of design/analysis shall be verifiable and include the following:

1. The objective of the analysis,
2. Design inputs and their sources,
3. Results of reference document searches or other applicable background data,
4. Assumptions with indication of those that must be verified as the design proceeds,
5. Computer calculations, including computer type, computer program identification, revision, inputs, evidence of, or reference to computer program verification, and the bases, or reference thereto, supporting the application of the computer program to the specific problem,
6. Independent review and approval.

4.3.5 Design verification methods shall be established to provide assurance that the design meets the specified design inputs. Acceptable verification methods include design reviews, alternate calculations, and qualification testing.

4.3.6 Design verification shall be performed by individuals or groups other than those who performed the original design. This verification may be performed by the originator's supervisor, if the supervisor is the only individual in the organization competent to perform the verification, and the need is documented and approved in advance by the supervisor's management.

4.3.7 Changes to design documents shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated. This shall ensure that the impact of the change is carefully considered, required actions documented, and information concerning the change transmitted to the affected persons and organizations.

4.3.8 When material substitutions or modifications in the design are made, Supplier shall:

1. Review prior design qualification tests to determine any adverse effect,

2. Evaluate whether or not new qualification tests are required,

3. Provide documented justification for not having to perform new qualification tests.

4.3.9 The software design process is documented, approved by the responsible design organization, and controlled in accordance with criteria defined in ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications", Part I: Requirement 3, Section 800 – Software Design Control, Part II: Subpart 2.7, or equal standard.

4.3.10 To procure and utilize a Commercial Grade items and services for nuclear power plants pursuant to 10CFR21, dedication activities and controls shall be implemented in accordance with ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications", Subpart 2.14 to ensure the item or service is adequate for its intended safety function.

4.4 Procurement Document Control

The Supplier's program for controlling procurement documents of items and services, which are not considered to be Commercial Grade, shall satisfy the requirements of ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" or requirements of relevant Code and Standard (See Attachment A), and shall include as a minimum, the following:

4.4.1 Applicable design bases, quality assurance requirements, and other requirements necessary to ensure 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 QA program consistent with the applicable requirements of this specification.

4.4.3. The procurement documents shall provide for access to the Subsupplier's facilities and records for inspection or audit by Supplier's and Purchaser's representatives.

4.4.4. Procurement documents shall identify the documentation required to be submitted.

4.4.5. Procurement documents shall include the Purchaser's requirements for reporting and approving dispositions of nonconformances.

4.4.6. A review of the procurement documents shall be performed to ensure that the documents include appropriate technical and quality requirements.

4.4.7. Procurement document changes that affect technical or quality requirements shall be subject to the same degree of control as used in preparing the original document.

4.4.8. Procurement documents for Safety-Related equipment or services shall include statement informing Subsuppliers of their responsibility to report any defect of basic component in accordance with 10CFR21 Requirements.

4.4.9. Procurement documents shall include the Purchaser's requirements for ordering materials, parts or components from original Subsuppliers/ Manufacturers and/or authorized distributors, to prevent supply of counterfeit/fraudulent material, items or components.

4.5 Instructions, Procedures, and Drawings

4.5.1 The Supplier shall ensure that all activities affecting quality and services are prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative criteria for determining that prescribed activities have been satisfactorily accomplished.

4.5.2 The need for and level of detail in written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

4.6 Document Control

The Supplier shall ensure 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 Procedures governing document control shall be established and provide for:

1. The identification of controlled documents,

2. The specified distribution of controlled documents for use at the appropriate location,

3. The identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents,

4. 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,

5. The review of controlled documents for adequacy, completeness, and approval prior to distribution,

6. A method to ensure the correct documents are being used.

4.7 Control of Purchased Items and Services

The Supplier's program for controlling purchased items and services shall satisfy the requirements of ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" or requirements of relevant Code and Standard (See Attachment A), and shall include as a minimum, the following:

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 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 its QA program and a direct evaluation of its facilities and the QA program implementation.

3. Verifying if Subsupplier possesses an ASME Certificate of Authorization for the items/services, or other relevant Certificate/ Accreditation related to the scope of supply.

4.7.3. Procedures shall be established and implemented for verification activities (surveillance, receipt inspection, and audit) as appropriate, to ensure 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 testing.

4.7.5 When Commercial Grade items or services are utilized in SR applications, the dedicating entity shall apply requirements in accordance with ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications", Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services" to ensure the item or service is adequate for its intended safety function. The Supplier shall:

1. Identify the critical characteristics (form, fit, function, material and process) of the commercial grade items and the methods for verifying that these critical characteristics have been met.

2. Establish and document measures to ensure that any changes (by Subsuppliers) in materials, product, design or manufacturing are identified and evaluated.

4.8 Identification and Control of Items

Supplier shall establish and document measures to identify and control materials, parts and components. These measures shall prevent the use of an incorrect or defective item, and suspicious (including counterfeit/fraudulent) material, parts or components that may not be as ordered. Items for production shall be identified (batch, lot, component, part) from the initial receipt and fabrication of items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

4.8.1 Traceability for these items shall be maintained with records and/or markings. Physical identification shall be used to the maximum extent possible, but if physical identification on the item is impractical or insufficient, physical segregation, procedural control or other appropriate means shall be used. Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

4.9 Control of Special Processes

Supplier shall establish and document measures to ensure that special processes, including welding, heat treating, cleaning, coating and nondestructive examination, are accomplished under controlled conditions in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

4.9.1 Special process personnel, procedures, and equipment shall be qualified and comply with the requirements of applicable codes and standards. For special processes not covered by existing codes or standards, or where item quality requirements exceed the requirements of established codes or standards, the

necessary qualifications of personnel, procedures, or equipment shall be defined.

4.9.2 All personnel performing nondestructive examination shall be qualified and certified in accordance with Recommended Practice ASNT SNT-TC-1A "Personnel Qualification and Certification in Nondestructive Testing" or shall be qualified in accordance with requirements of relevant Code and Standard (See Attachment A).

4.9.3 Documentation shall be maintained for currently qualified personnel, processes, or equipment in accordance with the requirements of pertinent codes and standards.

4.10 Inspection

The Supplier shall ensure that activities affecting quality are inspected for conformance to the documented instructions, procedures, and drawings used in the accomplishment of the activity.

4.10.1 Inspection activities shall be performed by persons other than those who performed the activity being inspected. Such persons shall not report directly to the immediate supervisors who are responsible for the work being inspected.

4.10.2 Inspection and test personnel shall be appropriately qualified. The program for qualifying inspection and test personnel shall be in accordance with the requirements of ANSI/ASME N45.2.6-1978, "Qualifications of Inspection, Examination, and Test Personnel for Nuclear Power Plants" or requirements of relevant Code and Standard (See Attachment A), and shall satisfy, as a minimum, the following:

1. Provisions shall be made for the indoctrination of inspection and test personnel as to the technical objectives of the work, the codes and standards that are to be used, and the quality assurance elements that are to be employed.

2. The need for formal training programs shall be determined, and such training activities shall be conducted, as required, to qualify inspection and test personnel.

3. Any special physical characteristics needed in order to perform inspection and test activities shall be identified. Inspection and test personnel requiring these characteristics shall have them verified by examination at intervals which shall not exceed one year.

4. The capabilities of inspection and test personnel shall be initially determined by an evaluation of the individual's education, experience training, test results, or proficiency demonstration.

5. The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed three years. Reevaluation

shall be performed by evidence of continued satisfactory performance or redetermination of capability in accordance with item 4, above.

6. Inspection and test personnel who have not performed inspection/test activities for a period of one year shall be reevaluated in accordance with item 4, above.

7. Inspection and test personnel shall be certified based on their qualifications. The certification shall be documented in an appropriate form including, as a minimum, the following information:

   a. Employer's name,

   b. Identification of the person being certified,

   c. Activities certified to perform,

   d. Basis used for certification (one or more of the following):

      i) Records of education, experience, and training,

      ii) Test results, where applicable,

      iii) Results of capability demonstration,

   e. Results of periodic evaluations,

   f. Results of physical examinations, when required,

   g. Signature of employer's designated representative who is responsible for such certification,

   h. Date of certification and date of certification expiration.

4.10.3 Written procedures shall require that inspections are performed according to instructions or checklists that are based on the instructions, procedures, and drawings used in accomplishing the inspected activity. Inspection procedures shall also require documentation of the qualitative or quantitative results of the specific parameters being inspected.

4.10.4 Examinations, measurements, or tests of items processed shall be performed for each work operation, where necessary to ensure quality. Where a sample is used to verify acceptability of a batch of items, the sampling procedure shall be based on recognized standard practices and adequately justify the sample size and selection process.

4.10.5 If inspection of processed items is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Process monitoring shall be performed by qualified personnel or qualified automated means. Both inspection and process monitoring shall be provided when control is inadequate without both.

4.10.6 Witness/hold points imposed by the Purchaser shall be indicated in appropriate documents.

4.10.7 Final inspection shall include a records review of the process results and resolution of nonconformances identified by prior inspection. Completed items shall be inspected for completeness, marking, calibration, adjustments, protection from damage, or other characteristics as required, to verify the quality and conformance of the item according to specified requirements. The acceptance of the item shall be approved by authorized personnel. Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

4.11 Test Control

The Supplier shall establish a test program to identify and document all testing required, demonstrating that the equipment will perform satisfactorily in service. All testing shall be performed in accordance with written test procedures that incorporate all requirements and test limits specified in the design documents.

4.11.1 Test procedures shall ensure that prerequisite such as calibrated instrumentation, appropriate equipment, qualified personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition, are met.

4.11.2 Test requirements, results, and acceptance criteria shall be documented and evaluated by authorized personnel to ensure that all requirements have been satisfied.

4.11.3 Equipment that fails testing shall be dispositioned to ensure appropriate corrective action and retest. If dispositioned as "use as is," adequate justification shall be documented.

4.11.4 Test personnel shall be qualified in accordance with the requirements of paragraph 4.10.2 of this specification.

4.11.5 Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements.

1. For computer programs used in design activities, computer program test procedures shall provide for assuring that the computer program produces correct results.

2. For computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process.

3. The procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as

hand calculation, calculations using comparable proven programs, or empirical data and information from technical literature.

4. In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system.

5. Periodic in-use manual or automatic self-check-in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

6. Test procedures or plans shall specify the following, as applicable:

   a. Required tests and test sequence,

   b. Required ranges of input parameters,

   c. Identification of the stages at which testing is required,

   d. Criteria for establishing test cases,

   e. Requirements for testing logic branches,

   f. Requirements for hardware integration,

   g. Anticipated output values,

   h. Acceptance criteria,

   i. Reports, records, standard formatting, and conventions.

7. Test results shall be documented and maintained. Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.

4.12 Control of Measuring and Test Equipment

The Supplier shall ensure that all tools, gauges, instruments, calibration standards, and other measuring and test equipment used in activities affecting quality are of the proper range, type, and accuracy to verify conformance to established requirements. Measuring and test equipment shall be controlled, calibrated, adjusted, and maintained at prescribed intervals against certified equipment having known valid relationships to nationally recognized standards. If no national standard exists, the basis for calibration shall be documented.

4.12.1 Documentation shall be maintained that provides the following information for measuring and test equipment used in activities affecting quality:

1. The identification of the items.

2. As-found calibration data or conditions.

3. As-left calibration data or conditions.

4. A list of the standards used to perform the calibration.

5. A statement or information that standards or equipment are traceable to the National Bureau of Standards or accepted values of natural physical constraints.

6. Calibration requirements that were not met.

7. Signature of the person within the calibrator's organization who is responsible for the quality of the service provided.

4.12.2 Suppliers of external calibration services must be accredited to ISO/IEC 17025 standard by a National Accreditation Body that is a signatory to the ILAC MRA. The service must be provided in accordance with their accredited ISO/IEC 17025 program and scope of accreditation. Subcontracting is prohibited. The customer must be notified of any conditions that adversely impact the laboratory's ability to maintain the scope of accreditation.

4.12.3 When measuring and test equipment is out-of-calibration, the validity of previous inspection or test results and of the acceptability of items previously inspected or tested shall be evaluated and documented.

4.12.4 Inspection, measuring, or test equipment consistently found to be out-of-calibration shall be repaired or replaced.

4.12.5 Records shall be maintained and equipment suitably marked to indicate calibration status.

4.12.6 Measuring and test equipment shall be properly handled and stored to maintain accuracy.

4.12.7 Measuring and test equipment shall be used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

4.13 Handling, Storage, and Shipping

The Supplier's program for handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall satisfy the requirements of ANSI/ASME N45.2.2-1978, "Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants" or requirements of relevant Code and Standard (See Attachment A), and shall include, as a minimum, the following:

4.13.1. When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

4.13.2. Item shall be stored within a fire resistant, weathertight, and well ventilated building or equivalent enclosure and shall be placed on skids or shoring to permit air circulation.

4.13.3 A preventive maintenance program for item in storage shall be maintained.

4.13.4 Item shall be suitably packaged to protect against detrimental contamination and physical damage during shipping. Caps and plugs shall be used to seal openings with sensitive internal surfaces and to protect threads and weld end preparations.

4.13.4 When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environment (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified.

4.13.5 Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or prior to use.

4.13.6 Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

4.14 Inspection, Test, and Operating Status

The Supplier shall establish measures to identify the status of inspection and test activities either on the items or in documents traceable to the items. These measures are necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently used.

4.14.1 Status shall be maintained through indicators such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.

4.14.2 The authority for application and removal of tags, markings, labels, and stamps shall be specified.

4.15 Control of Nonconforming Items

The Supplier shall ensure that items, services, or activities that do not conform to requirements are identified, documented, evaluated and dispositioned (use-as-is, rework, repair, or reject) in accordance with documented procedures.

4.15.1 Written procedures shall define the responsibility and authority of those personnel involved in issuing and dispositioning nonconforming items or conditions.

4.15.2 Procedures shall provide for evaluation of nonconforming items or conditions for reportability in accordance with 10CFR21. For Safety Related items and/or services ordered from the USA, Supplier and Subsupplier reporting pursuant to 10CFR21 shall be made to the NRC and NEK. For Safety Related items and/or services supplied from outside the USA, Supplier and Subsupplier shall be subject to the reporting pursuant to 10CFR21 to the NEK, only.

4.15.3 Written descriptions of nonconformances dispositioned "use-as-is" or "repair" shall include appropriate technical justification to substantiate the disposition and shall be submitted to the Purchaser for review and acceptance of those changes affecting customer design requirements.

4.15.4 Repaired and reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria. Repaired items can be reexamined in accordance with alternate acceptance criteria, if disposition has been approved by the Purchaser.

4.15.5 When a nonconforming item has been dispositioned as "reject", controls shall be implemented and adequate records shall be maintained to verify the item has not been used.

4.15.6 Nonconforming items shall be segregated, when practical, by placing items in clearly identified and designated hold areas until properly dispositioned. When size, weight, or access limitations preclude segregation, other precautions shall be employed to prevent inadvertent use of the item.

4.15.7 Nonconforming items shall not be shipped or installed without the prior written approval of the Purchaser's responsible personnel.

4.16 Corrective Action

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

4.16.1 In the case of significant conditions adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.

4.16.2 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 completion of corrective action.

4.16.3 Review of corrective actions shall be performed to determine if they were timely and effectively implemented.

4.17 Quality Assurance Records

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

4.17.1 Records shall include drawings, specifications, purchase documents, work orders, material certifications, calculations, inspection and test reports, work procedures, nonconformance and corrective action reports, audit reports, software design verification and computer program testing records, personnel, process, and equipment qualification records.

4.17.2 Inspection, test, and work performance monitoring records shall indicate the nature of observations, the acceptable limits of parameters checked, the qualitative or quantitative results, the actions taken in connection with any identified deficiencies, the date of the observation, and the identity of personnel involved.

4.17.3 Required records shall be legible, identifiable, and retrievable.

4.17.4 A system for controlling and monitoring legibility and accuracy for radiograph reproductions shall be included in the quality assurance program. This system shall include procedures for exposure, scanning, focusing, contrast, resolution, and distinguishing film artifacts.

4.17.5 All maintained records shall have clear identification markings that can be traced to a specific job or item and shall be entered into a system that provides for timely retrieval.

4.17.6 Records retention periods and storage requirements shall satisfy the requirements of ANSI/ASME N45.2.9-1979, "Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants" or requirements of relevant Code and Standard (See Attachment A), or the Supplier shall, as a minimum, transmit identifiable and reproducible copies of all records as delineated by Purchaser at the time of shipment.

4.18 Audits

The Supplier shall establish a system of audits to ensure compliance with all aspects of the quality assurance program and to determine its effectiveness. Written procedures and controls shall comply with the requirements of ANSI/ASME N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants" or requirements of relevant Code and Standard (See Attachment A), and shall include, as a minimum, the following:

4.18.1 Audits shall be scheduled at a frequency commensurate with the status and importance of the activity.

4.18.2 An audit plan which identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable

documents scheduled and audit procedures or checklists shall be developed and documented for each audit.

4.18.3 Auditors shall not have any direct responsibility for performance of the activities they audit.

4.18.4 Audit team shall be identified prior to the beginning of the audit, consisting of one or more auditors, and shall include an individual, who is a qualified Lead Auditor, appointed to lead the team.

4.18.5 Audits shall be performed in accordance with written procedures or checklist.

4.18.6 Audit results shall be documented by the auditing personnel and shall be reviewed by management responsible for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

4.18.7 Audit reports shall be signed by the audit team leader and shall include the following information:

1. Description of the audit scope.
2. Identification of the auditors.
3. Identification of persons contacted during audit activities.
4. Summary of audit results.
5. A statement on the effectiveness of the program elements which were audited.
6. Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

4.18.8 Follow-up action shall be taken to verify that corrective action is implemented as scheduled.

4.18.9 Audit records shall be maintained and shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

4.18.10 Lead Auditors shall be qualified in accordance with the requirements of ANSI/ASME N45.2.23-1978, "Qualification of Quality Assurance Program Audit Personnel for the Nuclear Power Plants", or requirements of relevant Code and Standard (See Attachment A), and shall satisfy, as a minimum, the following requirements:

I. Lead Auditors shall be trained to the extent necessary to ensure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the needs of each Lead Auditor: nuclear-related codes, standards and regulations; general structure of quality assurance programs; auditing techniques of examining, evaluating, and reporting; and audit planning.

2. Initial qualification of Lead Auditors shall be determined according to the individual's education, experience, training, auditing skills, and capabilities.

3. Lead Auditors shall pass an examination which shall evaluate their competence in auditing skills.

4. The proficiency of each Lead Auditor shall be assessed by management on an annual basis. Based on this assessment, management may extend the qualification, require retraining or require requalification.

5. The qualification of Lead Auditors shall be certified in writing in an appropriate form, including the following information:

   a. Employer's name,

   b. Lead Auditor's name,

   c. Date of certification or recertification,

   d. Basis for qualification (i.e., education, experience, training, examination, etc.),

   e. Signature of employee's designated representative who is responsible for this certification.

6. Records for each Lead Auditor shall be maintained and updated annually.

Attachment A
QA Program Requirements - Cross Reference Table

QA PROGRAM ELEMENTS	SAFETY RELATED ITEMS NON ASME CODE	SAFETY RELATED ITEMS ASME CODE		AUGMENTED QUALITY ITEMS	
	10CFR50 App. B ASME NQA-1/ANSI N45.2	ASME III NCA-4000	ASME III NCA-3800	ISO 9001*	ISO 17025*
1.0 GENERAL					
1.1; 1.2; 1.7	X	X	X	X	X
1.3	X				
1.4	X	X	X		
1.5	X	X	X		
1.6				X	X
2.0 DEFINITIONS	X	X	X	X	X
3.0 DOCUMENTS FOR SUBMISSION	X	X	X	X	X
4.0 QA PROGRAM REQUIREMENTS					
4.1 Organization	X	X	X	X	X
4.2 QA Program	X	X	X	X	X
4.3 Design Control					
4.3.1 – 4.3.9	X	X	X	X	
4.3.10	X	X	X		
4.4 Procurement					
4.4.1 – 4.4.7; 4.4.9	X	X	X	X	X
4.4.8	X	X	X		
4.5 Instructions, Procedures, and Drawings	X	X	X	X	X
4.6 Document Control	X	X	X	X	X
4.7 Control of Purchased Items and Services					
4.7.1 – 4.7.4	X	X	X	X	X
4.7.5	X	X	X		

Attachment A
QA Program Requirements - Cross Reference Table

QA PROGRAM ELEMENTS	SAFETY RELATED ITEMS NON ASME CODE	SAFETY RELATED ITEMS ASME CODE		AUGMENTED QUALITY ITEMS	
	10CFR50 App. B ASME NQA-1/ANSI N45.2	ASME III NCA-4000	ASME III NCA-3800	ISO 9001*	ISO 17025*
4.8 Identification and Control of Items	X	X	X	X	X
4.9 Control of Special Processes	X	X	X	X	X
4.10 Inspection	X	X	X	X	X
4.11 Test Control	X	X	X	X	X
4.12 Control of Measuring and Test Equipment	X	X	X	X	X
4.13 Handling, Storage, and Shipping	X	X	X	X	X
4.14 Inspection, Test, and Operating Status	X	X	X	X	X
4.15 Control of Nonconforming Items					
4.15.1; 4.15.3 – 4.15.7	X	X	X	X	X
4.15.2	X	X	X		
4.16 Corrective Action	X	X	X	X	X
4.17 Quality Assurance Records	X	X	X	X	X
4.18 Audits	X	X	X	X	X

Note: * Compliance with the requirements of international standards shall be certified by accredited organization.