QUALITY ASSURANCE MANUAL

ZQA-001

Revision G

October 1, 2014

Successful implementation of the requirements defined in this Quality Assurance Manual requires the concerted effort of all Zetec employees since everyone contributes to the quality of our products and services. We are committed to this quality program and to improving its effectiveness whenever possible.

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This Manual Expires 2 Years from Last Approved By Date

REVISION HISTORY

Revision	*Date*	*Description*	*Updated by*
G	9-Sep-2014	• Updated section 6.3 to remove the requirement for distribution of controlled copies of the Quality Manual. • Removed quality records table from section 17.3 and replaced it with reference to QAP-105. • Updated all referenced documents.	Nancy Stutzman

F	11-Nov-2012	• Added Mission and changed Vision (page 5)
		• Modifications in functions throughout the manual
		  ○ Added Quality Assurance Manager
		  ○ VP of Engineering replaced by VP of each business unit
		  ○ Calibration Laboratory changed to After Market Services
		  ○ Field Service and Field Applications to Product Support
		• Updated to reflect Internal group interactions (section 2.2.4)
		• Added compliance to RCC-M standard (2.3.1.1, 25.1.13)
		• Added compliance to ACCP standard (2.3.2.1, 24)
		• Organizational updates (2.2.3, 21.1.3)
		• Updated procedure references
		  ○ PDP to COP-006
		  ○ SHP-023 to OPP-10200
		• Updated external release statement (6.2.2)
		• Updated Table 17-1 Records Retention
		• Modification of paragraphs in sections (8.1, 16.1, 17.1)
			R. Kelso & K.Bolduc

E	10-May-2011	• Zetec Quality Policy – updated to support ISO/IEC 17025 reqmts • Added Table 2.1-1 to support CAN3-Z299.2 requirements • Updated 2.3.1.1 to reference CAN3-Z299.2/.3 • Section 2.3.3.4 – changed FSP-301-QA to FAP-008 • Sections 4.3.9, 7.3.5 – changed PUR-001 to OPP-10205 • Sections 5.1.4, 5.3.1 – updated references to QAP-020 • Section 5.3.3 – corrected COP-002 reference • Section 10.2.2 – changed ESCOP-1004 to QAP-013 • Added Section 25, Referenced Documents (Internal, External)	D. Wood

Revision	*Date*	*Description*	*Updated by*
D	2-Nov-2009	• Section 12.1.1- added ref to 01-1005 "Zetec General Mfg Workmanship Stds" in lieu of defining equipment cal ID reqmts (CAR 805). Updated 1.1.1 to ref Quality Mgmt Rep (CAR 864). • Section 2.3.2.2 – deleted statement about NDT/NDE program conforming to ISO/IEC 17025 requirements. Zetec's ISO/IEC 17025 registration covers calibration laboratory activities only. • Section 2.7 (Procedures) – moved to 5.1.4, 5.1.5 • Section 2.8 (Maint of the Quality Manual) – moved to 6.3.1 • Section 5.2 – updated to reflect current organization • Sections 5.3.2, 5.3.3 – added • Section 5.2.6 moved to 5.2.2; 5.2.7 moved to 5.2.3; 5.2.8 moved to 5.2.2; 5.2.9 moved to 5.2.4 • Changed Field Services to Field Applications • Replaced references to QAP-051 (Document Control) with COP-001; 01-1006 (Zetec General Drafting Standards) replaced with COP-002; CCS-013 (Calibration Standard Raw Matl Receipt Acceptance) replaced with ESCOP-1004.	D. Wood
C	3-Nov-2008	• Changed to alphabetic revision to accommodate IFS • Updated Zetec Vision • Added "PDP Lite" to section 3.3.1 • Updated document refs in sections 3.4.1, 10.2.3, 13.2.4 (note), 15.2.1, 16.3.3, 16.4.2, 16.4.3, 18.3.4, 18.5.1, 18.5.1.2, 19.2.2 • General wording clarifications in sections 5.3.5, 12.1.1, 18.5.1, 23.1.3, 23.1.4 • Added section 16.1.5 • Section 17.3.3 and Table 17-1 – updated employee file retention period to match Roper guidelines • Added Section 23 Note.	Diane Wood
1	30-Nov-2006	• Clarified the Quality Policy re ISO/IEC 17025:1999 requirements • Section 2.1.1 -- clarified inclusion of Zetec sites, U.S. & Intl • Updated org assignments per current Zetec org. Changed use of "department", "team" and "group" to "Organization". • Added sections 4.3.9 and 7.3.5 -- PO wording for nuclear safety related products and services • Added section 16.3.1 -- ref Triage and RCA processes • Added section 18.4.3 – ref to supplier approval & audit processes • Sections 9.2.3 and 23.2.1 -- consolidated references to personnel qualification processes • Added Section 24 (Acronyms)	Diane Wood
0	31-Mar-2006	Supersedes Snoqualmie Quality Manual Z-QA Rev. 22, Quebec Quality Manual Rev. E and Deep River Quality Manual Rev. 3. Updated to document Quality Management System processes for all 3 sites.	Diane Wood

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SECTIONS 1-18 correlate directly to Federal Regulation 10 CFR 50 Appendix B.
SECTIONS 19-22 satisfy the additional requirements of ISO 9001.
SECTION 23 (Training) supports both 10 CFR 50 Appendix B and ISO 9001 requirements.

ZETEC VISION

Zetec is the company that customers and industry rely upon for complex high-criticality engineered NDT solutions

ZETEC MISSION

Deliver effective high-value innovative NDT solutions that enhance safety in mission-critical environments.

ZETEC QUALITY POLICY

- Provide services and products which meet or exceed customer expectations of quality, reliability, and value
- Strive for a high level of professionalism in all dealings with internal and external customers
- Personnel involved in calibration activities will familiarize themselves with related processes and procedures and ensure compliance with all laboratory standards

DEFINITIONS

Quality terms used in this manual are defined in ISO 9001 and 10CFR50 Appendix B.

Quality Assurance	Refers to the Zetec organization responsible for overseeing the Zetec Quality Management System.
Quality Control/Inspector	Quality Control or Quality Inspectors are those persons tasked with conducting formal inspections to ensure compliance with product specifications on incoming or Zetec-built products.
Quality Management System	Refers to the collective set of quality related processes used at Zetec. Also sometimes referred to as the “Quality Assurance Program”.

Unique terms used in this manual are defined as follows. A complete acronym list is included in Section 24.

Eddy Current, Ultrasound	Specifically applies to the NDT applications.
Product Support	Services which are performed by Zetec Product Support personnel primarily involving acquisition and/or analysis of eddy current or ultrasound data. Additionally, Product Support may involve training or calibration/repair of Zetec manufactured equipment. Product Support activities are typically performed at the customer's facility although analysis of eddy current data may be performed at Zetec.

1. ORGANIZATION

1.1. Responsibility

1.1.1. The President has primary responsibility for all facets of the operation of Zetec, Inc., including quality assurance. The President has delegated the implementation of the quality assurance program to the Quality Assurance Managers. Any change or revision to the plan requires the written approval and acceptance of the President.

The Quality Managers also act as the Zetec Quality Management Representatives, and are responsible for:

1. **Ensuring that processes needed for the Quality Management System (QMS) are established, implemented and maintained,**
2. **Reporting to top management on the performance of the QMS and any need for improvement,**
3. **Ensuring the promotion of awareness of customer requirements throughout Zetec, and**
4. **Acting as liaison with external parties on matters related to the Zetec QMS.**

NOTE: The President is responsible for noncompliance notification applicable under 10 CFR Part 21 (see 01-1008 Corporate Policy, Reporting of Nuclear Related Safety Hazards, for additional information).

1.1.2. The Quality Assurance Organization is responsible for implementing Zetec's Quality Management System and ensuring continued compliance of the system with applicable standards and requirements.

1.1.3. The responsibilities of employees whose work affects quality are defined in their job descriptions which are maintained by the Human Resource Organization. All employees are responsible to meet the quality practices and goals of the department(s) they support.

1.1.4. All employees have complete authority to:

a. Immediately stop practices which are unsafe or outside of approved procedural limits.

b. Remove from service or halt any practice or further processing of any item, component or product that is found unacceptable or out of specification.

c. Halt shipments of products known to be defective or known to have been produced without using the proper Zetec procedures.

The employee should communicate the problem to their supervisor and to the Quality Assurance Organization so that a formal investigation can be conducted.

1.2. Organization Details

1.2.1. The company organizational structure is maintained by Human Resources.

2. QUALITY MANAGEMENT SYSTEM

2.1. Scope and Application

2.1.1. The scope of the Quality Management System includes the total operation of Zetec, including all offices in North America, Europe and Asia where products are manufactured, calibrated or repaired. The Quality Management System also includes all offices from which Product Support is provided. See Table 2.1-1 for details.

2.1.2. Measures are to be taken to ensure that services, equipment and other items supplied to or performed for customers by Zetec shall conform to the specified quality levels of applicable codes, standards, regulatory criteria and purchase order specifications. Monitoring, measurement and analysis are used, whenever practical, to demonstrate conformity and quality management system effectiveness.

2.1.3. The goal of the Quality Management System is to enable continuous improvements to ensure maximum customer satisfaction and eliminate the production of nonconforming parts/products.

Table 2.1-1 Activities by Site

Site	Site Main Activities
Snoqualmie, WA, USA	Design, Manufacturing, Purchasing, Sales, HR, Quality, Service, Field Applications, Professional Development
Quebec, Quebec, Canada	Design, Manufacturing, Purchasing, Sales, HR, Quality, Service
Paris, France	Sales, Purchasing, Service (See Note 1)
Seoul, Korea	Sales, Purchasing, Service
Malu, China	Manufacturing, Purchasing
Lynchburg, VA, USA	Service

Note 1: Activities performed by Zetec organizations located in Paris, France are done so under the Struers business license.

2.2. Responsibility

2.2.1. The Quality Assurance Organization is responsible for:

a. Ensuring the processes needed for the Quality Management System are established implemented and maintained.

b. Reporting to the President and other managers on the performance of the Quality Management System and any need for improvement.

c. Updating quality controls as necessary and ensuring that personnel assigned to “quality” functions are trained in the assigned function.

d. Ensuring that inspectors, when performing an inspection function, shall not inspect their own work.

2.2.2. Each manager is responsible for identification and acquisition of the personnel, technology, and material resources needed to meet or exceed Zetec’s quality standards.

2.2.3. Each Vice President, Manager and Supervisor shall ensure that appropriate communication processes are established within Zetec and that communications include quality issues and customer expectations. The applicable Vice President of each Business Unit is responsible for the evaluation of requests for new products.

2.2.4. Each department within the organization is responsible to create and maintain procedures and/or work instructions that describe department activities and reference interactions with other departments (where applicable). See Figure 2.2-1 Department Interaction Flow Diagram next.

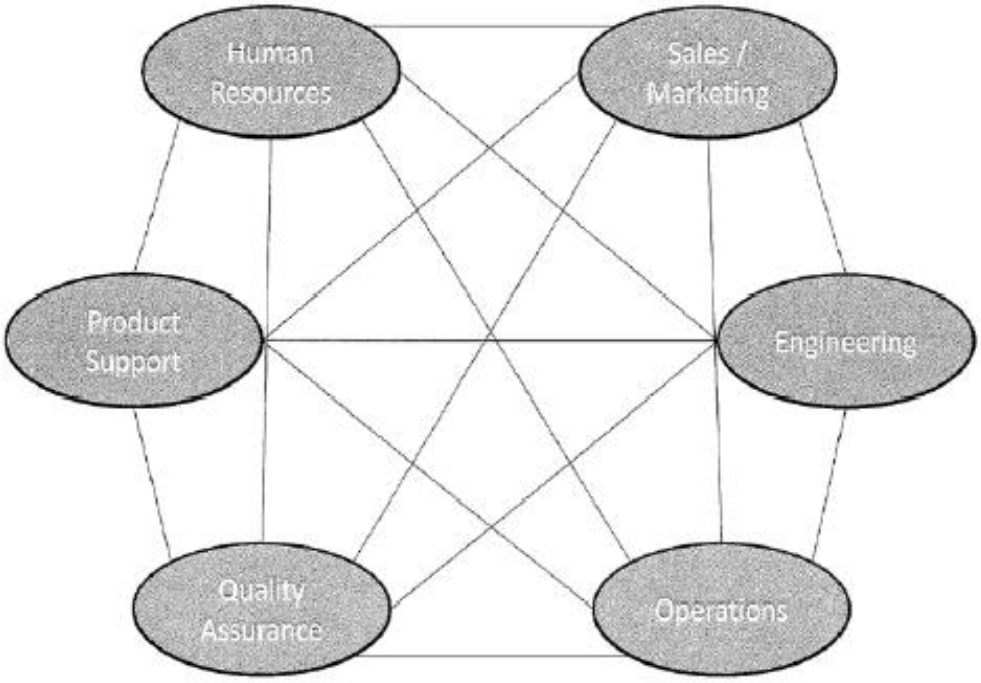

Figure 2.2-1 Department Interaction Flow Diagram

2.2.5. Each Business Unit shall monitor customer perceptions related to whether or not Zetec products and services meet their requirements. Business Development will determine the methods for obtaining this information.

2.3. References/Standards

2.3.1. Quality Management System

2.3.1.1. The Quality Management System is based on ISO 9001, ISO/IEC 17025, RCC-M, CAN-Z299.2/.3 and the applicable requirements of the ASME Boiler and Pressure Vessel Code, Federal Regulation 10 CFR Part 50 Appendix B, 10 CFR Part 21 and applicable sections of ANSI/N45.2.

2.3.1.2. Specific Quality Plans may be initiated if needed to satisfy unique customer requirements.

2.3.2. Non-Destructive Testing

2.3.2.1. Non-destructive testing procedure requirements are based on Section XI of the ASME Boiler and Pressure Vessel Code and/or the requirements of the NRC Regulatory Guide 1.83 and/or other particular specifications (i.e. ASNT/ACCP, CGSB, etc.). Acceptance standards shall be those applicable to a given project.

2.3.2.2. The measurement uncertainty values derived by EPRI for qualified NDE techniques are accepted by Zetec.

2.3.3. Product Support Personnel Certification

2.3.3.1. Certification of nondestructive testing personnel is based on the guidelines of the American Society for Nondestructive Testing "Recommended Practices for Nondestructive Personnel Qualifications and Certification", SNT-TC-1A.

2.3.3.2. The certification program also satisfies the requirements of ANSI/ASNT CP-189, except that ASNT certification is not required for Zetec Level III personnel.

2.3.3.3. Radiation safety and protection is based on Federal Regulation 10CFR Part 20 and URNS Division 8 (8.7).

2.3.3.4. Personnel performing nondestructive testing shall comply with the quality requirements defined in procedure "FAP-008 - Field Applications Quality Assurance Requirements" or equivalent.

2.3.4. Equipment Calibration

2.3.4.1. The calibration program is based on 10 CFR 50 Appendix B Section XII and ASME NQA-1 Supplement 12S-1.

2.3.4.2. The Zetec calibration program is also committed to meeting the requirements of ISO 10012-1 and ISO/IEC 17025.

2.3.4.3. Equipment calibration program guidance is further described in the procedure "General Requirements for Service and Calibration" (SLP-001 or equivalent).

2.4. Resource Management

2.4.1. General Resources

2.4.1.1. Resources must be provided to implement, maintain and continually improve the Quality Management System. Also, resources must be provided to enhance customer satisfaction by meeting their requirements.

2.4.1.2. The infrastructure needed to achieve product and service requirements shall be provided. Infrastructure includes buildings, workspace, process equipment and supporting services (IT, safety, security and maintenance).

2.4.1.3. The work environment needed to achieve product and service requirements shall be provided. Work environment includes temperature, noise levels, lighting, etc.

2.4.2. Human Resources

2.4.2.1. Personnel should be aware of the relevance and importance of their activities and how they contribute to the Quality Management System.

2.4.2.2. Job descriptions must be documented and revised as needed to define necessary personnel competence.

2.4.2.3. Personnel must be competent to perform assigned work based on education, training, skills and experience.

2.4.2.4. Personnel records shall be maintained. This includes information such as education, training, skills and experience.

2.5. Continuous Improvement

2.5.1. Continuous improvement shall be a goal of the Quality Management System.

2.5.2. Management Review of the Quality Management System shall typically be performed annually. The goal of the Management Review is to assess opportunities for improvement and the need for changes to the system, including the quality policy and quality objectives.

2.6. Customer Interface

2.6.1. Customer Communications -- Effective customer communications must be established as follows:

2.6.1.1. Each Business Unit provides product information and obtains customer and representative feedback.

2.6.1.2. The Customer Service Organization handles customer inquiries.

2.6.1.3. The Quality Assurance Team manages the customer complaint process and the corrective/preventive action process to ensure customer issues are addressed.

2.6.2. Customer Review/Audits

2.6.2.1. Zetec shall afford customers or their representatives the opportunity to clarify the customer's request and monitor work performed.

2.6.2.2. Reasonable access will be provided to all relevant areas of Zetec facilities. Confidentiality of other customer's information shall be maintained.

3. DESIGN CONTROL

3.1. Design control shall apply to all Zetec-designed or modified products provided by Zetec to an external customer.

3.2. Responsibility

3.2.1. The VP of each Business Unit is responsible for disposition of design review conflicts and final approval of new product designs.

3.2.2. Design of Zetec products is the primary responsibility of the Vice President of each Business Unit. The applicable Vice President must ensure that designs satisfy all statutory/regulatory requirements and additional requirements determined by Zetec, including design control and adherence to the Zetec New Product Development Process.

3.3. New Product Design Control

3.3.1. Control of the design of a new Zetec product is defined in COP-006 "Product Development Process".

3.4. Established Design Change Control

3.4.1. Control of changes to established electrical and mechanical, software and firmware designs are defined in COP-003 "Change control" which establishes change identification, documentation, review and approval requirements.

4. PROCUREMENT/PURCHASING DOCUMENT CONTROL

4.1. Purchase of components and raw material used in the manufacture of Zetec products or the conduct of Zetec services is controlled, as well as the procurement of services used in the manufacture of Zetec products (e.g., calibration services, EDM services, etc.)

4.2. Responsibility

4.2.1. The Procurement/Purchasing Department has primary responsibility for establishing and implementing procurement processes to ensure that purchased products conform to specifications.

4.2.2. The QA and Procurement/Purchasing teams are responsible for ensuring that suppliers and sub-contractors are evaluated and controlled as defined in QAP-018, "Supplier Approval Procedure" (or equivalent).

4.3. Procedure

4.3.1. All purchases for components, equipment, material or services within the scope of this section shall utilize written purchase orders.

4.3.1.1. This shall include all purchases involving specific quality requirements or specifications; e.g., Certificates of Compliance or Conformance (C of C), Certified Material Test Report (CMTR), MIL-STD's, ASME Boiler and Pressure Vessel Code or the Code of Federal Regulations.

4.3.1.2. All items requiring quality control receipt inspection shall be ordered using written purchase orders.

4.3.2. Purchase Orders shall be controlled and traceable by number.

4.3.3. Attachments may be used and, if used, shall be indicated on the main page of the purchase order.

4.3.4. Any special quality requirements shall be specified on the purchase order.

4.3.5. Special packaging or handling shall be specified on the purchase order, if required.

4.3.6. Any changes or revisions to quality requirements of the original purchase order shall be subject to the same review as the original order.

4.3.7. Requirements of procurement documents shall be extended to lower tier suppliers to the extent necessary to ensure quality.

4.3.8. Purchase orders for calibration services shall be initiated and approved by the Quality Management or designee.

4.3.9. Purchase orders for products and services that are defined as nuclear safety related per 01-1008, "Reporting of Nuclear Related Safety Hazards" shall include appropriate language as defined in OPP-10205, "10CFR50 Appendix B and 10CFR21 Safety Requirements for Purchase Orders" (or equivalent procedures).

5. DRAWINGS, PROCEDURES AND WORK INSTRUCTIONS

5.1. Scope and Application

5.1.1. This section applies to the documentation for control of activities and processes for:

a. The design, manufacture, repair and calibration of Zetec equipment and associated items.

b. Services provided by Zetec, Inc.

5.1.2. "Drawings" refers to detailed pictorial information describing the design, layout, specifications, tolerances, etc. for Zetec designed sub-assemblies and finished goods.

5.1.3. This manual is considered the 'top level' procedure. At a tier below this manual are Zetec policy and procedure documents which provide general guidance and requirements which sometimes span multiple departments. Below policies and procedures, a tier of work instructions exist which provide step-by-step instructions for a specific process and typically govern work conducted within a single department. Forms should be associated and released with the related procedure or work instruction.

5.1.4. Operational procedures shall be written as necessary to implement the Quality Management System defined in this manual (for additional details, see COP-008 "Development of Procedures, Work Instructions and Forms" or equivalent).

5.1.5. The policies and procedures detailed in this Quality Manual are applicable to Zetec personnel and to subcontractors performing services controlled by the Quality Management System. Compliance with the provisions of this Program Plan is mandatory. Prior approval of the President or the Quality Assurance Director/Manager shall be obtained in writing in the event a deviation is required due to events unforeseen or not specifically covered by the policies and procedures.

5.2. Responsibility

5.2.1. The Engineering team is responsible for the preparation of all Zetec drawings. Configuration & Change Management Team is responsible for revision control of such drawings. They are also responsible for the initiation and maintenance of department related procedures and work instructions.

5.2.2. The Operations team is responsible for the initiation and maintenance of manufacturing and in-process inspection procedures and work instructions. The Operations team includes After-Market Calibration Services.

5.2.3. The Product Support Organization is responsible for the preparation and maintenance of procedures and work instructions for product specific training, field and NDT inspections and related applications.

5.2.4. The Quality Assurance Organization is responsible for reviewing and approving new and updated Zetec policies and procedures to ensure they support the Quality Management System. Quality Assurance or designee should be included in the initiation and maintenance of checkout procedures related to probe quality control inspections, mechanical part inspections and supplier product receipt inspection.

5.2.5. Each department is responsible for initiating revisions to department procedures as needed to ensure their accuracy and completeness. Each department is also responsible to ensure that current documents are made available for use as appropriate during product assembly and checkout.

5.3. General

5.3.1. Instructions on the format and content for Zetec procedures and work instructions are documented in COP-008, "Development of Procedures, Work Instructions and Forms" (or equivalent).

5.3.2. Current working copies are maintained electronically for access by all Zetec employees. Electronic copies are also provided to customers as necessary.

5.3.3. Drawings -- General Drafting Standards are described in COP-002 “General Drafting and Design Guidelines” or equivalent.

6. DOCUMENT AND DRAWING CONTROL

6.1. Scope and Application

6.1.1. Document control applies to Zetec procedures for manufacturing and NDE/NDT programs/services (see COP-001 for additional details).

6.1.2. Drawing control applies to Zetec engineering drawings.

6.2. Responsibility

6.2.1. Department managers are responsible for the control and distribution of new and revised procedures, work instructions and drawings.

6.2.2. The President, Quality Manager or designee is required to approve the release of Zetec procedures (including this Quality Manual) outside of Zetec. In addition, the Vice President of the Business Unit must concur with the release of Zetec procedures and work instructions outside of Zetec. “For Operations’ procedures and work instructions, the V.P. of Operations & Supply Chain must concur with external release. In this case, approval by the V.P. of the Business Unit is optional.

6.3. Zetec Quality Manual

Zetec shall not issue controlled copies of the manual. External parties may download uncontrolled copies of the Quality Assurance Manual from Zetec’s website. Notifications regarding revisions/updates to the manual shall only be provided to external parties upon request.

6.4. Zetec Drawings

6.4.1. Drawings shall be constructed, approved and revised according to procedure COP-002 “General Drafting and Design Guidelines” (or equivalent).

6.4.2. Drawing corrections and interim changes are only to be made by designated personnel. They shall be made on a drawing print in Red ink, initialed and dated. The Manufacturing Engineer gets second signature from the Design Engineer and the delivers the print to CCM for review and formal revision.

6.5. Zetec Procedures and Work Instructions – Modifications to control and disposition of Zetec procedures and work instructions are documented in “Development of Procedures, Work Instructions and Forms”, (COP-008 or equivalent).

6.6. External Documents and Data -- Documents and data provided by customers shall be controlled as specified by the customer.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1. Responsibility

7.1.1. The Supply Chain Manager is responsible for procurement and receipt of purchased materials and equipment in support of manufacturing.

7.1.2. Each manager is responsible for establishing the requirements for purchased services and monitoring those services for any deficiencies.

7.2. Control of Purchased Materials and Equipment – For details, see “Receiving Inspection” procedure (QAP-006 or equivalent).

7.3. Control of Purchased Services

7.3.1. Services that must meet defined specifications and/or quality requirements shall be obtained under an approved contract or written purchase order. Applicable specifications and/or quality requirements shall be documented, for example:

a. NIST traceability for all calibration services and for EDM services related to items that will be certified.

b. Title 10 CFR 21 applicability for all NDE services.

7.3.2. The Quality Assurance Organization shall ensure that vendors supplying calibration services comply with established requirements.

7.3.3. The Product Support Organization shall ensure that subcontractors providing personnel for NDT comply with established requirements.

7.3.4. The Operations Organization shall ensure that suppliers providing services for manufacturing comply with established requirements.

7.3.5. Purchase orders to suppliers of products and services that are used in Zetec nuclear safety related products shall include appropriate language to ensure compliance with 10CFR50 Appendix B. For details, see “10CFR50 Appendix B and 10CFR21 Safety Requirements for Purchase Orders” (OPP-10205 or equivalent).

7.4. Suppliers of Materials and Services

7.4.1. Suppliers of products and services shall be on an Approved Supplier List (ASL). Supplier selection shall be based on the supplier's ability to meet Zetec purchasing requirements, including quality and delivery.

7.4.2. The Quality Assurance Organization shall be responsible for maintaining the Approved Supplier List. See the “Supplier Approval Procedure” (QAP-018 or equivalent) for additional details.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, COMPONENTS AND PRODUCTS

8.1. This section is to describe the measures established for the identification and control of materials, parts, components and products to ensure compliance with regulatory criteria, applicable codes and Zetec specifications which shall include all products and services

8.2. Responsibility

8.2.1. Operations supervisors are responsible for the identification and serialization of products.

8.2.2. All Zetec supervisors and managers are responsible for appropriate identification and control of materials, parts and components used in work performed by their organization.

8.3. Procedures

8.3.1. All applicable items shall be identified and serialized as early in the manufacturing process as practical. Serial number information shall be available in a controlled log.

8.3.2. Serial numbers are applied appropriately by stamping, etching, engraving, adhesive labeling or heat shrinkable tube tags.

8.3.3. M&TE used in the manufacture of Zetec products shall be identified and assigned unique serial numbers or Zetec asset numbers.

8.4. Identification of Services Provided By Zetec -- Identification of product support, calibration and other services performed by Zetec is specified in the appropriate department procedures.

9. CONTROL OF SPECIAL PROCESSES

9.1. Responsibility

9.1.1. The Product Support Organization is responsible for the conduct of nondestructive examinations (NDE) performed as a service under contract. The Director, Training/Professional Development is responsible to work with Product Support to implement programs for certification of personnel used in NDE services.

9.1.2. The Operations organization is responsible for control of welding, anodizing and heat treating special processes.

9.1.3. Quality Assurance and Operations are responsible for the inspection and testing of eddy current and ultrasonic probes using NDE techniques.

9.2. Non-Destructive Testing/Examination (NDT/NDE)

9.2.1. Procedures controlling inspections performed by the Product Support organization shall be documented.

9.2.2. General procedures for NDE data acquisition and analysis shall meet the "Procedure Requirements" paragraphs of ASME Section XI Appendix IV and/or ASME Section V Article 8.

9.2.2.1. Inspection procedures may be written to specific customer requirements.

9.2.2.2. Zetec Product Support procedures may be used to meet customer requirements.

9.2.3. The “Eddy Current Testing Personnel Qualification and Certification Procedure” (TRN-101 or equivalent) controls the certification of personnel for the applicable acquisition and analysis tasks.

9.2.4. Certification of NDT equipment used to perform inspections is controlled by written procedures. Procedures established are in accordance with Section 5 of this document.

10. INSPECTION

“Inspection” is defined as the act of verifying that a product or component meets required specifications and is suitable for its intended purpose. Inspection tasks are performed by “Receiving Inspectors” and “Final Inspectors” who are sometimes referred to as Quality Control inspectors. In this context, “inspection” does not include the NDE inspection service provided by Zetec.

10.1. Personnel Qualifications

10.1.1. Personnel performing inspections shall be appropriately trained for the inspection activity performed.

10.1.2. Personnel performing inspections shall pass an annual eye examination as required by the standard(s) applicable to the work being performed.

10.1.3. Inspectors, when performing an inspection function, shall not inspect their own work.

10.2. Procedures

10.2.1. Inspections shall be accomplished using documented procedures and instructions.

10.2.2. Receipt inspections shall be performed as specified according to the applicable procedures, e.g., “Receiving Inspection Procedure” (QAP-006 or equivalent) and “Calibration Standard Raw Material Receipt Inspection” (QAP-013 or equivalent).

10.2.3. Zetec manufactured products shall be final inspected per applicable procedures, e.g., “QC Inspection of EC Probe, Mechanical and Sheet Metal Parts” (QAP-001 or equivalent), “or Final Inspection Reporting for Electro-Mechanical Equipment” (QAP-003 or equivalent).

10.2.4. For items subject to sample inspection, a portion of a lot may be released for urgent production purposes under the following circumstances:

a. At least the normal sample size is held for inspection.

b. The items released are positively identified and recorded, in order to permit immediate recall in the event of nonconformance to specified requirements.

10.3. Inspector Authority

10.3.1. Personnel assigned to inspection tasks are obligated to:

a. Halt immediately any unsafe practice.

b. Remove from service or halt further processing of any suspect or defective product, component or practice.

10.4. Product Inspection Records

10.4.1. Inspection records shall be completed as specified in the applicable instructions.

10.4.2. Inspection records shall be retained as specified in QAP-105 (Management of Quality Records).

11. TEST CONTROL

11.1. Responsibility

11.1.1. The Engineering or Applications Team is responsible for specifying the requirements for testing of all products manufactured by Zetec.

11.1.2. The Operations team is responsible to ensure that engineering prescribed tests are conducted. Operations are also responsible to ensure that test procedures are maintained and that changes are reviewed by Engineering as appropriate.

11.2. Procedures

11.2.1. Equipment shall be functionally tested prior to shipment to ensure compliance to design requirements.

11.2.2. Functional testing of Zetec manufactured products shall be conducted and documented per instructions provided in appropriate procedures and/or work instructions.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

12.1. Responsibility

12.1.1. It is the responsibility of all users of measuring and test equipment to ensure that equipment has been appropriately calibrated and certified prior to use as defined in SLP-003 “M&TE Control and Verification”.

12.1.2. It is the responsibility of Quality Assurance to monitor vendors that calibrate measuring and test equipment to ensure traceability to the National Institute of Standards and Technology.

12.1.3. It is the responsibility of the Operations Calibration Laboratory Organization to calibrate equipment, issue calibration certifications and maintain records of all certifications issued.

12.2. Procedures

12.2.1. Zetec retains the services of a competent laboratory to certify test equipment traceable to the National Institute of Standards and Technology.

12.2.2. All test equipment used to perform calibrations or make certified measurements shall have a prominently displayed certification tag attached to the equipment and a certification letter maintained on file.

12.2.3. Calibration and certification shall be done using documented procedures.

13. HANDLING, STORAGE AND SHIPPING

13.1. Responsibility

13.1.1. Handling, storage, packaging, preservation and shipping are the responsibility of the Operations and Material Handling (Receiving, Shipping, and Warehouse) Organizations.

13.2. Procedures

13.2.1. All products shall be handled with sufficient care to preclude damage (including cosmetic damage such as scratches).

13.2.2. Receiving of major components shall be handled and processed per “Receiving Inspection” (QAP-006 or equivalent).

13.2.3. Preservation techniques shall be employed prior to storage or shipping, as appropriate, to ensure product protection and reliability.

13.2.4. Items being shipped shall be handled, packed and marked using standard commercial techniques and packaging per “Shipping” procedure (OPP-10200 or equivalent).

NOTE: Specific customer shipping and marking requirements as identified in purchase orders/contracts and accepted by Zetec shall be complied with and noted on documentation using the order entry system.

NOTE: Export licenses shall be obtained as required to comply with the U.S. Bureau of Industry and Security (BIS) Export Administration Regulations. Reference 01-1010 “Compliance with U.S. Export Regulations” Corporate Policy.

14. INSPECTION, TEST AND OPERATING STATUS

14.1. Responsibility

14.1.1. The Quality Assurance Organization is responsible for ensuring compliance with documented procedures for quality control inspections.

14.1.2. The Quality Assurance Organization is also responsible to ensure tests and inspections are completed per documented procedures and that test and inspection results are recorded.

14.1.3. The Operations Organization is responsible for ensuring compliance with documented procedures for in-process inspection tasks.

14.2. Procedures

14.2.1. Inspected items shall be distinguishable from items awaiting inspection.

14.2.2. Nonconforming items shall be identified and/or segregated from conforming items.

14.2.3. Inspection or test status shall be indicated on appropriate process or inspection documentation or marked on the inspected item(s) as defined in the applicable procedure.

15. NONCONFORMING MATERIALS, PARTS OR COMPONENTS

15.1. Responsibility

15.1.1. The Quality Assurance Organization is responsible for managing the nonconforming material process.

15.1.2. The Material Review Board is responsible for reviewing and dispositioning of nonconforming material.

15.1.3. All employees are responsible for identifying and reporting any non-conforming material they find.

15.2. Procedure

15.2.1. Control of non-conformances shall be accomplished according to “Control of Non-conformance” (QAP-014) or equivalent.

16. CORRECTIVE ACTION

16.1. The Corrective Action process shall be used to resolve Quality Management System process issues, product deficiencies, customer complaints, safety issues and internal and external audit findings. A corrective action request shall be initiated in the following situation:

Any time a potentially reportable incident occurs as defined in 10 CFR 21 and 01-1008 “Reporting of Nuclear Related Safety Hazards”.

16.2. Responsibility

16.2.1. Quality Assurance: Administers the Corrective (and Preventive) Action Request (CAR) processes, maintains CAR database, and approves CAR plans. Reviews and assigns owners to CARs and escalates to management as necessary.

16.2.2. Any employee may initiate a Corrective Action Request, including requests on behalf of customers or suppliers.

16.3. Procedure

16.3.1. The handling of customer complaints should be managed and investigated per the processes defined in the “Customer Complaint Triage Process” (01-1011 or equivalent) and the “Root Cause Analysis Process” (01-1009 or equivalent), as applicable.

16.3.2. Initiation, routing and completion of the CAR form are defined in the “Corrective and Preventive Action Administration” (QAP-021) or equivalent.

16.3.3. Deviations - In the event that unanticipated circumstances create a situation that precludes strict adherence to this document or associated operating procedures, a "Request for Acceptance of Customer Nonconformance" (QAP-014FC or equivalent) shall be used to document the situation and solution, as well as document the customer acknowledgement. This form requires the approval of the Quality Manager or designee. This form is also used to document customer acknowledgment and acceptance of non-conforming products/services.

16.3.4. Customer complaints shall be investigated and a Corrective and Preventive Action Request should be initiated where appropriate.

16.4. Documentation Required

16.4.1. Corrective / Preventive Action Request (QAP-021FA or equivalent).

16.4.2. Request for Customer Acceptance of Nonconformance (QAP-014FC or equivalent).

16.4.3. Supplier Request for Acceptance of Nonconformance (QAP-014FD or equivalent).

17. QUALITY ASSURANCE RECORDS

17.1. The application of these records applies to all documents identified in QAP-105 (Management of Quality Records), which lists the minimum general requirements.

Additional customer contract/purchase order requirements may be accepted and implemented on a case by case basis.

Note: Zetec does not maintain customer plant records. All data sheets, other recorded media and test reports are the property and responsibility of the customer.

17.2. Responsibility

17.2.1. All Zetec organizations are responsible to maintain quality records for the work they perform. Specific quality records should be defined in department procedures.

17.2.2. The Quality Assurance Organization is responsible for ensuring that Quality Assurance records are maintained.

17.3. Procedures

17.3.1. All Quality Assurance records shall be managed according to "Management of Quality Records" (QAP-105).

18. AUDITS

18.1. Responsibility

18.1.1. The Quality Assurance Organization is responsible for all audits except for Product Support Inspection audits.

18.1.2. Quality Assurance management is responsible to ensure that an independent audit is conducted of the Quality Assurance processes.

18.1.3. The Product Support Organization is responsible for Product Support Inspection Audits.

18.2. Zetec Internal Audits

18.2.1. Zetec internal audits will be formally conducted a minimum of once each calendar year.

18.2.2. The detailed requirements for internal audits are contained in “Quality Assurance Audit Activities” (QAP-22 or equivalent).

18.3. Product Support Inspection Audits

18.3.1. The assigned audit representative shall perform an audit of work in progress as early in the inspection as is practical.

18.3.2. Subsequent audits may be performed using available objective evidence in the form of calibration logs and NDE data as recorded.

18.3.3. In the case of special examinations, audits shall be performed on a schedule commensurate with the status and importance of the examination.

18.3.4. The results of all audits shall be reported on “In Plant Audit Report” form FAP-008FR (or equivalent). Information that is required to complete this form is available at the data analysis station.

NOTE: When an audit of Zetec analysis is to be performed, alternate forms may be used to meet customer requirements.

18.3.5. The Audit Representative is normally the data analyst. Since this function is normally performed at a location remote from the inspection site and the data analyst has no responsibility for the work performance, he/she is considered unbiased and qualified to perform the audit.

18.4. Supplier Audits

18.4.1. Companies providing products or services that could affect the quality of Zetec products or services are subject to audit, as necessary, to assure the necessary quality level.

18.4.2. Audit results shall be documented in audit reports.

18.4.3. The supplier approval process is defined in ”Supplier Approval Procedure” (QAP-018 or equivalent). Details of the audit process used to verify supplier quality management systems are included in the “Quality Assurance Audit Activities Procedure” (QAP-022 or equivalent).

18.4.4. Critical suppliers (as defined in QAP-018 or equivalent) shall be assessed at least annually to determine the need for audit and/or surveillance activities.

18.5. Personnel

18.5.1. Personnel performing internal or commercial external audits shall be appropriately trained as defined in “Qualification and Certification of QA

Audit Personnel" (QAP-054 or equivalent) and shall not have direct responsibilities in the areas being audited.

18.5.1.1. Auditor selection and designation shall be based on an evaluation of the individual's education, training, auditing skills and capability.

18.5.1.2. Auditor proficiency must be maintained as defined in QAP-054.

18.5.2. Personnel leading the conduct of external nuclear safety related audits shall meet the qualifications specified in ANSI N45.2.23.

19. SERVICING OF ZETEC PRODUCTS

19.1. Responsibility

19.1.1. The Calibration Laboratory Organization supervisor is responsible for the servicing of Zetec products.

19.1.2. The After Market Service Organization supervisor is responsible to ensure that procedures used by his/her team are documented.

19.2. Procedure

19.2.1. Contracts involving repair/calibration of Zetec products shall be reviewed and evidence of this review shall be documented (see section 21).

19.2.2. Upon receipt of customer items for repair or calibration, the product information shall be entered into a computer database for tracking and a Return Materials Authorization, (RMA) (or equivalent) shall be generated to accompany the item(s).

19.2.3. The items shall be examined and any apparent shipping damage shall be reported to the customer. Any instance of damage, deterioration or shortage of customer owned items shall be reported to the customer.

19.2.4. For items requiring calibration, the received condition shall be documented as specified in applicable procedures.

19.2.5. Customer items for repair or calibration shall be stored in a manner and location to preclude damage or deterioration, while awaiting work.

19.2.6. When items are ready for return to the customer they shall be packed in a manner to preclude shipping damage, as specified in "Shipping" (OPP-10200 or equivalent).

19.2.7. Personnel performing calibration of Zetec products shall be appropriately trained.

19.2.8. All repaired items shall be functionally tested to ensure proper operation. Additionally, if a repair could have affected the calibration of an item, the item must be recalibrated as part of the repair process.

19.2.9. All test equipment used for calibrations performed at Zetec shall be calibrated. This requirement also applies to calibrations performed at the customer's facility using test equipment owned by Zetec, Inc. This

requirement does not apply to test equipment provided by the customer for use at his/her facility.

19.3. Documentation

19.3.1. Certification of calibration shall be performed as specified in applicable procedures (see SLP-002 – Guidelines for calibration certificates).

19.3.2. All servicing of customer items shall be documented on a service order as specified in applicable procedures.

19.3.3. Service Laboratory procedures are defined to describe the processes in the calibration laboratory. (SLP-001 to SLP-008)

20. ANALYSIS OF DATA

20.1. Responsibility

20.1.1. Department managers are responsible for selecting appropriate measures and goals to support the Zetec Quality Management System.

20.1.2. Zetec management is responsible for reviewing quality measures and goals at regularly scheduled Quality Management System reviews.

20.2. Documentation -- Performance measures are quality records as defined in Section 17. Retention shall be for at least one year.

21. CONTRACT REVIEW

21.1. Responsibility

21.1.1. Each Business Unit is responsible to ensure that contracts for the purchase of Zetec products and calibration or repair work are routed for review. Business Development is also responsible to ensure that the contract review process is defined and documented and that employees are trained as appropriate.

21.1.2. The Product Support Organization is responsible for the review of all contracts for inspection ~~or training~~ services to be provided by Zetec as well as contracts for the rental/lease of Zetec equipment. Product Support is also responsible to ensure that their contract review processes are defined and documented and that Product Support employees are trained as appropriate.

21.1.3. The Director, Training/Professional Development, or designee is responsible for the review of all contracts for training services to be provided by Zetec as well as contracts used for training instructors.

21.1.4. The Engineering or Applications team is responsible for review of all contracts that contain technical or design requirements.

21.2. Contract Review

21.2.1. All contracts shall be reviewed by the responsible persons prior to execution (whenever the contract is received prior to the required delivery).

21.2.2. Contracts containing specific quality requirements shall be reviewed by the Quality Assurance Manager (or designee) for non-standard specifications and documentation requirements. All non-standard requirements shall be identified to Operations management for entry as Notes in the order entry system.

21.2.3. Contracts requiring design effort shall be reviewed by the applicable Vice President of each Business Unit for design specifications, documentation requirements and delivery date(s). Additionally, the Vice President of each Business Unit is responsible for the review of contracts for rental/licensing of Software.

21.3. Documentation of Contract Review

21.3.1. Contract review shall be documented by the cognizant Vice President (or designee), by signing and dating the contract or an attached routing sheet.

21.3.2. Actions taken to resolve concerns with the customer about an order shall be documented.

22. CONTROL OF CUSTOMER-SUPPLIED PRODUCT

22.1. Scope --This section applies to all customer-supplied product received by Zetec, Inc. for incorporation into Zetec products or for related activities.

NOTE: This section does not apply to products when ownership transfers to Zetec.

22.2. Responsibility

22.2.1. The Operations and Supply Chain Managers are responsible for all material received for fabrication into Eddy Current standards.

22.2.2. The Operations and Supply Chain Managers are responsible for customer supplied product sent to Zetec for incorporation into Zetec manufactured products.

22.2.3. The After Market Service Organization Supervisor is responsible for items sent to Zetec for calibration and repair.

22.2.4. The Engineering or Applications Organization is responsible for material sent for evaluation and/or development of Zetec product designs.

22.2.5. Product Support is responsible for customer supplied product sent to the department for evaluation/development of inspection techniques.

22.3. Procedures for Customer Supplied Product or Equipment

22.3.1. On receipt, material shall be inventoried and inspected. Any damage or deficiency shall be reported to the customer.

22.3.2. The customer-supplied product shall be positively identified by tagging, marking, or storing in a segregated designated area until used or returned to the customer.

22.3.3. Customer supplied product shall be stored in a manner and location to preclude damage or deterioration.

22.3.4. Any instance of damage, deterioration or shortage of customer supplied product shall be reported to the customer in writing.

23. TRAINING / PROFESSIONAL DEVELOPMENT

NOTE: WHILE APPLICABLE STANDARDS MAY USE THE TERM "TRAINING", ZETEC RECOGNIZES THE FUNCTIONS DESCRIBED IN THOSE STANDARDS AND IN THIS SECTION AS A PART OF THE ZETEC "PROFESSIONAL DEVELOPMENT" ORGANIZATION.

23.1. Responsibility

23.1.1. The Professional Development Director is responsible for all NDT training functions and documenting the qualification processes. The Professional Development Director is also responsible for maintaining the files containing the NDT examinations of Zetec employees, which are Quality Records.

23.1.2. Each manager is responsible to ensure that all employees in their department receive appropriate training to enable them to perform their jobs effectively and efficiently.

23.1.3. Human Resources is responsible for scheduling Cardiopulmonary Resuscitation (CPR) and First Aid and other personnel safety related training classes to meet the needs of the company. Human Resources is also responsible to ensure that all new employees are provided training related to company practices and the Quality Management System.

23.1.4. Each organization is responsible to maintain records of training described in 23.1.1 through 23.1.3 above.

23.2. Nondestructive Testing (NDT) Training

23.2.1. NDT training provided in preparation for certification shall be accomplished as specified in the "Eddy Current Testing Personnel Qualification and Certification Procedure" (TRN-101 or equivalent).

23.2.2. Completed examinations for certification of Zetec employees shall be retained by the Professional Development Director or designee.

23.3. Documentation – Training records will be retained as quality records.

24. ACRONYMS AND ABBREVIATIONS

ACCP	ASNT Central Certification Program
ANSI	American National Standards Institute
ASL	Approved Supplier List
ASME	American Society of Mechanical Engineers
ASNT	American Society for Nondestructive Testing
BOP/HX	Balance of Plant / Heat Exchanger
BIS	Bureau of Industry and Security

C of C	Certificate of Compliance, Certificate of Conformance
CA	Corrective Action
CAR	Corrective Action Request (sometimes referred to as CPAR Corrective / Preventive Action Request
CFR	Code of Federal Regulations
CMTR	Certified Material Test Report
CPR	Cardio-Pulmonary Resuscitation
EC	Eddy Current
EDM	Electrical Discharge Machining
EPRI	Electric Power Research Institute
IEC	International Electro-technical Commission
IRS	Internal Revenue Service
ISO	International Standards Organization
IT	Information Technology
M&TE	Measuring and Test Equipment
MIL-STD	Military Standard
NDE	Non-Destructive Evaluation
NDT	Non-Destructive Testing
NIST	National Institute of Standards and Technology
NRC	Nuclear Regulatory Commission
PDP	Product Development Process
PO	Purchase Order
QA	Quality Assurance
QMS	Quality Management System
RMA	Return Material Authorization
UT	Ultrasonic Testing

25. REFERENCES AND GOVERNING DOCUMENTS

25.1. External Documents Referenced herein include the following:

25.1.1. 10 CFR Part 20, Standards for Protection Against Radiation

25.1.2. 10 CFR Part 21, Reporting of Defects and Noncompliance

25.1.3. 10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

25.1.4. ANSI/ASNT CP-189, ASNT Standard for Qualification and Certification of Nondestructive Testing Personnel

25.1.5. ANSI/N45.2, Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants

25.1.6. ASME Boiler and Pressure Vessel Code (Section XI)

25.1.7. ASME NQA-1 Supplement 12S-1, Quality Assurance Requirements for Nuclear Facilities Applications

25.1.8. CAN3-Z299.2 / .3 (CSA Standard) Quality Assurance Program – Category 2 and/or Category 3

25.1.9. ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories

25.1.10. ISO 10012-1, Quality assurance requirements for measuring equipment

25.1.11. ISO 9001, Quality management systems - Requirements

25.1.12. NRC Regulatory Guide 1.83, Inservice Inspection of Pressurized Water Reactor Steam Generator Tubes

25.1.13. RCC-M, Design and Construction Rules for Mechanical Equipment of PWR Nuclear Islands.

25.1.14. SNT-TC-1A, American Society for Nondestructive Testing (ASNT) "Recommended Practices for Nondestructive Personnel Qualifications and Certification"

25.1.15. URNS Division 8 (8.7)

25.2. Internal documents referenced herein include the following:

25.2.1. 01-1005, ZETEC General Workmanship Standards

25.2.2. 01-1008, Reporting of Nuclear Related Safety Hazards

25.2.3. 01-1009, Root Cause Analysis Process

25.2.4. 01-1010, Compliance with U.S. Export Regulations

25.2.5. 01-1011, Customer Complaint Triage Process

25.2.6. COP-001, Document Control

25.2.7. COP-002, General Drafting and Design Guidelines

25.2.8. COP-003, Change Control

25.2.9. COP-006, Product Development Procedure

25.2.10. COP-008, Development of Procedures, Work Instructions and Forms

25.2.11. FAP-008, Field Applications Quality Assurance Requirements

25.2.12. OPP-10200, Shipping

25.2.13. OPP-10205, 10CFR50 Appendix B and 10CFR21 Safety Requirements for Purchase Orders

25.2.14. QAP-001, QC Inspection of EC Probe, Mechanical and Sheet Metal Parts

25.2.15. QAP-003, Final Inspection Reporting for Electro-Mechanical Equipment

25.2.16. QAP-006, Receiving Inspection Procedure

25.2.17. QAP-013, Calibration Standard Raw Material Receipt Inspection Procedure

25.2.18. QAP-014, Control of Nonconformance

25.2.19. QAP-018, Supplier Approval Procedure

25.2.20. QAP-021, Corrective and Preventive Action Administration (also QAP-021FA CAR Form)

25.2.21. QAP-022, Quality Assurance Audit Activities

25.2.22. QAP-105, Management of Quality Records

25.2.23. SLP-001, General Requirements for Service and Calibration

25.2.24. SLP-002, Guidelines for Calibration Certificates

25.2.25. SLP-003, M&TE Control and Verification

25.2.26. SLP-004, Inter-Laboratory Comparison (ILC) Testing

25.2.27. SLP-005, Product Service Training

25.2.28. SLP-006, Returns Management

25.2.29. SLP-007, Requirements for Field Calibrations and Services

25.2.30. SLP-008, Rules for the use of A2LA Accreditation Symbol

25.2.31. TRN-101, Eddy Current Testing Personnel Qualification and Certification Procedure

25.2.32. ZPS06, Resource & Training

25.2.33. ZPS09, Order Management

25.2.34. ZPS10, Product Realization & Shipping

END OF DOCUMENT