



## QUALITY ASSURANCE MANUAL

### ZQA-001

### Revision J

**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

<i>Revision</i>	<i>Date</i>	<i>Description</i>	<i>Updated by</i>
J	21-Dec-2016	<ul style="list-style-type: none"> <li>• Replaced reference to Reg Guide 1.83 with NEI 97-06 (in section 2.3.2).</li> <li>• Updated 25.1.1 to be consistent with TRN-101.</li> <li>• Added Principal NDE Level III responsibilities to section 25.1.</li> <li>• Clarified 3.2</li> </ul>	Nancy Stutzman
H	19-Jul-2016	<ul style="list-style-type: none"> <li>• Update references to related documents.</li> <li>• Streamlined manual to reduce duplication of information available in procedures.</li> </ul>	Nancy Stutzman
G	9-Sep-2014	<ul style="list-style-type: none"> <li>• Updated section 6.3 to remove the requirement for distribution of controlled copies of the Quality Manual.</li> <li>• Removed quality records table from section 17.3 and replaced it with reference to QAP-105.</li> <li>• Updated all referenced documents.</li> </ul>	Nancy Stutzman
F	11-Nov-2012	<ul style="list-style-type: none"> <li>• Added Mission and changed Vision (page 5)</li> <li>• Modifications in functions throughout the manual               <ul style="list-style-type: none"> <li>○ Added Quality Assurance Manager</li> <li>○ VP of Engineering replaced by VP of each business unit</li> <li>○ Calibration Laboratory changed to After Market Services</li> <li>○ Field Service and Field Applications to Product Support</li> </ul> </li> <li>• Updated to reflect Internal group interactions (section 2.2.4)</li> <li>• Added compliance to RCC-M standard (2.3.1.1, 25.1.13)</li> <li>• Added compliance to ACCP standard (2.3.2.1, 24)</li> <li>• Organizational updates (2.2.3, 21.1.3)</li> <li>• Updated procedure references               <ul style="list-style-type: none"> <li>○ PDP to COP-006</li> <li>○ SHP-023 to OPP-10200</li> </ul> </li> <li>• Updated external release statement (6.2.2)</li> <li>• Updated Table 17-1 Records Retention</li> <li>• Modification of paragraphs in sections (8.1, 16.1, 17.1)</li> </ul>	R. Kelso & K.Bolduc
E	10-May-2011	<ul style="list-style-type: none"> <li>• Zetec Quality Policy – updated to support ISO/IEC 17025 reqmts</li> <li>• Added Table 2.1-1 to support CAN3-Z299.2 requirements</li> <li>• Updated 2.3.1.1 to reference CAN3-Z299.2/.3</li> <li>• Section 2.3.3.4 – changed FSP-301-QA to FAP-008</li> <li>• Sections 4.3.9, 7.3.5 – changed PUR-001 to OPP-10205</li> <li>• Sections 5.1.4, 5.3.1 – updated references to QAP-020</li> <li>• Section 5.3.3 – corrected COP-002 reference</li> <li>• Section 10.2.2 – changed ESCOP-1004 to QAP-013</li> <li>• Added Section 25, Referenced Documents (Internal, External)</li> </ul>	D. Wood

<i>Revision</i>	<i>Date</i>	<i>Description</i>	<i>Updated by</i>
D	2-Nov-2009	<ul style="list-style-type: none"> <li>• 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).</li> <li>• 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.</li> <li>• Section 2.7 (Procedures) – moved to 5.1.4, 5.1.5</li> <li>• Section 2.8 (Maint of the Quality Manual) – moved to 6.3.1</li> <li>• Section 5.2 – updated to reflect current organization</li> <li>• Sections 5.3.2, 5.3.3 – added</li> <li>• 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</li> <li>• Changed Field Services to Field Applications</li> <li>• 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.</li> </ul>	D. Wood
C	3-Nov-2008	<ul style="list-style-type: none"> <li>• Changed to alphabetic revision to accommodate IFS</li> <li>• Updated Zetec Vision</li> <li>• Added “PDP Lite” to section 3.3.1</li> <li>• 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</li> <li>• General wording clarifications in sections 5.3.5, 12.1.1, 18.5.1, 23.1.3, 23.1.4</li> <li>• Added section 16.1.5</li> <li>• Section 17.3.3 and Table 17-1 – updated employee file retention period to match Roper guidelines</li> <li>• Added Section 23 Note.</li> </ul>	Diane Wood
1	30-Nov-2006	<ul style="list-style-type: none"> <li>• Clarified the Quality Policy re ISO/IEC 17025:1999 requirements</li> <li>• Section 2.1.1 -- clarified inclusion of Zetec sites, U.S. &amp; Intl</li> <li>• Updated org assignments per current Zetec org. Changed use of “department”, “team” and “group” to “Organization”.</li> <li>• Added sections 4.3.9 and 7.3.5 -- PO wording for nuclear safety related products and services</li> <li>• Added section 16.3.1 -- ref Triage and RCA processes</li> <li>• Added section 18.4.3 – ref to supplier approval &amp; audit processes</li> <li>• Sections 9.2.3 and 23.2.1 -- consolidated references to personnel qualification processes</li> <li>• Added Section 24 (Acronyms)</li> </ul>	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 19-24 Satisfy the additional requirements of ISO 9001:2008.

Section 25 (Training) Supports Both 10 CFR 50 Appendix B and ISO 9001:2008 requirements.

## **ZETEC VISION**

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

## **ZETEC MISSION STATEMENT**

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

## **ZETEC QUALITY POLICY**

- Zetec is committed to The Inspection Advantage by providing products and services that meet or exceed customer expectation of quality, reliability and value.
- Zetec strives to continually improve the effectiveness of the Quality Management System and comply with industry standards.
- Zetec provides its employees with the resources necessary to achieve superior quality and expertise; including training to ensure successful implementation of policies and procedures.

This quality policy has been issued under the authority of Top Management and is supported by Quality Objectives. The overall Quality objectives established are reviewed during management reviews.

Everyone at ZETEC recognizes their responsibilities to the Quality Management System; including the application of good professional practices, familiarizing themselves with quality documentation and implementing policies/procedures in their work.

## **DEFINITIONS**

Note: 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 26.

- **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.
- **Nuclear Safety Related** Nuclear Safety Related includes a structure, system or component that affects the safety function necessary to assure:
  - the integrity of the reactor coolant pressure boundary;
  - the capability to shut down the reactor and maintain it in a safe shutdown condition;
  - the capability to prevent or mitigate the consequences of accidents which could result in offsite exposures.

## 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:

- 1.1.1.1. Ensuring that processes needed for the Quality Management System (QMS) are established, implemented and maintained,
- 1.1.1.2. Reporting to top management on the performance of the QMS and any need for improvement,
- 1.1.1.3. Ensuring the promotion of awareness of customer requirements throughout Zetec, and
- 1.1.1.4. 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. Refer to COP-0108-PL-Z (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. Escalate to supervisor and/or Quality Assurance Organization any item, component or product that is found unacceptable or out of specification for proper disposition
  - c. Halt shipments of products known to be defective or known to have been produced without using the proper Zetec procedures.

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 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, Engineering Applications, Professional Development
Quebec, Quebec, Canada	Design, Manufacturing, Purchasing, Sales, HR, Quality, Service, Engineering Applications, Professional Development
Paris, France	Sales, Purchasing, Service (See Note 1)
Seoul, Korea	Sales, Purchasing, Service
Shanghai, China	Sales, Purchasing, Service
Houston, TX, USA	Sales

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).
  - 2.2.5. Each Business Unit shall monitor customer perceptions related to whether or not Zetec products and services meet their requirements. Product Management, along with Sales, will determine the best 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, 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 NEI 97-06 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 APM-3008-PR-S, Field Applications Quality Assurance Requirements.
- 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.
  - 2.3.4.2. The Zetec calibration program is also committed to meeting the requirements of ISO/IEC 17025.
  - 2.3.4.3. Equipment calibration program guidance is further described in procedure SLP-0001-PR-Z, General Requirements for Service and Calibration
- 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, humidity, 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 should be documented and revised as necessary to define necessary personnel competence.
    - 2.4.2.3. Personnel must be competent to perform assigned work based on education, training, skills and experience. Note: Effectiveness of training is verified as necessary.

- 2.4.2.4. Personnel records shall be maintained. This includes information such as education, training, skills and experience. Refer to HRS-3012-PR-S (Training Records Procedure) and HRS-1006-PR-Q (Human resources management).
- 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. The review shall be performed in accordance with QAS-0049-PR-Z (Quality Management System Management Review).
- 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. Refer to COP-0111-PR-Z (Customer Triage Process).
    - 2.6.1.2. The Customer Service Organization handles customer inquiries.
    - 2.6.1.3. The Quality Assurance Team manages the customer complaint/ corrective and preventive action process to ensure customer issues are addressed. Refer to QAS-0021-PR-Z (Corrective and Preventive Action Administration).
  - 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 customers' 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 product managers are responsible for defining product requirements (Voice Of Customer, functional, regulatory, statutory, etc.)
  - 3.2.2. 3.2.2. The Leader of each Business Unit is responsible for approval of new product proposals.
  - 3.2.3. Engineering is responsible for developing products that meet requirements identified by the product managers and approved by Business Unit leaders.

- 3.3. New Product Design Control
  - 3.3.1. Control of the design of a new Zetec product is defined in COP-0006-PR-Z (Product Development Procedure).
- 3.4. Established Design Change Control
  - 3.4.1. Control of changes to established electrical and mechanical, software and firmware designs are defined in ENG-3003-PR-S (Configuration and Change Management) and ENG-1000-PR-Q (Request and approval of a technical change (CR) which establishes change identification, documentation, review and approval requirements).

#### **4. PROCUREMENT/PURCHASING DOCUMENT CONTROL**

- 4.1. Purchase of parts and materials used in the manufacture of Zetec products are controlled. Zetec services, including services used in the manufacture of Zetec products (e.g., calibration services, EDM services, etc.) are also controlled.
- 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 QAS-0018-PR-Z (Zetec Supplier Approval Procedure).
- 4.3. Purchase orders for products and services that are defined as nuclear safety related per COP-0108-PL-Z (Reporting of Nuclear Related Safety Hazards), shall include appropriate language as defined in SCM-0205-PR-Z (10 CFR50 Appendix B and 10CFR21 Safety Requirements for Purchase Orders), SCM-1002-PR-Q (Procurement Procedure) 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 the design, manufacture, repair, calibration and service of Zetec equipment and associated items, along with field services.
  - 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" document. Refer to COP-0008-PR-Z (Development of Documents) for additional details regarding document tiers.



- 5.2. 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 document 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.

## 6. DOCUMENT AND DRAWING CONTROL

- 6.1. Responsibilities are defined in COP-0001-PR-Z (Document Control) and COP-0008-PR-Z (Development of Documents).
- 6.2. Document control applies to Zetec documents described in section 5. Refer to COP-0001-PR-Z (Document Control) for additional details.
- 6.3. Instructions on the format and content for Zetec procedures and work instructions are documented in COP-0008-PR-Z (Development of Documents).
- 6.4. Zetec Drawings shall be constructed, approved and revised according to procedure ENG-3002-PR-S (General Drafting and Design Guidelines), COP-0001-PR-Z (Document Control), ENG-3003-PR-S, Configuration and Change Management (Snoqualmie) and industry standards.
- 6.5. Documents and data provided by external parties shall be governed following COP-0001-PR-Z (Document control).
- 6.6. Current working copies are maintained electronically for access by all Zetec employees. Electronic copies are also provided to customers as necessary if approved for external release.
- 6.7. Zetec shall not issue controlled copies of the Zetec Quality Manual. External parties may download uncontrolled copies of the Quality Assurance Manual from Zetec's website. Notifications regarding revisions/updates to the manual may be provided to external parties upon request.

## 7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

- 7.1. Suppliers are approved following QAS-0018-PR-Z (Supplier Approval Procedure). Supplier selection shall be based on the supplier's ability to meet Zetec purchasing requirements, including quality and delivery.

- 7.2. Responsibility
    - 7.2.1. The Supply Chain is responsible for procurement and receipt of purchased materials and equipment in support of manufacturing.
    - 7.2.2. Each manager is responsible for establishing the requirements for purchased services and monitoring those services for any deficiencies.
  - 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:
      - NIST traceability for all calibration services and for EDM services related to items that will be certified.
      - Title 10 CFR 21 applicability for all NDE services.
    - 7.3.2. 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 SCM-0205-PR-Z (10 CFR 50 Appendix B and 10CFR21 Safety Requirements for Purchase Orders).
  - 7.4. Purchased parts shall meet the requirements described in COP-0005-PR-Z (Zetec General Workmanship Standards for fabricated materials) as applicable.
- 8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, COMPONENTS AND PRODUCTS**
- 8.1. This section describes 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.
  - 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.
    - 8.3.2. Serial numbers are applied according to respective product documentation.
    - 8.3.3. M&TE used in the manufacture of Zetec products shall be identified and assigned unique serial numbers or Zetec asset numbers.
      - 8.3.3.1. Reference standards used for calibration must be traceable to International Standards.
    - 8.3.4. 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 Organizations (e.g., Aftermarket Service, RevospECT) are responsible for the conduct of nondestructive examinations (NDE) performed as a service under contract. Technical Training Manager is responsible to work with Product Support organizations 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 ultrasound 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.
- 9.2.3. Inspection procedures may be written to specific customer requirements.
- 9.2.4. Zetec Product Support procedures may be used to meet customer requirements.
- 9.2.5. 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.
- 9.2.6. 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. Refer to QAS-0016-PR-Z (Documenting Qualification and Designation of Quality Control Inspectors).
- 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.
- 10.1.4. For instruments and probes: an inspector may not perform final inspection and pre-check on the same item.

- 10.1.4.1. For some minor accessories, it is acceptable for an inspector to perform both checks.
- 10.1.5. Receipt inspections, final inspections and raw material inspections shall be performed per the applicable procedures listed in section 27.
- 10.2. Inspector Authority
  - 10.2.1. Inspectors are authorized to remove, or halt further processing of, any suspect or defective product or component. Inspectors are also authorized to halt practices that are detrimental to the quality of Zetec products.
- 10.3. Inspections shall be performed following documented requirements. Refer to QAS-3001-PR-S (QC Inspection of EC Probe, Mechanical and Sheet Metal Parts), QAS-3003-PR-S (Final Inspection Reporting for Electro-Mechanical Equipment), QAS-3006-PR-S (Receiving Inspection Procedure) and QAS-3013-PR-S (Calibration Standard Raw Material Receipt Inspection Procedure).
- 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 QAS-0105-PR-Z (Management of Quality Records).
  - 10.4.3. Records shall indicate the person(s) authorizing release of product for delivery to the customer.

## 11. TEST CONTROL

- 11.1. Responsibility
  - 11.1.1. The Engineering/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 the 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-0003-PR-Z (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 Calibration Laboratory to perform in-house calibrations in accordance with released procedures.

12.2. Procedures

12.2.1. All test equipment used to perform calibrations or make certified measurements shall have a prominently displayed calibration label attached to the equipment and a certificate maintained on file.

12.2.2. Calibration and certification shall be done using documented procedures. (See section 27.).

### 13. HANDLING, STORAGE AND SHIPPING

13.1. Handling, storage, packaging, preservation and shipping are the responsibility of the Operations Organization.

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 the applicable procedure (QAS-3006-PR-S, Receiving Inspection and SCM-1002-PR-Q, Procurement Procedure).

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 SCM-3102-PR-S, Shipping and SCM-1001-PR-Q, Shipping procedure.

**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. Refer to COP-0003-PL-Z (Compliance with U.S. Export Regulations).

### 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 for ensuring 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 procedures.

## **15. NONCONFORMING MATERIALS, PARTS OR COMPONENTS**

- 15.1. The Quality Assurance Organization is responsible for managing the nonconforming material process.
- 15.2. All employees are responsible for identifying and reporting any non-conforming material they find.
- 15.3. Control of non-conformances shall be accomplished according to the appropriate procedures (QAS-3014-PR-S and QAS-1001-PR-Q).

Note: In the event that unanticipated circumstances create a situation that precludes strict adherence to this document or associated operating procedures, a request for customer acceptance of nonconformance shall be used to document the situation and solution, as well as document the customer acknowledgement. (Refer to QAS-3014-PR-S

## **16. CORRECTIVE AND PREVENTIVE ACTION**

- 16.1. The Corrective and Preventive Action process should be used to resolve Quality Management System process issues, product deficiencies, customer complaints, safety issues, internal and external audit findings, potential nonconformities or potential issues. 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 COP-0108-PL-Z (Reporting of Nuclear Related Safety Hazards).
- 16.2. Quality Assurance administers the Corrective and Preventive Action Request processes per QAS-0021-PR-Z (Corrective and Preventive Action Administration).
- 16.3. Any employee may propose a Corrective and Preventive Action Request, including requests on behalf of customers or suppliers.
- 16.4. The handling of customer complaints should be managed and investigated per QAS-0021-PR-Z (Corrective and Preventive Action Administration), COP-0111-PR-Z (Customer Triage Process) and QAS-0109-PR-Z (Root Cause Analysis Process), as applicable.

## **17. QUALITY ASSURANCE RECORDS**

- 17.1. Management of Quality Records is documented in QAS-0105-PR-Z (Management of Quality Records).

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.

## 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 all audits are performed by personnel independent of their function.

18.1.3. The Product Support Organizations are responsible for Product Support Inspection Audits.

18.2. Zetec Internal and Supplier Audits are performed per QAS-0022-PR-Z (Quality Assurance Audit Activities).

18.3. Product Support Inspection Audits are performed per APM-3008-PR-S (Field Applications Quality Assurance Requirements).

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 an In-Plant Audit Report (form APM-3008-FR-S 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. Personnel

18.4.1. Personnel performing internal or external audits shall be appropriately trained as defined in QAS-0054-PR-Z (Qualification and Certification of QA Audit Personnel) or equivalent, and shall not have direct responsibilities in the areas being audited.

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

## 19. CONTROL OF PRODUCTION

19.1. Production activities are planned and carried out under controlled conditions. Controlled conditions include the following, as applicable:

19.1.1. The availability of information that describes the characteristics of the product

19.1.2. The availability of approved procedures or work instructions

19.1.3. The availability of manufacturing, measuring, testing and inspection equipment.

19.1.4. Availability of parts and material

- 19.2. Personnel involved in production activities shall be appropriately trained.
- 19.3. Production activities are described in procedure PRO-1002-PR-Q, Production activities realization Procedure.

## **20. SERVICING OF ZETEC PRODUCTS**

- 20.1. The Calibration Laboratory Organization supervisor/ After Market Service Organization supervisor is responsible for the servicing of Zetec products, and for ensuring that procedures used by his/her team are documented
- 20.2. Procedure
  - 20.2.1. Contracts involving repair/calibration of Zetec products shall be reviewed. Evidence of reviews shall be documented.
  - 20.2.2. Returned products are processed per SLP-0006-PR-Z (Returns management).
  - 20.2.3. When items are ready for return to the customer they shall be packed in a manner to preclude shipping damage. Refer to SCM-3102-PR-S (Shipping) and SCM-1001-PR-Q (Shipping procedure).
  - 20.2.4. Personnel performing calibration of Zetec products shall be appropriately trained. Refer to SLP-0005-PR-Z (Product Service Training).
  - 20.2.5. All test equipment used for calibrations performed at Zetec shall be calibrated. Refer to SLP-0001-PR-Z (General Requirements for Service & Calibration).
  - 20.2.6. Calibrations performed outside Zetec's laboratories (e.g., at customer sites) are performed following SLP-0007-PR-Z (Requirements for Field Calibrations and Services).
- 20.3. Documentation
  - 20.3.1. Certification of calibration shall be performed as specified in applicable procedures (see SLP-0002-PR-Z – Guidelines for calibration certificates).
  - 20.3.2. All servicing of customer items shall be documented on service orders. Refer to SLP-0077-WI-Z (Service Work Order Management).
  - 20.3.3. Service Laboratory procedures are defined to describe the processes in the calibration laboratory. Refer to SLP-0001-PR-Z (General Requirements for Service and Calibration), SLP-0002-PR-Z (Guidelines for Calibration Certificates), SLP-0003-PR-Z, (M&TE Control and Verification) and SLP-0008-PR-Z (Rules for the use of A2LA Accreditation Symbol).

## **21. MONITORING AND ANALYSIS OF DATA**

- 21.1. Department managers are responsible for selecting appropriate measures and goals to support the Zetec Quality Management System.
- 21.2. Zetec management is responsible for reviewing quality measures and goals at regularly scheduled Quality Management System reviews.
- 21.3. Records are maintained per QAS-0105-PR-Z (include title to be consistent).

## 22. CONTRACT REVIEW

- 22.1. 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 Units are also responsible for ensuring that the contract review process is defined and documented, and that employees are trained as appropriate. (Refer to SLS-1001-PR-Q, Order Management.)
- 22.2. The Product Support Organization is responsible for the review of all contracts for inspection 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.
- 22.3. The Technical Training Manager, or designee is responsible for the review of all contracts for Eddy Current (EC) training services to be provided by Zetec as well as contracts used for training instructors.
- 22.4. The Engineering or Applications team is responsible for review of all contracts that contain technical or design requirements, including software
- 22.5. Contract Review
  - 22.5.1. All contracts shall be reviewed by the responsible persons prior to execution (whenever the contract is received prior to the required delivery).
  - 22.5.2. 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.
  - 22.5.3. Contracts requiring design effort shall be reviewed by the applicable Director/Vice President of each Business Unit for design specifications, documentation requirements and delivery date(s).
- 22.6. Documentation of Contract Review
  - 22.6.1. Contract review shall be documented by the cognizant Vice President (or designee), by signing and dating the contract or an attached routing sheet.
  - 22.6.2. Actions taken to resolve concerns with the customer about an order shall be documented.

## 23. CONTROL OF CUSTOMER-SUPPLIED PRODUCT

- 23.1. Scope

This section applies to all customer-supplied product received by Zetec, Inc. for incorporation into Zetec products or for related activities. This section does not apply to products when ownership transfers to Zetec. Refer to SLP-0006-PR-Z (Returns Management) and APM-1002-PR-Q (Control of Customer-supplied Property).
- 23.2. Responsibility
  - 23.2.1. The Operations and Supply Chain Managers are responsible for all material received for fabrication into Eddy Current standards and/or incorporation into Zetec manufactured products.

- 23.2.2. The After Market Service Organization Supervisor is responsible for items sent to Zetec for calibration and repair.
- 23.2.3. The Engineering or Applications Organization is responsible for material sent for evaluation and/or development of Zetec product designs.
- 23.2.4. Product Support is responsible for customer supplied product sent to the department for evaluation/development of inspection techniques.

## **24. PROCEDURES FOR CUSTOMER SUPPLIED PRODUCT OR EQUIPMENT**

- 24.1. The customer-supplied product shall be positively identified by tagging, stored and handled in a manner that prevents damage or loss of traceability. Refer to SLP-0006-PR-Z (Returns Management) and APM-1002-PR-Q (Control of Customer-supplied Property).

## **25. 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.

- 25.1. Responsibility
  - 25.1.1. The Technical Training Manager is responsible for coordinating all NDT training activities.
  - 25.1.2. The Professional Development Specialist is responsible for maintaining the files containing the NDT examinations of Zetec employees, which are Quality Records.
  - 25.1.3. 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.
  - 25.1.4. Human Resources is responsible for scheduling 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.
  - 25.1.5. Principal NDE Level III is responsible for approving formal NDT course outlines and ensuring that training meets all specified requirements.
  - 25.1.6. Each organization is responsible for maintaining records of training described in 25.1.1 through 25.1.4 above.
- 25.2. Nondestructive Testing (NDT) Training
  - 25.2.1. 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).
  - 25.2.2. Completed examinations for certification of Zetec employees shall be retained by the Professional Development Specialist or designee.
  - 25.2.3. Training records will be retained as quality records per QAS-0105-PR-Z (Management of Quality Records).

## 26. ACRONYMS AND ABBREVIATIONS

26.1.	ACCP	ASNT Central Certification Program
26.2.	ANSI	American National Standards Institute
26.3.	ASL	Approved Supplier List
26.4.	ASME	American Society of Mechanical Engineers
26.5.	ASNT	American Society for Nondestructive Testing
26.6.	BOP/HX	Balance of Plant / Heat Exchanger
26.7.	BIS	Bureau of Industry and Security
26.8.	C of C	Certificate of Compliance, Certificate of Conformance
26.9.	CA	Corrective Action
26.10.	CAR	Corrective Action Request
26.11.	CFR	Code of Federal Regulations
26.12.	CMTR	Certified Material Test Report
26.13.	EC	Eddy Current
26.14.	EDM	Electrical Discharge Machining
26.15.	EPRI	Electric Power Research Institute
26.16.	IEC	International Electrotechnical Commission
26.17.	ISO	International Standards Organization
26.18.	IT	Information Technology
26.19.	M&TE	Measuring and Test Equipment
26.20.	MIL-STD	Military Standard
26.21.	NDE	Non-Destructive Examination
26.22.	NDT	Non-Destructive Testing
26.23.	NIST	National Institute of Standards and Technology
26.24.	NRC	Nuclear Regulatory Commission
26.25.	PDP	Product Development Process
26.26.	PO	Purchase Order
26.27.	QA	Quality Assurance
26.28.	QMS	Quality Management System
26.29.	RMA	Return Material Authorization
26.30.	UT	Ultrasound Testing

## 27. REFERENCES AND GOVERNING DOCUMENTS

- 27.1. External Documents are listed in ZQA-001-FA-Z (Appendix of External Standards).
- 27.2. Internal documents referenced herein include the following:
  - 27.2.1. APM-1002-PR-Q, Control of customer supplied property
  - 27.2.2. APM-3008-PR-S, Field Applications Quality Assurance Requirements
  - 27.2.3. APM-3008-FR-S, In-Plant Audit Report
  - 27.2.4. COP-0001-PR-Z, Document Control
  - 27.2.5. COP-0003-PL-Z, Compliance with U.S. Export Regulations
  - 27.2.6. COP-0005-PR-Z, Zetec General Workmanship Standards for fabricated materials

- 27.2.7. COP-0006-PR-Z, Product Development Procedure
- 27.2.8. COP-0008-PR-Z, Development of Documents
- 27.2.9. COP-0108-PL-Z, Reporting of Nuclear Related Safety Hazards
- 27.2.10. COP-0111-PR-Z, Customer Complaint Triage Process
- 27.2.11. ENG-1000-PR-Q, Change Control Procedure Request and approval of a technical change (CR)
- 27.2.12. ENG-3002-PR-S, General Drafting and Design Guidelines
- 27.2.13. ENG-3003-PR-S, Configuration and Change management
- 27.2.14. HRS-1006-PR-Q, Human Resource Management
- 27.2.15. HRS-3012-PR-S, Training Records Procedure
- 27.2.16. PRO-1002-PR-Q, Production activities Realization Procedure
- 27.2.17. QAS-0016-PR-Z, Documenting Qualification and Designation of Quality Control Inspectors
- 27.2.18. QAS-0018-PR-Z, Zetec Supplier Approval Procedure
- 27.2.19. QAS-0021-PR-Z, Corrective and Preventive Action Administration
- 27.2.20. QAS-0022-PR-Z, Quality Assurance Audit Activities
- 27.2.21. QAS-0049-PR-Z, Quality Management System Management Review
- 27.2.22. QAS-0054-PR-Z, Qualification and Certification of QA Audit Personnel
- 27.2.23. QAS-0105-PR-Z, Management of Quality Records
- 27.2.24. QAS-0109-PR-Z, Root Cause Analysis Process
- 27.2.25. QAS-1001-PR-Q, Management of Nonconformities
- 27.2.26. QAS-3001-PR-S, QC Inspection of EC Probe, Mechanical and Sheet Metal Parts
- 27.2.27. QAS-3003-PR-S, Final Inspection Reporting for Electro-Mechanical Equipment
- 27.2.28. QAS-3006-PR-S, Receiving Inspection Procedure
- 27.2.29. QAS-3013-PR-S, Calibration Standard Raw Material Receipt Inspection Procedure
- 27.2.30. QAS-3014 -PR-S, Control of Nonconformance
- 27.2.31. SCM-0205-PR-Z, 10CFR50 Appendix B and 10CFR21 Safety Requirements for Purchase Orders
- 27.2.32. SCM-1001-PR-Q, Shipping
- 27.2.33. SCM-1002-PR-Q, Procurement Procedure
- 27.2.34. SCM-3102-PR-S, Shipping
- 27.2.35. SLP-0001-PR-Z, General Requirements for Service and Calibration
- 27.2.36. SLP-0002-PR-Z, Guidelines for Calibration Certificates
- 27.2.37. SLP-0003-PR-Z, M&TE Control and Verification
- 27.2.38. SLP-0004-PR-Z, Inter-Laboratory Comparison (ILC) Testing
- 27.2.39. SLP-0005-PR-Z, Product Service Training
- 27.2.40. SLP-0006-PR-Z, Returns Management
- 27.2.41. SLP-0007-PR-Z, Requirements for Field Calibrations and Services
- 27.2.42. SLP-0008-PR-Z, Rules for the use of A2LA Accreditation Symbol



- 27.2.43. SLP-0077-WI-Z, Service Work Order Management
- 27.2.44. SLS-1001-PR-Q, Orders Management
- 27.2.45. TRN-101, Eddy Current Testing Personnel Qualification and Certification Procedure
- 27.2.46. ZQA-001-FA-Z, Appendix of External Standards
- 27.2.47. ZQA-001-FB-Z, QA Manual - External Standards Cross-Reference



28. HIGH-LEVEL PROCESS FLOW DIAGRAM

